U.S. Department of Health and Human Services
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Seventh Meeting of the Clinical Center Research Hospital Board February 2, 2018

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Clinical Center Research Hospital Board

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital; Chair, National Institutes of Health (NIH) Clinical Center Research Hospital Board (CCRHB)

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

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

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

Ruth Brinkley, M.S.N./Adm., KentuckyOne Health

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

Carolyn Clancy, M.D., Deputy Under Secretary for Health for Organizational Excellence, Veterans Health Administration, U.S. Department of Veterans Affairs

Jeanette Erickson, D.N.P., RN, Senior Vice President for Patient Care Services and Chief Nurse, Massachusetts General Hospital (by telephone)

Paul O'Neill, M.P.A., Non-Executive Chairman, Value Capture, LLC

Richard Shannon, M.D., Executive Vice President of Health Affairs and Professor of Medicine, University of Virginia Health System

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

Executive Summary

The seventh meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on February 2, 2018, on the main campus of NIH. The meeting was open to the public and was 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 9:02 a.m. and welcomed all those in attendance. She announced that Peter Pronovost, M.D., Ph.D., has stepped down from the CCRHB.

Francis S. Collins, M.D., Ph.D., NIH Director, described a recent flood of water and antifreeze resulting from a broken pipe at the top of the ambulatory care facility. He also reported that the recent federal government shutdown was short, so most Clinical Center operations did not experience a major interruption. In addition, the Clinical Center is contributing to progress in sickle cell disease that could lead to the use of genetic therapy vectors and gene editing to cure the disease. Dr. Collins thanked the CCRHB members for all they do to guide NIH and the Clinical Center.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, welcomed Gwenyth Wallen, Ph.D., RN, the new Chief Nurse Officer, and Jeremy Davis, M.D., the new Surgeon-in-Chief, to the Clinical Center. The Clinical Center has taken steps to prevent similar incidents to the extent possible, but Clinical Center facilities are experiencing challenges related to extreme cold and dry weather. In the 2017 Federal Employee Viewpoint Survey, employees rated 40 of 71 items as strengths, compared with 30 strengths in 2016. In 2018, the Clinical Center's top focus area will be space.

A session on patient safety at the Clinical Center featured five presenters. Richard Childs, M.D., Clinical Director, Division of Intramural Research, National Heart, Lung, and Blood Institute (NHLBI), said that the efforts to reinforce patient safety that were spearheaded by the Clinical Center have spread to staff supporting clinical research across Institutes and Centers (ICs) and that the Safety Tracking and Reporting System (STARS) has greatly improved patient safety tracking. Carter Van Waes, M.D., Ph.D., Clinical Director, National Institute on Deafness and Other Communication Disorders, described the activities of the NIH Medical Executive Committee, which assesses the quality and safety of patient care at NIH, develops policies for medical practice and clinical care, and recommends medical staff appointments and clinical privileges.

Gwenyth Wallen, Ph.D., RN, Chief Nurse, Nursing Department, Clinical Center, reported that the Nursing Department strives for zero central line–associated bloodstream infections (CLABSIs) and 100% knowledge-based medication administration. CAPT Diane Aker, M.B.A., RN, Senior Nurse Manager, 3NE, described quality improvement activities on her unit and reported that as of January 21, the unit had been CLABSI free for 23 weeks. This success resulted from several Clinical Center strategies, including root cause analyses, 30-day room cleaning, and nursing staff reeducation on central line care. Georgie Cusack, M.S., RN, AOCNS,

Director of Education and Patient Safety at NHLBI, described her responsibilities, which include reeducating staff who administer medications outside the window indicated in the protocol and improving the process for collecting research bone marrow specimens.

Laura M. Lee, M.Sc., RN, Director, Office of Patient Safety and Clinical Quality, provided a patient safety and clinical quality update. To accelerate antibiotic administration for febrile neutropenia, the Clinical Center took several actions, such as encouraging staff to escalate issues and limit use of stat orders to certain types of situations. To reduce the incidence of perioperative hemorrhage, the new massive transfusion protocol has steps for the nurse, lead physician, and Department of Transfusion Medicine. A subcommittee of the Patient Safety, Clinical Practice, and Quality Committee is determining the volume and characteristics of high-risk, low-volume procedures, and results of a culture of patient safety survey show the need for improvements.

Tara Palmore, M.D., Clinical Center Hospital Epidemiologist, described the Clinical Center's hand hygiene policies and plans to increase compliance with them. Specifically, the Clinical Center is expanding compliance monitoring to the entire health care staff and reminding patients more frequently that hand hygiene is an essential part of their care.

Dr. Wallen described the work of the Safe Patient Handling Task Force, which will develop and implement a Clinical Center–wide safe patient handling program. The task force plans to complete a gap analysis and describe the current state, best practices, and recommendations.

Harvey Klein, M.D., Chief, Clinical Center Transfusion Medicine Department, provided an update on the Center for Cellular Engineering (CCE), which manufactures gene therapies for inherited disorders, post-transplant and cancer immunotherapies, bone marrow stromal cells, and induced pluripotent cells. The current facility cannot meet the growing demand for cell therapies by intramural investigators and lacks the capacity to meet the requirements of precision medicine. The new CCE will expand the number of cell-processing rooms from 4 to 18 by 2021, and its staff will grow from 51 in 2017 to 182 in 2020.

The meeting included a closed session.

The next face-to-face CCRHB meeting is scheduled for April 20, 2018.

Meeting Summary
Friday, February 2, 2018

Welcome and Board Chair's Overview

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

The seventh meeting of the CCRHB took place on February 2, 2018, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and was webcast live. Dr. Forese called the meeting to order at 9:02 a.m. and thanked those present for their attendance. She announced that Peter Pronovost, M.D., Ph.D., has stepped down from the CCRHB.

NIH Director's Remarks

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

Dr. Collins predicted that the CCRHB would be pleased to hear all that has been accomplished since NIH invited members to join the board. The first update would come from James Gilman, M.D., the Center's Chief Executive Officer (CEO), who would describe a recent antifreeze flood that resulted from a broken pipe at the top the ambulatory care facility and led the Clinical Center to evacuate the outpatient clinic. This incident was a dramatic example of the consequences of delayed maintenance, and NIH must work harder to convince Congress that this maintenance cannot be delayed indefinitely.

While the Clinical Center was responding to this crisis, the federal government shut down. Fortunately, the shutdown lasted just three days, so most Clinical Center operations did not experience a major interruption. As dedicated public servants, NIH personnel try to make the best use of the agency's resources and the instructions from Congress on how to use them. Managing the $34 billion NIH operation is a challenge, especially when the current budget amount is not known.

