



People
Places
Capabilities

The NIH Clinical Center at

65

STRATEGIC PLAN



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On the 65th anniversary of this “House of Hope,” the NIH Clinical Center Embraces Change and Supports Landmark Clinical Research

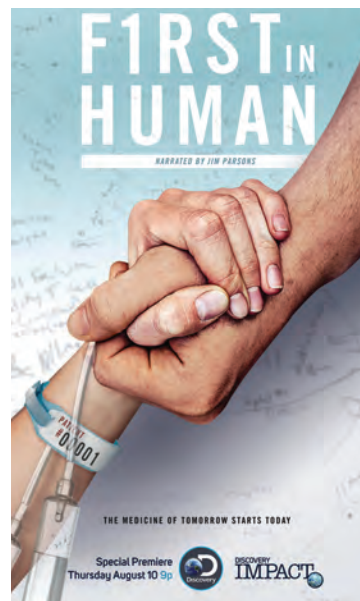
As I proudly navigate my third year as the Clinical Center’s (CC) first Chief Executive Officer, I offer this strategic plan as a reflection on the cultural transformation underway in the CC and with the promise of exciting changes ahead. The year 2018 marked the 65th anniversary of the opening of the Clinical Center. But it also marks an inflection point for the “House of Hope” as we continue the transition to a high reliability clinical research organization ensuring the best achievable patient outcomes.

In those three years since beginning the journey, we’ve introduced significant changes to governance of the Clinical Center (separating the oversight of *clinical research science* from the CEO’s oversight of *operational and hospital administrative management*); established a new CC Mission and strategic aims; revised our Guiding Principles; and integrated a new CC Research Hospital Board (CCRHB). The CC organizational chart (Appendix 1) supports the new governance model. These changes have been grounded in an unwavering commitment by the CC workforce to fortifying a culture and practice of safety and quality.

Ten years before the CC opened, Public Law 78-410 authorized the Public Health Service Act (July 1, 1944), to establish the Clinical Center (<https://go.usa.gov/xmMZt>). Historically, the CC has been (and continues to be) the site of many clinical breakthroughs in areas such as chemotherapy for the treatment of cancer, antiretroviral therapy for patients infected with human immunodeficiency virus (HIV), the management of patients with Ebola, and a multitude of other scientific discoveries and accomplishments (Appendix 2).

From the first patient admission in 1953, the CC continues to be the “House of Hope” for those afflicted with rare and refractory diseases as well as diseases of national and/or international significance. About 1,600 clinical research studies are under way at any given time at the CC, most of them sponsored by the Institutes and Centers (ICs) at NIH. These different ICs study disorders such as cancer, acquired immunodeficiency syndrome (AIDS), heart conditions, eye problems, dental issues, depression, and nerve diseases, to name just a few. For all of the studies, the CC provides the resources required to implement safe, cutting edge clinical research. Discoveries made at the CC have influenced biomedical science and public health processes throughout the prior 65 years. These successes are well-chronicled, including on these CC websites: <https://go.usa.gov/xmMK2>, <https://go.usa.gov/xmMKb>.

In 2017, a documentary produced by the Discovery channel titled, *First in Human*, showcased the powerful real-life experiences of doctors, researchers, staff, patients and their caregivers in the CC. The three-episode series was filmed over the course of a year (<https://go.usa.gov/xmMKK>). The series title, *First in Human*, captures the essence of the CC. Since its beginning, the CC has served as a global leader in the conduct of Phase 1 clinical research trials, which is the first stage of research testing in humans. The CC has specialized resources and infrastructure to support such studies. Indeed, many of the great scientific discoveries made at the CC began as first-in-human Phase 1 trials.



published around the globe. This strategic plan is written during a period of great progress in medical science. Advances in understanding cell biology and genomics, accompanied by advances in the techniques of cellular engineering, including gene editing, allow fulfillment of a portion of the promise of Precision Medicine – creating a therapy specific to an individual. These techniques are as applicable to rare and hard to treat diseases as to more common conditions.