Many types of exciting science are going on at the Clinical Center. For example, the Clinical Center is contributing to progress in sickle cell disease that could lead to the use of genetic therapy vectors and gene editing to cure the disease, perhaps within five years.

Dr. Collins thanked the CCRHB members for all they do to guide NIH and the Clinical Center, and he expressed his gratitude to Dr. Gilman for being such an effective leader of this enterprise.

NIH Clinical CEO Update

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

Dr. Gilman announced that this was National Wear Red Day.

Staff Changes

Dr. Gilman announced the appointment of Gwenyth Wallen, Ph.D., R.N., the Clinical Center's new Chief Nurse Officer. She is an excellent leader in nursing operations and research and uniting these two nursing communities aligns well with Dr. Wallen's expertise and serves as an important part of the Nursing Department's future plans.

Jeremy Davis, M.D., is the Clinical Center's new Surgeon-in-Chief. As a staff clinician at the National Cancer Institute (NCI), Dr. Davis participates in many research projects but does not lead his own laboratory. Dr. Davis is an active surgeon with a strong reputation for participation in patient safety and clinical quality initiatives and a strong history of interdisciplinary cooperation with nurses, administrators, and other Clinical Center personnel. The Clinical Center now covers half of Dr. Davis' salary, and NCI is using the money to support a midlevel provider to help Dr. Davis focus more of his efforts on the Clinical Center.

Thomas A. Fleisher, M.D. retired from NIH after 37 years, most recently as Head of the Clinical Center's Department of Laboratory Medicine. Karen Frank, M.D., Ph.D., D(ABMM), is the new Acting Chief of the Department of Laboratory Medicine. Dr. Frank has done an excellent job so far and may be a candidate for the permanent position.

The searches for the new chief operating officer (COO) and chief of radiology and imaging sciences have been completed, and these individuals should be announced soon. The COO position must be signed off by the new Secretary of Health and Human Services. Dr. Collins recently met with Alex M. Azar II, the new Secretary, and predicted that Mr. Azar will be very engaged in the issues of concern to NIH and the Clinical Center.

Facilities

The Clinical Center facilities are experiencing challenges related to extreme cold and dry weather, and the lack of humidity in the operating room is a constant concern.

A cleaning crew hit a fire suppression sprinkler in a tissue culture room on November 19. This room in 3T was out of service for a prolonged period, and staff were required to use other tissue culture rooms. The Clinical Center has now increased the frequency of its microbiologic and airborne particle monitoring. Staff met three times a week to review progress, and NIH and Clinical Center leaders have had to approve the use of all products harvested or produced in any rooms in 3T during the cleanup. The Clinical Center postponed treatment of a few patients who could wait but proceeded with cell-based therapy for most patients needing cells by using extra caution and vigilant oversight of all processes.

The antifreeze flood that Dr. Collins mentioned occurred on the 14th level of the ambulatory care research facility, which had to be evacuated for a few days to allow a thorough cleanup. The Office of Research Facilities did an excellent job of making it possible to return to the facility,

and nurses did a great job of helping identify other sites to see patients. Patients who came to the clinic for an appointment reported to a central location and were directed or escorted to the correct location. The greatest challenge was for clinics, such as those for audiology and ophthalmology,that required equipment not available in other rooms. All clinics except OP13, which is immediately below the flood location, are back in full operation. The cause of the flood was a connector in a six-inch pipe that was commonly used in the 1980s. These pipes are used throughout the Clinical Center, and the Office of Research Facilities must address this issue.

When Dr. Gilman arrived at the Clinical Center, the Institute and Center (IC) directors who requested an increase in cell processing capacity, which required completion of the 2J renovations. These renovations had been underway for a long time with many setbacks. Donna Phillips, Director Acquisitions in the NIH Office of Research Facilities, assumed leadership of the project and finished the work by the January timeline for completion.

Work in the new hospice rooms is currently underway.

2017 Federal Employee Viewpoint Survey (FEVS)

The Clinical Center administers the FEVS every year. In 2017, the survey had a 56% response rate, which was 16% higher than in 2016.

- Employees rated 40 of the 71 items as strengths, compared with 30 strengths in 2016.
- Another three items were rated as challenges, compared with five in 2016, and one of the three was an opportunity, whereas the 2016 FEVS did not identify any opportunities.
- Twenty-one items had at least a 5% increase in positive rates, compared with two in 2016.
- The number of positive ratings did not decline for any item in 2017, whereas positive ratings declined for seven items in 2016.

These results have been shared with employees at town hall meetings, and action plans are being developed by department heads to address the challenges.

Fiscal Year (FY) 2018 Budget

The Clinical Center received a 6.2% increase for FY 2018 from its FY 2017 budget. The Clinical Center is using the additional funds to increase its pharmacy staff, support the Center for Cellular Engineering (CCE), hire more nurses to help implement a primary nurse model, and expand the Office of Clinical Research Support Services.

Focus Areas in Calendar Year 2018

In 2018, one of the top areas of focus will be space, of which the Clinical Center has a finite amount, and some of the goals for this year will require more active space management. The Clinical Center also plans to modify its protocol review process to include enhanced analyses for determining whether all requested resources are truly necessary.

The FEVS results showed a need to improve training for new supervisors in certain aspects of management and leadership and this is another 2018 priority. This year, the Clinical Center will also assess the efficiency of operations in the day hospital and outpatient clinics. Patients often spend too much of their time at the Clinical Center waiting, and often too many patients show up

at the day hospital at the same time. The pharmacy is often blamed for medication delays, but a contributing problem is inefficient workflow management to smooth out the peaks and valleys for medication preparation and administration. These issues will be addressed in 2018.

The Clinical Center will continue to address workplace harassment prevention and response, including patient harassment of providers. The lynchpin for dealing with harassment is training and prevention, but the Clinical Center cannot train its patients. It must therefore train its providers and staff in how to react. This kind of behavior will not be accepted, and a work group will develop policies and procedures for harassment.

Meeting Agenda

Dr. Gilman closed his remarks by reviewing the day's agenda.

Discussion

Regarding oversight of facilities, Dr. Tuckson asked whether the Maryland health department reviews building safety at the Clinical Center. Dr. Gilman replied that as a federal government facility, the Clinical Center is not subject to the State of Maryland health department oversight.

Role of the Surgeon-in-Chief

Dr. Forese asked about Dr. Davis's role, and Dr. Gilman explained that Dr. Davis works closely with the perioperative community, including anesthesiologists and nurses. Dr. Davis receives support from the Clinical Center Office of Patient Safety and Clinical Quality, and he will address issues such as operating room scheduling. He also chairs the Surgery Advisory Committee and has a vote on the Medical Executive Committee (MEC).