As this plan is written, significant changes are also occurring in the operational healthcare environment. Complementary and integrative health approaches, such as meditation and natural products, are now entering the mainstream of medicine as traditional means of dealing with problems, such as pain, have failed to provide benefits that outweigh risks. Wearable technologies that record massive amounts of data and transmit the data wirelessly to processors capable of storing and analyzing these data will drive new community-based research efforts long into the future. Finally, migration from a care delivery model focused on illness to one focused on health is a generational change that will mature in the near future.

Our strategic plan is titled “*The NIH Clinical Center at 65: People, Places, and Capabilities.*” It reveals efforts by all key CC stakeholders to bring the safety of patients, who are our partners in research, into the forefront of our complex medical landscape. We also want to ensure that patient safety and clinical quality receive as much focus as our efforts to advance clinical science. While there is no room for complacency as we continue to develop the culture of patient safety, the CC staff is just as proud now of our patient safety metrics and outcomes as we are of the research results that are presented and

As we prepare to move forward, our aims are:

- Continuing to lead the world in conducting first-in-human clinical research while maintaining our focus on rare and refractory diseases
- Increasing the use of the CC by the NIH intramural research program while simultaneously accelerating the CC’s status as a national resource for the extramural community
- Demonstrating profound respect for our patients, whom we recognize as our full partners in the clinical research enterprise
- Partnering with the ICs to recruit, develop, and retain the next generation of great NIH clinical researchers and the CC staff that will support their efforts

This planning effort identified four main aims that will serve as guideposts to our priorities in the next five plus years. The priorities described in this plan were established in alignment with how NIH sets its research priorities. With our IC colleagues, resources are identified (including clinical staff, equipment, facilities, and infrastructure) to provide safe delivery of patient-centric care in support of scientific research aligned with public health needs. The influence of the Mission, Guiding Principles and aims permeate this strategic plan and serve as a foundation to leverage the CC’s future.

Since its inception, the CC has provided the collaborative environment for outstanding scientists, dedicated clinicians, and patients and their families to work together, regardless of the patient’s ability to pay. That principle will not change. The following pages describe a renewal of dedication to the safety and satisfaction of our patient-partners, sustained by the clinical research mission that will continue unabated as we find and develop the people, build the facilities, and integrate the capabilities that will enable superior clinical research at the CC for the next decade.

This plan is the culmination of extensive input from all key CC stakeholders: the CC Governing Board and the CCRHB; NIH-wide leaders including IC Directors, Scientific and Clinical Directors; NIH scientists, clinicians, and administrators; extramural collaborators; CC and IC staff; visitors, and our partners in research, our patients. CC and IC leaders participated in 7 planning sessions over the course of one year to process the abundant stakeholder input, and identified priorities to share with all readers of this plan. Gratitude is given for the direction and thoughtful contributions of so many individuals who have made our recent accomplishments a reality and our future plans possible.



While many of the details of changes that will take place in the CC over the next five years remain indistinct and are yet to be determined, these three domains: people, places, and capabilities will clearly remain important to the CC's success.

PEOPLE

A generation of clinical researchers who brought the CC to prominence are in the process of retirement or reducing their clinical research activities. These researchers were supported by CC staff who often spent their entire careers at the NIH. Finding and developing the next generation of great clinical investigators and the staff members who will support them in the CC is a focal point of this plan that can only be accomplished by working with our Institute partners.

Making full use of the existing development programs such as the Medical Research Scholars Program (MRSP) and relationships with academic institutions in the National Capital Region (Washington, D.C., area) are key elements of the strategy. Understanding generational differences with respect to career expectations is another component.

Finally, the CC needs to develop a systematic, intentional retention program that will require us to fully understand the various expectations, desires, and dreams of our talented and dedicated staff members. Continuing to invest in our staff is the foundation of our planning efforts and the future of the CC.

PLACES

Key operational aspects of healthcare delivery continue to evolve. Conceived as a facility focused almost entirely on inpatients, the CC's outpatient infrastructure was added in the 1980s. This infrastructure which houses not only outpatient clinics but common services used by all investigators such as the Departments of Radiology and Imaging Sciences, Perioperative Medicine (Surgery), Transfusion Medicine, and Laboratory Medicine requires replacement. A new Surgery, Radiology, and Laboratory Medicine Wing is on the drawing board.

Conventional imaging suites, operating rooms, and hybrid suites in which invasive procedures can be completed while being guided by one or more imaging methods are all contained in this plan. Cell processing and batch preparation of experimental pharmaceuticals require strict asepsis and the construction and sustainment of specialized facilities designed to meet very stringent standards.

Many renovations to existing facilities to meet these higher standards as well as construction activities for new facilities are underway. First-in-human clinical research in the future requires facilities designed to meet more exacting standards as well as extraordinary skill and specialized expertise to maintain the facilities.

CAPABILITIES

Healthcare delivery in the 21st century requires more than updated and new buildings and the replacement of key staff members. Efforts to make the CC a national resource have been underway for a number of years as the CC hosts research projects of outside investigators.

In almost every instance, however, these projects still require the patient to travel to the NIH campus for at least a portion of their evaluation and treatment. While these efforts will be refined and continued, technology now offers many opportunities to extend the reach and influence of the CC both nationally and globally.

To date, these efforts have focused on education, consultation, and collaboration. Employing technologies to provide care remotely for our patient-partners and to facilitate clinical research must be explored.

Dr. Kevin Hall
talks to a healthy
volunteer in the
Metabolic Unit.

CLINICAL CENTER GUIDING PRINCIPLES

Permeating all sections of this plan are both the CC's new Mission Statement: "We provide hope through pioneering clinical research to improve human health" and these seven Guiding Principles, recently revised to integrate the organizational journey to high reliability:

1: Individual and collective passion for high reliability in the safe delivery of patient-centric care in a clinical research environment

Patients and their families are full partners in the research enterprise. Risks related to a therapy that has never been used in humans for the first time may be unavoidable. CC staff will be relentless in anticipating preventable harm, applying a systems approach to eliminate risks whenever possible, and mitigating those that remain.

2: Diversity and inclusion of people and ideas

The best scientific and clinical outcomes and the organizational climate and culture that produce those outcomes require that all staff, volunteers, patients, family members, and visitors be treated with dignity and respect. Whereas we all share a love for science and for our patient-partners, there will be many differences of opinion about other issues surrounding clinical research and patient care that we will confront. We will appreciate and celebrate those differences while ensuring that the needs of women and minorities remain an area of focus to promote elimination of health disparities across the organization.