Reed Tuckson, M.D., asked whether Dr. Davis's role is administrative or clinical. Dr. Gilman replied that Dr. Davis has both types of responsibilities and that he performs surgery. He can advise a surgeon who has limited experience with a complex procedure not to do the procedure.

Dr. Forese asked whether Dr. Davis could inform a surgeon who refuses to do timeouts that he or she may not operate. John Gallin, M.D., Associate Director for Clinical Research and Chief Scientific Officer at the Clinical Center, confirmed that Dr. Davis has this authority and that he will weigh in on whether a surgeon has appropriate privileges. In some cases, however, Dr. Davis will ask Dr. Gilman to determine whether a surgeon may perform a given operation. Dr. Gilman added that one challenge with the rare and refractory diseases of many Clinical Center patients is that the surgeries involved are not commonly done in many hospitals.

Carter Van Waes, M.D., Ph.D., commented that when a surgeon at the Clinical Center performed a rare procedure that resulted in a patient death, the Surgical Administrative Committee determined whether the surgeon had consulted appropriately with other services, and the MEC met with the physicians involved. The Clinical Center compared what occurred with the experiences of the Mayo Clinic and other institutions with similar levels of activity, and the center presented this incident to the Joint Commission. Several recommendations on whether to perform these types of procedures at the Clinical Center in the future resulted. Dr. Forese pointed out that the ideal time for such discussions is before an incident, and Dr. Van Waes explained that such discussions do take place.

Dr. Tuckson asked about the locus of accountability for quality at the Clinical Center, which conducts a wide range of procedures, including some that are rare for patients with a low likelihood of survival. He asked whether the Surgeon-in-Chief has the authority to ensure delivery of high-quality care. Dr. Gilman said that Dr. Davis will work closely with Dr. Gilman, the perioperative medicine staff, and others to improve both business operations and quality of care.

Richard Shannon, M.D., said that the choice of Dr. Davis represents an important structural change, because staff clinicians have not typically held this type of leadership role at the Clinical Center. The fact that half his time will be covered by the Clinical Center will create accountability, and Dr. Davis will work with Dr. Gilman, who is the ultimate enforcer. The next step will be to create new systems, such as perioperative risk assessments, and develop work processes for daily scheduling in the operating room. This is an early stage of a fundamental change, and Dr. Shannon characterized this important restructuring as "encouraging." Dr. Forese agreed and congratulated Dr. Gilman and his team for this accomplishment.

Government Shutdown

Brig Gen James Burks, M.B.A., commended Dr. Gilman on the phenomenal evolution that he and his team have led in his first year at the Clinical Center. He asked about the impact of the continuing resolution and the recent federal government shutdown on the Clinical Center. Dr. Gilman explained that the Clinical Center does not have a line item in the NIH budget and that the recent shutdown had a smaller impact on the Clinical Center than on other ICs. The Clinical Center was not permitted to accept new patients during the shutdown, with a few exceptions, but Dr. Gilman did approve a few admissions for patients who met certain criteria.

Antifreeze Flood

Dr. Forese asked about drills at the Clinical Center for incidents like the antifreeze flood. Dr. Gilman said that the center has an emergency management plan and that it does conduct exercises. The center completed an after-action review for the flood that brought together approximately 70 people, including the NIH Fire Chief, who said that the staff did an excellent job managing the flood. During the flood, the Clinical Center activated its emergency operations center, which met frequently throughout the cleanup and kept NIH leaders fully informed.

Harassment Policies and Procedures

Dr. Shannon turned the committee's attention to provider harassment by patients, which raises a major moral dilemma for providers. Hospitals train their staffs to act constructively and effectively when they are offended, but the situations that are the focus of this training typically involve peers or supervisors. Increasingly, patients are using racial/ethnic or gender slurs when talking to providers, and leaders need to make clear that the Clinical Center is a place of mutual respect. It is challenging for a provider to manage this type of situation in the moment and a goal should be toidentify tools that leaders can use to support providers in these situations.

Jeanette Erickson, D.N.P., RN, said that the Clinical Center needs to establish harassment policies and procedures for everyone and that patients should sign a statement accepting the Clinical Center's values before they engage with it. Staff need not only classroom training but also role-playing experience. Dr. Erickson added that the person who is being harassed cannot

resolve the problem and that a team needs to support the victim and explain to the patient that the organization will not tolerate this behavior.

Dr. Collins asked whether a national effort is developing best practices for patient harassment of providers so that institutions can learn from one another. Dr. Erickson replied that many groups are addressing harassment, but she was not aware of a national movement to consolidate these efforts. Dr. Shannon suggested a collaborative forum to determine how to help providers act constructively in such situations. Dr. Forese believes that harassment is becoming more common as and she hopes that national efforts will address this issue recognizing that the Clinical Center needs interventions now.

Prioritization Efforts

Dr. Forese asked about the status of efforts to identify research priorities and decide which activities to move forward. Dr. Gallin said that he and his colleagues have worked hard to identify which resources are scarce, and one of the scarcest resources is cell production. A team of IC clinical directors has prioritized all protocols based on a set of criteria. Some protocols from early-stage investigators are high on the list, and some from experienced investigators are low, so the prioritization process was successful. The ICs are now giving scores of 1 to 10 to their protocols based on several metrics; ICs rarely give their protocols perfect scores, showing that their scores are honest. The Clinical Center will determine whether the scores predict how the protocols do; if so, this tool could be used for prioritization in the future. Dr. Gilman added that he is not involved in scientific prioritization and that his job is to increase capacity so that protocols can be implemented.

Beatrice Bowie thanked Dr. Gilman for the new wheelchairs in the Clinical Center and for cleaning up so efficiently after the antifreeze leak. Dr. Gilman said that the Clinical Center has acquired excellent new wheelchairs, but they need seatbelts, and patients cannot push themselves in these chairs. The Clinical Center can provide other wheelchairs with hand controls for patients who want more independence.

Patient Safety at the Clinical Center: Right Path?

Infrastructure and Cultural Changes Since the Red Team Report: An IC's Perspective

Richard Childs, M.D., Clinical Director, Division of Intramural Research (DIR), National Heart, Lung, and Blood Institute (NHLBI)

The NHLBI DIR conducts first-in-human studies of new therapeutics and diagnostics for heart-, lung-, and blood-related diseases. These studies are often bench discoveries translated to the bedside from intramural researchers. The division also characterizes the pathophysiology and genomics of common and rare diseases.