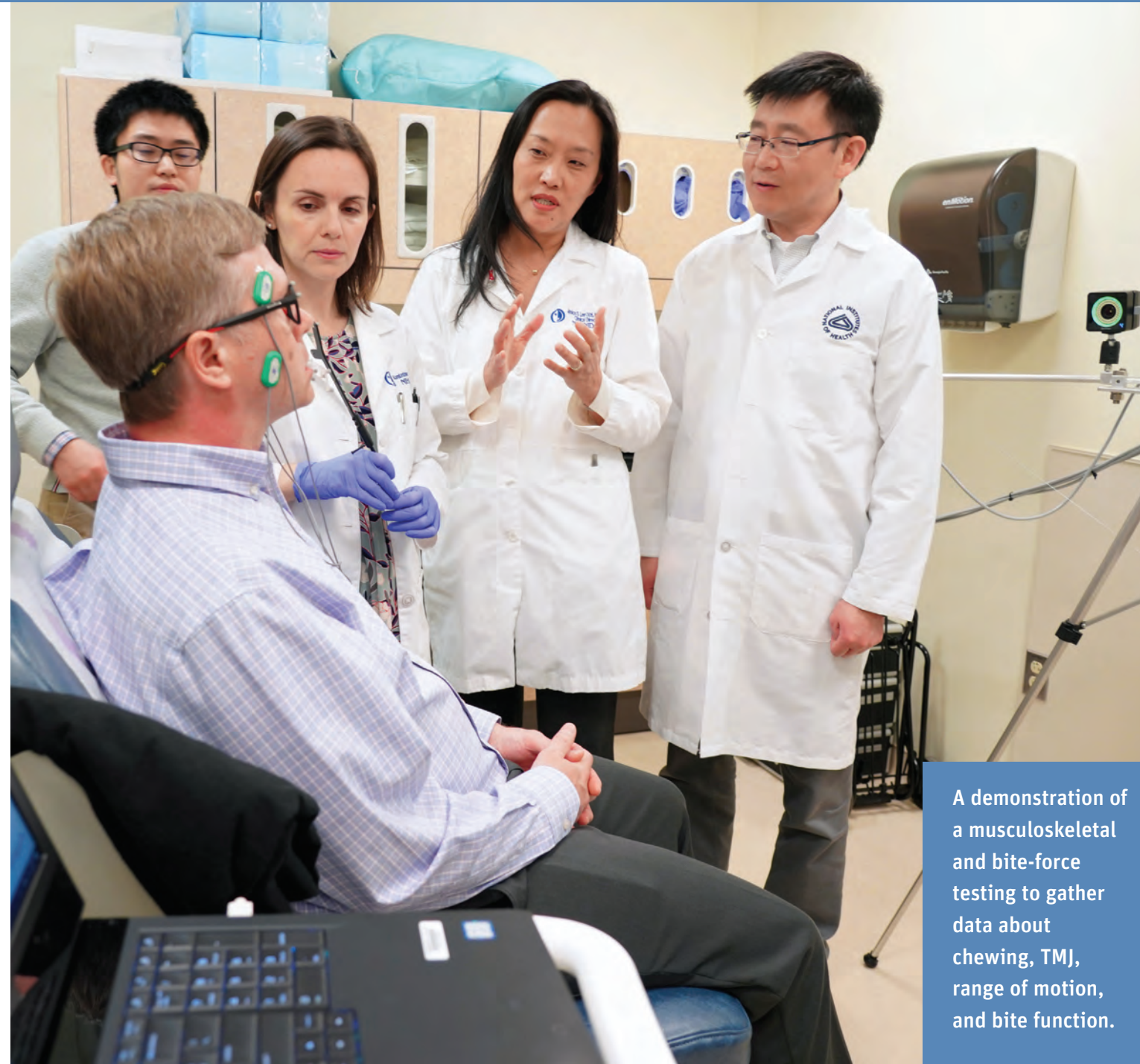
Note: Specifically aligned with this guiding principle are current efforts to enhance participation in CC clinical studies by women and minorities in support of 42 USC 289a-2(a)(3).

3: Compassion for our patients, their families, and one another

Whereas our mission is to conduct the research necessary to improve human health, we understand that feeling cared for counts! It counts tremendously! Patients often come to the CC when they have no other options. We will not add to their burden by failing to assist them in every way possible. Also, we will treat other staff members with the same compassion and civility that we show our patients and their families.

4: Innovation in both preventing and solving problems

Researchers are problem solvers by their very nature. However, even great problem solvers may inadvertently suffer lapses and commit errors when required to address issues urgently. Many of these errors may be avoided by anticipating problems and assessing risk before initiating a research study or a complex clinical task, and then establishing contingency plans that can be exercised if a problem occurs. In our relentless efforts to eliminate medical errors, prevention plays a key role.



A demonstration of a musculoskeletal and bite-force testing to gather data about chewing, TMJ, range of motion, and bite function.

5: Accountability for the optimal use of all resources

Biomedical research in general entails considerable expense, and clinical research is especially costly. CC staff must be cost-conscious without compromising patient safety or compliance with all relevant statutes and regulations.