The DIR has one of the largest clinical research programs in the NIH intramural program, with 199 active clinical research protocols. NHLBI accounts for more than 4,000 clinical trial–related inpatients days at the Clinical Center. A large percentage of our trials enroll high-risk patients undergoing high-risk procedures.

The Clinical Center is well structured and staffed to support high acuity patients undergoing investigational procedures that may be associated with serious and sometimes life-threatening complications. In this regard, more than 1,500 patients have received experimental allogeneic stem cell transplants at the Clinical Center since 1993. This invasive procedure is often done in patients with substantial morbidity from their illness, and the procedure itself can be associated with substantial morbidity. The Clinical Center therefore needs—and has—an outstanding critical care medicine department as well as excellent medical support and ancillary services for these patients. A consortium meets every two months to standardize procedures and practices for ensuring that patients receive the safest and best supportive care.

To revitalize NHLBI's clinical research, Dr. Childs led team which conducted an overview of the DIR's clinical research program, which showed a lack of a comprehensive and standardized clinical research infrastructure and oversight. A strategic plan was developed with the goals of optimizing regulatory compliance and research efficiency as well as doing more with less by centralizing research nurses and creating an Office of Research Education and Patient Safety and an Office of Clinical Research Support Services.

NHLBI was already addressing many of the concerns that were highlighted by the Red Team, and the report gave these efforts momentum. Since the Red Team issued its report, a cultural change has occurred in the perception of patient safety. The efforts to reinforce patient safety spearheaded by the Clinical Center have spread to staff supporting clinical research across ICs. All personnel involved in clinical research now take ownership for patient safety and no longer view it as the sole responsibility of the nursing staff. For example, many different types of personnel now fill out occurrence reports, an activity which was previously largely limited to nursing staff.

The Clinical Center's daily patient safety huddle, which Dr. Gilman attends, has made safety a very visible high priority The Safety Tracking and Reporting System (STARS) has greatly improved patient safety tracking, and any event that could affect patient safety must now be reported. All events that are reported are reviewed and addressed in a timely way. Clinicians have changed their attitudes toward patient safety events; instead of just hoping that a given event is unlikely to happen again, they now proactively engage to take steps to make sure that these events do not happen again.

The NHLBI Office of Patient Education and Safety now reviews and audits all clinician notes and NHLBI-related STARS reports every day. The number of NHLBI events almost doubled in the last two years, not because more events were occurring, but because more were proactively reporting these events. The office also looks carefully for and identifies trends that need to be addressed.

Dr. Childs shared two examples of untoward events. The first was a near miss in which an atypical antibiotic was not administered promptly for neutropenic fever in a pediatric patient

with severe aplastic anemia. An immediate root cause analysis revealed communication lapses (including failure to escalate the issue and unclear communication within the pharmacy about the drug's availability and location) as well as pharmacy staffing issues (e.g., new hires) to have contributed to this delay. A deep dive evaluated the timeliness of stat antibiotic administration, communication pathways were improved, and first-line antibiotics are now available on patient care units.

In the second case, an adult with aplastic anemia developed viral encephalitis associated with increased intracranial pressure. Delays occurred in identifying the problem and administering appropriate medications. The immediate root cause analysis revealed a lack of urgency in the acute response, and communication lapses (including failure to escalate the issue), lack of awareness that the needed medications were readily available on the unit, and a delay in notifying neurology consultants. Within 6 weeks, strategies were developed to prevent this problem from recurring, including a "brain code" algorithm, a neurological care bundle in the intensive care unit, and active engagement of the Suburban Hospital stroke team.

Discussion

Dr. Tuckson was pleased to learn of the progress in addressing patient safety from NHLBI's perspective. He asked Dr. Childs to assess NHLBI's experiences with the Clinical Center team and how decisions are made to stockpile needed medications. Dr. Childs reported that the people involved in this incident would have been expected to know that the medications were in the crash cart. A misperception that mannitol, which was used for the adult patient, forms a precipitate precluding it from being stored in the crash cart and therefore needing to be made by the pharmacy was identified to play a role in the delay of administration of this medication.

Dr. Tuckson asked whether the NHLBI team meets with Clinical Center personnel to review the potential risks to each patient and ensure that personnel know what to do. Dr. Childs said that the pediatric patient he had described had a high likelihood of developing bacteremia and that twice-daily drills enabled staff to practice what to do if she developed a fever and needed an atypical antibiotic. The patient spiked a fever late at night, a fellow ordered the antibiotic, and pharmacy staff were confused about the antibiotic's location. Identifying where the antibiotic was physically stored was unfortunately not included in these drills.

Dr. Collins reported that when the Red Team issued its report, some staff were concerned that the new requirements for physicians and nurses would make it more difficult to conduct cutting-edge research, but NIH leaders thought that this was a misguided priority. Now that many new systems are in place to enhance safety, he wondered whether the people running research protocols find it more difficult to do their research. Dr. Childs replied that these individuals now feel confident that they have addressed deficiencies that could both compromise their research and put patients at risk. They do not find that the new requirements slow down their research, and almost all have bought into the new culture that safety is the highest priority for our patients. If deficiencies occur, nurses and other personnel, including fellows and attending physicians, now submit reports, which Dr. Childs believes is a great testament to the new culture existing at the Clinical Center.

Dr. Gilman said that the two examples show a cultural shift from blaming the pharmacy staff when medications are not provided promptly to viewing prompt administration of medications as everyone's responsibility. Dr. Childs agreed that everyone involved now owns the problem.

Dr. Tuckson asked about the pharmacy's formulary. Dr. Gilman said that the Clinical Center is not under pressure to avoid stocking drugs that it might need. The issue was not that the drugs were not procured but, rather, that not all pharmacy staff knew where the drugs were.

Dr. Forese asked whether the other ICs have made similar changes to those of NHLBI. Dr. Childs said that some of the infrastructure improvements at NHLBI have not yet occurred at smaller ICs, but the largest ICs with active clinical research programs have similar structures and resources to those of NHLBI. The Clinical Center either provides or is working to provide resources that are available to support clinical research that are currently available and utilized by the larger ICs.

Brig Gen Burks asked how to ensure that all ICs rise to this level of responsiveness. Dr. Gilman said that an effort is underway to standardize research support, help all ICs do a better job, and free investigators from some tasks that are difficult for them, given their other responsibilities.

Patient Safety and Quality at the Clinical Center from the Perspectives of the MEC and National Institute on Deafness and Other Communication Disorders (NIDCD)
Carter Van Waes, M.D., Ph.D., Clinical Director, NIDCD; and Chair, Medical Executive Committee

The MEC, which is made up of the IC clinical directors, assesses the quality and safety of patient care at NIH, develops policies for medical practice and clinical care, and recommends medical staff appointments and clinical privileges. Laura Lee, M.S., Director, Office of Patient Safety and Clinical Quality at the Clinical Center, reports to the committee every other week. The committee also receives reports from its subcommittees on such topics as infection control, blood product safety, medical record compliance and quality, medication management, code blue and rapid response, and bioethical issues. The committee receives feedback from patients and surveys of care and services.

MEC activities in 2017 included launching the Patient Safety, Clinical Practice, and Quality (PSCPQ) Committee, assessing the role of the committee and clinical director in credentialing and the care of pediatric patients, developing a neurologic emergency algorithm, and ensuring rapid transport of patients to area hospitals when needed. The MEC also assessed the accuracy of patient and provider information in the NIH Clinical Research Information System (CRIS), evaluated the hospital's hospice beds, addressed fluid shortages, and ensured 24/7 hospital operations support to ensure subspecialist availability for rapid responses.

Some procedures, especially those that are high risk and low volume, require a certain volume and currency for safe performance. The MEC asked the clinical directors and the Credentialing Committee to determine whether privileges renewed in the past were still current. In 2017, 66 providers voluntarily reduced their privileges, and 36 modified existing privileges. Others have increased their privileges, and some privileges are on hold until providers complete required training.

The MEC is helping centralize clinical research services, launch the Office of Research Support and Compliance, and ensure timely reporting of clinical research–related events. The committee is also changing the processes for informed consent, scientific review, and protocol prioritization.

The committee's goals for 2018 are to:

- Develop metrics for evaluating clinical competence and outcomes
- Translate recommendations of the PSCPQ Committee for peer review to improve ongoing professional practice evaluation and privileging
- Improve clinical documentation quality
- Enhance support for protocol development, review, and implementation
- Sustain timely reporting of events
- Enhance the Institute for Patient Safety and Quality

The Clinical Center patient safety huddle has enhanced awareness of clinical and safety issues and enables real-time problem solving. The medical and surgical morbidity and mortality (M&M) conferences have raised awareness of patient safety issues and started building a community focused on safety and quality. Prospective risk assessments are replacing reactive responses to risk, and more programs are using outside expertise to supplement clinical programs (e.g., otolaryngology surgeons or hospitalists for the Medical Oncology Branch).

To ensure that NIDCD otolaryngologists have the technical skills to perform specialized procedures proficiently and safely, NIDCD has arranged to bring Johns Hopkins University otolaryngology subspecialists to NIH. Through an arrangement with Walter Reed, NIDCD now has access to a pediatric otolaryngologist, and a Walter Reed resident has been assigned full time to NIDCD. The Institute has also expanded its research office to include a research nurse, protocol navigator, and data managers to assess quality of care, improve care, and ensure timely reporting. Monthly quality and patient safety meetings provide opportunities to review quality metrics and 30-day outcomes. The hospital-wide tracheotomy consult services conducts rounds three times a week to improve tracheotomy education and patient care. Ongoing professional evaluations and performance plans now address patient safety and quality of care.

Discussion

Dr. Tuckson asked whether the difficulty of maintaining credentials and privileges for procedures performed rarely at NIH is a deterrent for researchers who want to maintain their clinical skills. Dr. Van Waes replied that this is a concern for some NIH clinicians who cannot

maintain their previous volume of practice. The solution that Dr. Van Waes had discussed has enabled NIDCD to attract top-notch academic surgeons from Johns Hopkins University who might otherwise not have been able maintain their skills. NIDCD has also expanded the types of research it can do with these skills.

Dr. Tuckson characterized these solutions as "smart." He asked Dr. Gilman about difficulties retaining clinicians because of privileging challenges. Dr. Gilman replied that the surgeons of greatest concern are staff clinicians, not senior investigators, because the clinicians might need their surgical skills to make a living. He believes that the Clinical Center will have opportunities to address the need for certain subspecialists through arrangements like those of NIDCD with Johns Hopkins to help these staff clinicians maintain skills in certain areas.

Dr. Shannon asked about criteria for continuing medical education (CME) for clinical staff and whether these are based on licensure requirements. Dr. Van Waes said that most NIDCD clinical staff are licensed in Maryland, but they can be licensed in any state, and NIDCD asks clinicians to adhere to their state's standard. Dr. Van Waes requests copies of CME certificates to ensure that clinicians maintain needed skills. All clinicians must maintain their board certifications, and all surgeons are board certified (or board eligible in their first year). Dr. Gilman added that the Clinical Center offers many CME-approved conferences every week.

Nursing as a Partner in Achieving High Reliability
Gwenyth Wallen, Ph.D., RN, Chief Nurse, Nursing Department, Clinical Center

Nursing has always had a seat at the table at the Clinical Center, but its voice is becoming stronger. Dr. Wallen is an active member of MEC, for example, and nurses are beginning to speak a common language with their interdisciplinary colleagues and each other about safety and quality.

The morning safety huddle continues to change the Clinical Center's culture as personnel become more comfortable bringing issues to the meeting. For example, staff members questioned a huddle discussion of a STARS report about a patient who did not receive a requested hard-boiled egg. Dr. Wallen said that this missing egg was very important to the patient and that the Chief of Nutrition needed to know about this incident and use it to enhance the patient experience. This type of issue is appropriate to bring to the patient safety huddle.

Unit-based quality patient safety groups are enhancing interdisciplinary staff engagement in improvements. These groups allow IC and Clinical Center staff to jointly identify and address trends. Although nursing has a tradition of unit practice councils, those groups do not focus on patient safety and quality, but these new quality patient safety groups do.

Clinical Center staff better understand the role of nurses in ensuring the high reliability of the Clinical Center and ICs. Nursing has always been important to enhancing patient-related outcomes at the Clinical Center, but realization is growing that others (including people who

deliver meals or provide environmental care services) in addition to nurses must be involved in patient safety issues, such as preventing falls. Processes are improving through the realignment of the Department of Perioperative Medicine and the interventional radiology nurses into the Nursing Department.

The Nursing Department strives for zero central line–associated bloodstream infections (CLABSIs) and 100% knowledge-based medication administration (KBMA). The KBMA compliance rate had been 95% for a long time, but Dr. Wallen urged her staff to raise it, which they did by addressing some systemic issues. Finally, STARS and the new culture of being a high-reliability organization is leading to timelier follow-up on occurrence reports.