6: Excellence in clinical scientific discovery and application

The CC has an extraordinary legacy of achievement in advancing clinical medicine. From the first cure of malignancy with chemotherapy to the first use of effective antiretroviral therapy to the explosive development of immunotherapies for cancer, the CC will continue to be in the vanguard of clinical breakthroughs that require our unique resources and expertise to develop.

7: Commitment to professional growth and development

Everything we do in the CC is dependent on the commitment of our staff to biomedical science and taking care of patients. The CC must remain in the forefront as new knowledge develops and tools and processes of clinical science and patient care evolve. We can only do so by continuing to invest in our people.



CLINICAL CENTER MISSION STATEMENT

We provide hope through pioneering clinical research to improve human health.



Leah Gober, a
2018-2019
Medical Research
Scholars Program
participant.

For many years, leadership in the CC rested with senior staff born during or just after World War II. Most came from the generation whose parents lived through the Great Depression. They value structure, stability, and job security and were known for a strong work ethic. Members of generations that came after, uphold these values and have effectively established expectations related to work life balance and career development. The details of generational differences and the impact those differences have on trans-generational understanding are beyond the scope of this document. It is sufficient to note that within a decade the CC will be led by representatives of new generations facing different challenges from global issues to environmental crises and new socio-cultural priorities. Acceptance of this reality is a necessary starting point if we are to recruit and retain the best and brightest.

Communication

The CC must provide forums that enable trans-generational and interdisciplinary communication. In particular, the voices of new generations must be heard at the most senior levels of the CC. The opportunities must be well-integrated, recurring, and systematic if the CC is to adapt personnel practices and policies that will serve the next generations as well as, or better than, the past and current practices and policies.

New generations are accustomed to a world of instant, wide-ranging, and barrier free communication tools that allow them to quickly and dynamically interact with both friends and complete strangers. The information cycle has no beginning and no end. Our efforts to enhance trans-generational communication must account for the disruptive developments of a revolution in communication.

Similarly, efforts to advance the principles of high reliability in healthcare require increased open-minded approaches based on educational background or training, keeping the patient at the center of everything we do, and recognizing that diversity of opinions provides the greatest opportunity for successful outcome and the best results for the patient.

Culture of Patient Safety, and Regulatory Compliance

Our efforts to improve the patient safety program and move aggressively into the realm of high reliability in healthcare delivery have been transformative over the past three years. Eliminating patient harm in the clinical research environment is a huge undertaking. It requires a critical review of existing systems and processes

to identify risk and efficiencies. It requires a focus on staff education and training. Most of all it requires empowerment of frontline staff. We have made great progress in our journey toward high reliability, but we still have much to do. While we address other aspects of CC culture, we will remain relentless in our efforts to protect our patient-partners from preventable harm.

Regulatory requirements governing clinical research are numerous and complex. The CC must provide assistance to investigators who need to meet these requirements without detracting unnecessarily from the scientific efforts. Smaller IC's require more assistance than larger IC's. The Office of Research Support and Compliance (ORSC) was established in 2017 and ensures the quality and integrity of clinical research and product manufacturing/compounding conducted at the NIH. As its name suggests, this office provides regulatory and compliance support and guidance for all NIH researchers in the areas of protocol navigation and coordination, quality assurance auditing and monitoring, support for Food and Drug Administration (FDA) regulated studies and centralized facility oversight. During the period of time covered by this plan, the CC will continue to develop a robust ORSC that will continue to facilitate clinical research efforts while making it easier for investigators to deal with ever increasing regulatory requirements.

A high priority focus on organizational performance metrics by our CC Research Hospital Board (CCRHB) involves standing metrics reports and updates for every quarterly meeting with a focus on metrics for operations, safety performance, infection control, nursing quality, clinical outcomes, quality and regulatory compliance, employee safety, etc. Programmatic improvements are consistently implemented in response to CCRHB members' recommendations. Metrics reported to the CCRHB are also posted regularly on the CC website: <https://go.usa.gov/xmesj>.