Dr. Wallen identified several areas for growth:

- Develop a roadmap to adopt Six Sigma principles
- Engage systems engineers to build capacity for interdepartmental efficiencies across transitions of care
- Enhance communication between ICs and Clinical Center nurses to anticipate the clinical requirements of protocols
- Increase alignment with clinical nurses outside the Clinical Center's Nursing Department
- Achieve a Pathways to Excellence designation and Magnet status

Discussion

Dr. Erickson thanked Dr. Wallen for taking the important role of chief nurse seriously in overseeing the nursing discipline. This can be challenging, especially when nurses do not report to chief nurses. Working closely with all nurses, even if they do not report to Dr. Wallen, will enhance the Clinical Center. Achieving Magnet status will do a great deal for the Nursing Department and will help align the entire organization with standards of patient care quality and safety. That framework provides a roadmap for measurements required to enhance care quality and outcomes.

Dr. Forese said that the CCRHB believes that having all nurses who deliver clinical care in the Clinical Center report to the chief nurse is a best practice, and the board encourages NIH to implement this recommendation.

Follow-Up Items:

- Consider requiring all nurses who deliver clinical care in the Clinical Center to report to the Clinical Center's Chief Nurse.

Patient Safety at the Clinical Center: Are We on the Right Path?

CAPT Diane Aker, M.B.A., RN, Senior Nurse Manager, 3NE, Clinical Center

CAPT Aker described some quality improvement activities on 3NE, the adult hematology/oncology blood and bone marrow transplant unit. As of January 21, the unit had

been CLABSI free for 23 weeks. The fourth quarter of 2017 was the first CLABSI-free quarter in this unit since 2013, showing the commitment of unit staff to patient safety.

The number of CLABSIs spiked significantly in the Clinical Center in 2016, and several strategies were identified to prevent these infections:

- Root cause analysis for each identified CLABSI
- Thirty-day room cleaning and patient engagement in personal hygiene
- Staff reeducation for all nursing staff in central line care

Additional strategies used on 3NE are:

- Use of alcohol caps on all infusion lines and idle central lines
- Identification of dressing change days to prevent delays
- Development of showering guidelines to ensure that dressings remain intact and prevent transmission of waterborne contaminants that could be pathogenic in immunocompromised patients
- Development of unit orientation guidelines

KBMA is a challenge on 3NE, which has an average of 12,000 to 14,000 medication passes per month. The KBMA rate has increased dramatically to 99% since 2014, and 3NE is still striving to reach 100%. In the last 60,069 medical passes in 2017, KBMA was used in 60,053, or 99.99%. The nine misses involved a nurse who had not been trained in KBMA and a few system-related issues, such as a nonfunctioning computer system.

The unit holds monthly patient safety and clinical quality meetings with all partners to review STARS reports and identify areas where performance can be improved. The meetings also include discussions of hand hygiene compliance, medication management, patient safety moments, CLABSI rates, falls prevention, daily rounds, and Clinical Center updates.

Opportunities for improvement include ensuring research integrity through increased real-time auditing of chemotherapy and biotherapy administration, increased research participant engagement (e.g., through patient satisfaction surveys), and new strategies to communicate improvement trends and engage partners across ICs.

Cultural Changes Since the Red Team Report: Institute Nursing Perspective
Georgie Cusack, M.S., RN, AOCNS, Director of Education and Patient Safety, NHLBI

Because NIH conducts clinical trials, it needs to ensure clinical care safety and protocol integrity. Ms. Cusack's primary role at NHLBI is to make sure that researchers, coordinators, nurse practitioners, and physician assistants undergo mandatory training and that standard operating procedures are written as needed. Her responsibilities also include the following:

- Attend the daily patient safety huddle
- Respond to all NHLBI Occurrence Reporting System (ORS) and STARS reports

- Collaborate with Clinical Center departments on performance improvement opportunities related to ORS events, protocol deviations, and other issues affecting research participant safety
- Perform medical record audit reviews for NHLBI in collaboration with the Clinical Center Quality Committee and Medical Records Department
- Perform clinical audits for the clinical director as needed

In collaboration with the Clinical Center's Nursing Department, Ms. Cusack helps lead education for bedside and research nurses on pharmacokinetic sample draws and provide reeducation if a sample is not drawn or is drawn outside the protocol window. In addition, Ms. Cusack works with the 3SWN nurse manager to improve the process for collecting research bone marrow specimens, and she has collaborated with the unit and the pharmacy to ensure that the needed syringes are available in the designated locations.

Ms. Cusack's wish list for future collaborations includes timely responses to STARS events from all colleagues and use of metrics throughout the Clinical Center to facilitate adequate staffing for research participants.

Discussion

Dr. Forese asked whether Ms. Cusack meets regularly with her peers from other ICs. Ms. Cusack replied that she does meet with peers from some ICs. For example, they all attend patient safety huddles, and if she identifies trends, she often contacts staff from other ICs to find out whether they have seen similar trends.

Dr. Tuckson thanked Ms. Cusack for her enthusiasm and asked whether she reviews the protocols and potential complications for each new patient admitted to the Clinical Center with house staff. Ms. Cusack replied that she does not but that the team does conduct twice-daily rounds and weekly grand rounds. Ellen Berty asked whether patients are invited to rounds. Dr. Childs replied that this does happen occasionally in response to a patient or family request.

Brig Gen Burks said that the greatest ally in accomplishing anything in a medical facility is the chief nurse executive. The presentations had demonstrated that the Clinical Center has reached a major milestone in its journey toward high reliability and patient safety. A 99.99% KBMA rate is very good, and it resulted from empowering, supporting, and engaging nursing staff. He suggested that the CCRHB consider making the kinds of presentations at this meeting a standing agenda item.

Ms. Bowie thanked Dr. Wallen for her role in the sickle cell disease sleep study, which has resulted in important benefits for patients.

Follow-Up Items:

- Consider making presentations on patient safety by Clinical Center staff a standing agenda item.

Patient Safety and Clinical Quality Update

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

Clinical Emergencies: Febrile Neutropenia

The focus on febrile neutropenia began with the near miss involving a pediatric patient that Dr. Childs had described. In addition, several STARS reports involved delayed antibiotic administration for febrile neutropenia. Ms. Lee therefore did a "deep dive" and created a flowchart of the processes to deliver a stat antibiotic to a patient. At first, those involved blamed the pharmacy for the near miss. But once they saw the flowchart, they realized that everyone has a role in the process.

The Clinical Center calls for stat medications to be administered to patients within 60 minutes. In August and September of 2017, this goal was achieved in 53% of cases. The median time for stat antibiotic administration that took more than 60 minutes was 87 minutes.

To reduce this interval, the Clinical Center took several immediate actions. For example, staff were encouraged to escalate issues and make sure that the information reached the person who needed it. Staff were asked to limit their use of stat orders to certain situations. In addition, first-line antibiotics were placed in patient care units, so it was no longer necessary to wait for the pharmacy. Because of Hurricane Maria, the fluids needed to mix antibiotics are in short supply, so the Clinical Center permits nurses to administer a broader range of antibiotic doses through intravenous push.

In November and December 2017, 72% of stat antibiotics for febrile neutropenia were administered within 60 minutes. The goal in the next two to three months is to reach 90%, and Ms. Lee believes that this goal is achievable.

Clinical Emergencies: Perioperative Hemorrhage

As result of a trigger tool group review and new surgical M&Ms, the number of cases of this massive blood loss rose—not because perioperative hemorrhage was more common but because staff were paying more attention. Most events occurred during high-risk kidney-sparing surgery or involved post-procedure bleeding complications. Over the last 3 years, the Clinical Center has performed 30 massive transfusions (more than 10 units of red blood cells administered in a 24-hour period).

An interdisciplinary team developed a new massive transfusion protocol that includes several steps for the nurse, lead physician, and Department of Transfusion Medicine. For example, the nurse is responsible for optimizing room temperature (target: 75°F), the physician lead activates the massive transfusion protocol, and a department fellow receives orders for blood products and clinical status updates and verbally confirms the next blood product issuance. The Clinical Center invokes this protocol when four units of packed red blood cells are administered within an hour and ongoing bleeding or hypotension are anticipated or the patient has laboratory or clinical status consistent with blood loss.

High-Risk, Low-Volume Procedures
These procedures are a longtime challenge for the Clinical Center and have been the focus of the new PSCPQ Committee. A subcommittee is determining the volume and characteristics of these types of procedures through a practitioner survey and a CRIS review.

Military medicine might have the best approach because military surgeons must be combat ready even when they are not in combat. Ms. Lee has been working with an expert at Walter Reed, which uses a systems approach for high-risk, low-volume procedures. The strategies include active and early engagement of attending and senior staff, reliance on external expertise, standardization of care processes, and rigorous outcomes reviews.

Follow-Up Items:

- Provide feedback on Clinical Center management of high-risk, low-volume procedures to Ms. Lee by email.

Culture of Patient Safety Survey: Preliminary Findings
The Agency for Healthcare Research and Quality (AHRQ) developed the culture of patient safety survey that the Clinical Center sent to all Clinical Center staff in 2017. The Clinical Center last administered the survey in 2012, and although it had planned to administer the survey every three years, it did not do so in 2015.

Ms. Lee compared the preliminary results from the Clinical Center with the results in the AHRQ database of several hundred hospitals. The Clinical Center results are below average in every domain, and the reasons why are not clear. Although scores improved between 2012 and 2017 for most of the 12 domains in the Clinical Center results, scores dropped for overall perceptions of patient safety, teamwork across units, staffing, and handoffs and transitions. Clearly, the Clinical Center has work to do.

Discussion
Dr. Erickson suggested that the low survey scores from Clinical Center staff could be due to negatively worded questions and insufficient communications with staff about these questions. She was not discouraged by the results, because Clinical Center staff have greater awareness of each domain.

Ms. Berty asked why the Clinical Center does not administer the survey more often. Ms. Lee explained that yearly changes are often too small for the Clinical Center to affect. However, the center does plan to administer the survey more often, perhaps every two years.

Dr. Forese commended Ms. Lee for the approach to high-risk, low-volume procedures, noting that every hospital struggles with this issue. The Clinical Center has the added challenge of performing such procedures in first-in-human studies.

Dr. Shannon suggested that the Clinical Center complete a debriefing on each high-risk, low-volume procedure to identify lessons learned, identify and plan for the most likely things to go wrong, and find out how staff did. The military playbook has the right approach of building a scenario, determining how much is known, and finding out how much has been learned from each case.

Hand Hygiene

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

Hand hygiene is a core technique and behavior to prevent infections in any health care setting. Although the benefits of hand hygiene are widely known, people do not necessarily practice it at every appropriate moment.

The Clinical Center's guidelines for hand hygiene are based on recommendations from the World Health Organization and the Centers for Disease Control and Prevention, as well as common sense. The Clinical Center requires everyone with patient contact to wash their hands with soap and water or an alcohol-based hand gel in several situations, including immediately before entering and after leaving a patient room.

Based on observations by Dr. Palmore and a few others who have been trained to collect these data, hand hygiene compliance immediately before entering and after leaving a patient room peaked to almost 100% in the fall of 2011 (after a *Klebsiella pneumoniae* outbreak) and the fall of 2014 (when a patient with Ebola virus infection was in the center's isolation room). Currently, the compliance rate is about 60% to 70%.

A new hand hygiene initiative is designed to increase compliance in a sustained way by changing hand hygiene culture. The Clinical Center is expanding compliance monitoring to the entire health care staff, because a study found that requiring all health care staff to submit a handful of hand hygiene observations each month increased compliance rates from 70% to 90% to about 95% and reduced hospital-acquired infections by 6%.

It is not easy for staff to tell peers that they neglected to wash their hands, even though such reminders increase compliance. Some hospitals use a code word to inform other staff members that they forgot to wash their hands, and the Clinical Center will try this approach.

Finally, the Clinical Center will remind patients more frequently that hand hygiene is an essential part of their care. For example, table tent cards in patient care areas and rooms could be a continuous, low-key reminder. If the code word works, patients could be taught the word and remind personnel to wash their hands when needed.

Discussion

Dr. Shannon said that this kind of disciplined problem solving is key to making progress in solving refractory, recurrent problems. He was pleased that the Clinical Center was basing its

strategies on other success stories and the literature instead of trying to invent its own solutions each time. He looked forward to seeing the results of this approach.

Safe Patient Handling Task Force

Gwenyth Wallen, Ph.D., RN, Chief Nurse, CC Nursing Department

The Clinical Center established the Safe Patient Handling Task Force in response to concerns that nursing staff and patient care technicians might not know how to safely transfer patients and that injuries have resulted from the lack of a comprehensive program for safe patient transfer. In 2017, the Clinical Center had 164 staff injuries, and 13 involved patient transfer, mostly by nurses and a few patient care technicians. Therefore, 13 people could have been out of the workforce for several months or even years if they had a severe injury.

The task force will develop and implement a Clinical Center–wide safe patient handling program to eliminate patient handling injuries in all patient care areas. The target population is all staff in the Clinical Center with direct patient contact, regardless of IC affiliation. Eventually, the task force will target everyone in the Clinical Center, because people who do not normally have direct patient contact might assist with patient transfer in some cases.