Operational metrics, including patient census trends, protocol activity, and staffing are tracked closely by the executive team and reported to the CC Governing Board. Looking ahead, organizational plans include a strategic review of the CC's current metrics portfolio, addition of medication management metrics, identification

In particular, the voices of new generations must be heard at the most senior levels of the CC.

of additional outcomes metrics to complement process assessments and the launch of a public display of clinical metrics on patient care units and other public spaces in the CC.

Culture of Mentorship, Diversity and Inclusion

People have very different notions of what mentorship means. However, there may be a more general consensus about the attributes of a mentoring culture. These attributes include an expectation of teamwork, shared accountability for successes and failures, respect for both expertise and experience, and a full understanding that the clinical research mission of the CC transcends generations and disciplines. Thus, each generation of researchers, research support staff, clinicians, administrators, and clinical research nurses learns from the previous generation and passes knowledge and wisdom to the generation that follows. Leaders are crucial to this culture, but peers and staff at all levels are equally as important.

Our guiding principle of diversity and inclusion reflects our commitment to staff, patients, family members, and volunteers alike. Of particular note is the NIH's program to combat all forms of harassment, including gender harassment, throughout the NIH community. Within the overarching NIH program is a CC effort to identify and address harassment or bullying involving patients or their family members. This initiative is in its infancy. However, its success is crucial if we are to establish the culture and environment that attracts the best employees regardless of gender, ethnicity, religion, race, gender identification, or sexual orientation.

Recruiting

Understanding generational differences is crucial to improving our ability to recruit the next generation of "NIH-ers". The National Capital Region and neighboring areas have a wealth of top-shelf schools producing medical scientists, nurses, administrators, and practitioners. The CC Office of Clinical Research Training and Medical Education maintains relationships with many of these institutions. The CC Nursing Department has relationships with programs from across the country, and a number of CC departments have arrangements with local programs training



Far left, a member of the Pharmacy Department checks a medication.

Left, a graduate of the 2018 Clinical Research Nurse Residency program gathers with fellow CRNs.

technologists and technicians. Residency programs for new graduates in disciplines like pharmacy and nursing will be important in attracting talented new staff members. Training agreements and residency programs will be supported and, when possible, expanded. This will give the CC a chance to experience more students and trainees early in their careers. The education and training mission complements and completes the patient care and research missions of the CC.

Recruiting of key CC staff cannot be done in a vacuum. Leaders among the CC staff provide service support to other ICs while a number also maintain independent research programs. The ability to balance research and research support is the unique and defining characteristic of CC leaders. It's very important to involve IC staff who are dependent on the CC for common services (such as laboratory testing or imaging) in the search and selection process of CC departmental leaders.

CC department chiefs lead groups of 150 or more staff members. Morale impacts the engagement,

Our guiding principle of diversity and inclusion reflects our commitment to staff, patients, family members, and volunteers alike.

satisfaction, and retention of staff clinicians, technologists, technicians, and administrative staff alike. Adding new voices to the recruiting and selection processes will be especially important as the CC continues to recruit and retain a diverse group of staff members and leader.

One key program hosted by the CC that has palpable strategic importance to the NIH is the Medical Research Scholars Program (MRSP). There needs to be adequate resources for the logistical support of this program, assuring that promising students have a positive NIH experience early in their careers. The hope is that it may lead to additional NIH training and scientific experiences later in their careers. Under new leadership, the goal is for the MRSP to expand its footprint within the NIH Intramural Research Program, the internal research program of NIH. The CC will do its part in support of this goal.

Additional key programs are the Presidential Management Fellows and Management Intern programs. CC participation in these programs should be a high priority and more consistent.

Retention

The unique clinical mission of the CC within the NIH family makes it very hard for our centralized human resources office to tailor retention efforts to CC staff. Many CC personnel practices and policies are set by the Office of Personnel Management, the Department of Health and Human Services, and NIH, but there is still a great deal under CC control.