The task force is reviewing best practices from government and regulatory agencies and from programs that have been successfully implemented in large health care systems. The task force is also conducting a gap analysis that includes a review of staff injury data related to patient handling, availability and adequacy of patient transfer equipment, and high-risk patient handling tasks in clinical areas. The task force found that the Clinical Center has no formal safe patient handling program or systematic process to assess patient mobility and handling needs. Training for health care providers is inadequate, and anecdotal reports suggest insufficient access to lift and transfer devices.

In the first quarter of 2018, the task force will complete the gap analysis and describe the current state, best practices, and recommendations. It will organize its work around components of nationally recognized safe patient handling programs, which include policy development, incident management, technology and equipment, patient risk assessment, program champions, and training and education.

Center for Cellular Engineering (CCE)

Harvey Klein, M.D., Chief, Clinical Center Transfusion Medicine Department

History of Cellular Therapies at the Clinical Center

The history of cellular therapies at the Clinical Center began in 1984 with the establishment of the Special Services Laboratory that processed bone marrow and monocytes and studied cell trafficking. Other highlights in this history included the 1990 performance of the first cellular gene therapy to successfully correct severe combined immunodeficiency in a child and, in 1997, construction of a facility for hematopoietic graft engineering.

CCE Capabilities
Until recently, the CCE had four culture rooms in 3T. Cell processing activities include:

- Current good manufacturing practice (cGMP) manufacturing of non-investigational new drug (IND) standard products and core manufacturing for phase I and II IND clinical trials
- cGMP joint manufacturing support
- Development of new products and procedures
- Investigator support for regulatory IND development and support and clinical consultative and therapy management services
- Characterization and release of assays for peripheral blood stem cells and other cell products

The products that the CCE manufactures include gene therapies for inherited disorders, post-transplant and cancer immunotherapies, bone marrow stromal cells, and induced pluripotent cells for regenerative medicine. The CCE has 32 active protocols and expects to add a total of at least 14 new protocols in 2019 and 2020.

CCE Facilities Status
The 3T facility cannot meet the growing demand for cell therapies by intramural investigators. In addition, it lacks the capacity to meet the requirements of precision medicine for the manufacture of cells that target specific diseases and mutations.

CCE Expansion
The new CCE will be a trans-intramural program that is centrally funded and embedded in the Clinical Center's Department of Transfusion Medicine. A policy oversight steering committee will have representatives from participating ICs, and Dr. Gallin will chair a users' advisory committee. A scientific prioritization process led by the associate director for clinical research will oversee the facility's use.

The Clinical Center's old intensive care unit in 2J has been renovated, and it has seven new cell processing rooms, four of which are staffed and operational. The total number of cell processing rooms will grow to 18 by 2021. A modular facility with four cell culture rooms will be installed on the east terrace of the Clinical Center, and CCE staff will cover two shifts as well as weekends when needed. When the new CCE is complete, it will provide new product development and management, cell therapy manufacturing, product assurance and characterization testing, research and practice development, and technical and operational support.

In the CCE business plan, which has been approved, the CCE's full-time equivalent staff will grow from 51 in FY 2017 to 182 in FY 2020. Total operating costs will rise during this period from $13.1 million to $35.7 million.

By mid-2018, the CCE will have 11 operational cell processing rooms, and the terrace facility is expected to open in October 2018. 3T will close for renovations; when it reopens, it will be used to manufacture products that do not require cGMP space. This space will eventually close when cell processing rooms in 12E open in 2020 or 2021.

The new CCE will help recruit and retain first-class intramural researchers, who require first-class facilities. This expanded resource will also help the Clinical Center increase its hospital patient census, support NIH's engagement in precision medicine, and save money, because the cost of manufacturing cellular products in house is about a third less than that of outsourcing this service. Ultimately, the CCE will offer the easiest and most dependable solution to create, manufacture, test, and bring to scale customized cellular therapies for NIH clinicians and scientists.

It takes years to build and validate suitable cGMP space, and Dr. Klein recommended that NIH consider building a new wing for the hospital because of the difficulty of building cGMP quality into the existing facility. Although cell processing facilities are expensive, contracting out these services is even more expensive, in addition to being less flexible and less efficient.

Dr. Klein closed his presentation with a video about careers at the CCE.

Discussion

Dr. Forese asked whether the funds required for the CCE expansion have been committed. Dr. Klein replied that the FY 2018 funds have been and that the FY 2019 funds are probably also committed. After that, the Clinical Center will need to determine whether the CCE's growth and development are in accordance with projections. The CCE has high visibility and was one of the top priorities in the latest NIH 10-year plan.

Dr. Tuckson asked whether the CCE could provide services to external institutions to recoup some of its costs. Dr. Klein said that the CCE does plan to provide some services for extramural research through a U grant program, but providing services outside NIH would probably not recover CCE costs. Dr. Gallin added that the CCE may provide services at cost to the Clinical Center, but it may not generate profits. Furthermore, the CCE may provide services beyond NIH only if it has excess capacity.

Dr. Gilman said that Dr. Klein's laboratory has not only done great science, but it was also one of the very few laboratories to receive safety recognition from across NIH. He commended Dr. Klein for acting on suggestions from many outside experts on the CCE plans.

Closing Statement and Adjournment of Open Session

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital, and Chair, CCRHB

Dr. Forese closed the seventh meeting of the CCRHB at 2:51 p.m. by thanking NIH staff and the CCRHB members. The next face-to-face CCRHB meeting is scheduled for April 20, 2018.

Closed Session

This section of the meeting was closed to the public in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 USC. The materials and discussion could disclose information on the internal personnel practices or rules of the National Institutes of Health, as well as personal information associated with the individuals under consideration for leadership positions, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Adjournment of Closed Session

Dr. Forese adjourned the closed session at 3:15 p.m.

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

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

AHRQ	Agency for Healthcare Research and Quality
CCE	Center for Cellular Engineering
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
cGMP	current good manufacturing practice
CLABSI	central line–associated bloodstream infection
CME	continuing medical education
CRIS	Clinical Research Information System
DIR	Division of Intramural Research
FEVS	Federal Employee Viewpoint Survey
FY	fiscal year
ICs	Institutes and Centers
IND	investigational new drug
KBMA	knowledge-based medication administration
M&M	morbidity and mortality (conference)
MEC	Medical Executive Committee
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIDCD	National Institute on Deafness and Other Communication Disorders
NIH	National Institutes of Health
ORS	Occurrence Reporting System
PSCPQ	Patient Safety, Clinical Practice, and Quality
STARS	Safety Tracking and Reporting System