Schedules and work assignments are one such area under CC control. Details of the updated personnel practices and policies will evolve over time. However, one anticipated key attribute will be greater flexibility. When establishing work schedules, we need to make more allowances

for individual career goals, aptitudes, potential, stage of career development, and personal and family circumstances that change over time. The opportunity to telework is often cited in employee surveys as an important satisfier, and telework is encouraged within the federal government. Efforts to establish policies that increase teleworking opportunities will be explored (while recognizing that not all work in the CC lends itself to telework, that telework-friendly projects may be time limited, and telework requests should be reviewed based on the needs of the CC as well as the desires of the staff members).

Staff members are often reluctant to forego new work opportunities to continue to do the same job year after year. Opportunities for staff members, especially those just completing their education, to explore varied opportunities within their disciplines rather than being expected or required to stay in the same narrow lane have to be carefully studied. The goal is to retain as many staff members as possible who are capable of doing any number of jobs well.

Financial retention incentives (e.g., loan repayment programs) are available but poorly understood and, all too often, applied in an ad hoc manner. Similarly, education and training opportunities cover a broad spectrum but even these benefits are not always addressed systematically. Without the creation of excessive bureaucracy, the use of retention incentives should be applied in a more systematic and programmatic fashion. Use of these incentives should be more transparent than has past been the case.

A disciplined, systematic retention program starts with a better understanding of the goals, aspirations, and dreams of our staff members. An annual paint-by-numbers review as part of a deadline-driven performance appraisal doesn't cut it. Individual development plans should be the rule and not the exception. Research indicates that Millennials welcome feedback. Regular (e.g. quarterly) meetings for constructive feedback and counseling will allow earlier detection of employee dissatisfaction. Such meetings can also spur consideration of the timely, more effective use of retention incentives.



A daily safety huddle provides a real time understanding about potential or existing safety, quality and service issues.

Awareness

We encounter many regional and national healthcare leaders who are unaware that NIH runs a research hospital, fully accredited by The Joint Commission. Recruiting the best talent and retaining that talent requires that the CC establish a separate identity within the larger NIH brand. Opportunities to market the unique resources and capabilities of the CC must be actively sought and addressed in a strategic fashion – one message with many voices. Awareness is important to our staff recruiting efforts. The recognition that stems from elevated public awareness contributes to retention as well.

Organization

The unique mission of the CC resulted in the evolution of a unique structure. In the CC, service providers such as the pharmacy, laboratory medicine, radiology, transfusion medicine, perioperative medicine, and rehabilitation medicine are larger than in many comparable facilities in order to support both clinical care and ICs' clinical research. However clinical departments such as medicine, pediatrics, and surgery are small in comparison to

The goal is to retain as many staff members as possible who are capable of doing any number of jobs well.

other academic medical centers. As the time commitments to independent scientific efforts have grown, a number of clinical researchers have yielded clinical responsibilities to staff members devoting most of their time to providing patient care.

In commercial healthcare, the spread of the hospitalist movement is indicative of the perceived value of specialization of function, as opposed to training and education. In the CC, Critical Care Medicine Department functions rely on hospital-based intensivists exclusively. The pediatrics inpatient and observation units are rapidly evolving toward that model as well. The medical oncology service uses hospitalists during the busy day shifts Monday through Friday but, at present, reverts to a more traditional model in which IC-based teams provide coverage during weekends and nights.

While there are no current plans to require use of the hospitalist model throughout the CC, the movement in that direction is clear. At the same time that the impact of using the hospital-based physician model on patient safety, patient and family satisfaction, and patient engagements is assessed, the resource requirements of employing this model more generally will be determined as this strategic plan is implemented.

Summary

Even in the electronic age, all measures of healthcare quality – clinical, functional, economic, and patient perceptions – are determined in the human domain. Recruiting, developing, and retaining the right people requires building the right culture and then organizing the staff in ways that simplify the enormous complexities encumbering the clinical research environment.



The proposed Surgery, Radiology, and Laboratory Medicine Wing.

The entire Clinical Center complex is designated as Building 10, but the complex is perhaps best understood as three buildings rather than a single one. The initial construction is referred to as the Magnuson Building. Dedicated in 1953 by President Harry S. Truman, the Magnuson Building housed laboratories, patient care areas, and offices of the clinicians and investigators. Of note, only a small segment of one of the floors was designated for outpatient medicine. A unique feature of the Magnuson Building was the co-location of patient care rooms and the laboratories where clinical scientists did their work to confirm diagnoses, characterize disease processes (phenotyping), and attempt to find effective treatments. This unique design facilitated lengthy inpatient stays to take full advantage of the unique architecture and co-location of patients and investigators. The Magnuson portion of the Building 10 complex lacks many features of contemporary healthcare architecture, and this building is no longer used for inpatient care. Nevertheless, it has shown remarkable durability and, after appropriate renewal, is still being used for offices and laboratories.

Surgery, Radiology, and Laboratory Medicine Wing

As evidence demonstrated that prolonged hospital stays resulted in iatrogenic harm, (a complication resulting from a medical treatment or intervention); and, as healthcare in America migrated to less expensive outpatient care with reductions in hospital length of stay, the second major building program of the Building 10 complex resulted in the structure referred to as the Ambulatory Care Research Facility (ACRF). Built in 1983, the ACRF houses the outpatient clinics as well as the Department of Laboratory Medicine offices and clinical laboratory work areas. The westward extension of this construction still houses part of the Department of Transfusion Medicine, the operating rooms and the offices of the Department of Perioperative Medicine, and the imaging suites and offices of the Department of Radiology and Imaging Sciences. The cardiac catheterization laboratory of the National Heart, Lung, and Blood Institute is also housed in this complex.

While this building provided much needed outpatient space, the ACRF was not constructed to be as durable as the Magnuson portion of Building 10. The construction does not facilitate inspection and preventive maintenance of water pipes, mechanical-heating, ventilation, and air conditioning (HVAC) systems, and electrical systems. When one of these systems fails, repair is equally difficult. The difficulty and expense of maintaining and repairing the systems in the ACRF have grown significantly.

The fact that this construction houses the service providers in the disciplines of radiology, laboratory medicine, transfusion medicine, and surgery that are so integral to clinical care and research makes replacement of a portion of the ACRF construction an imperative. The slate of requirements for the new Surgery, Radiology, and Laboratory Medicine (SRLM) Wing are being

Modern HVAC systems and automated building control systems ensure that the areas where drugs are prepared are maintained under carefully controlled conditions.

finalized and bridging documents are being prepared. The project will proceed to design once funding is secured. The importance of completing this project as soon as possible cannot be overemphasized.

Pharmacy

An FDA inspection in 2015 found that the NIH pharmacy infrastructure and processes fell short of contemporary industry practices. This FDA finding has triggered a determined effort to provide aseptic processing areas approaching those in commercial pharmaceutical manufacturing facilities. The first project completed, the interim intravenous admixture unit (iIVA) opened in April of 2017. It provides clean room capabilities for both hazardous and non-hazardous medications. Modern HVAC systems and automated building control systems ensure that the areas where drugs are prepared are maintained under carefully controlled conditions.

However, the iIVA was designed more for compliance than workflow. When patient activity is high, the drug preparation capacity of the pharmacy is exceeded. This results in delays that dissatisfy patients and staff alike. Pharmacy staff, working with Institute partners and nursing staff, have been very successful at minimizing the impact of capacity issues on patients. However, the real solution of a permanent IVAU will be realized in two years, as the design has recently been finalized. Interim projects to expand the capacity of the iIVAU and to provide swing space for pharmacy operations are underway and will ensure that the permanent IVAU can be occupied as soon as possible.

Radiopharmacy

The history of the radiopharmacy capability at the CC has been fraught with complexity and setbacks. Foreseeing many of the compliance issues described for the pharmacy, planning for a new radiopharmacy began in 2010 as part of a series of projects to upgrade the entire Radiology and Imaging Sciences Department. As construction began in 2014, compounding radiopharmaceuticals was outsourced to a commercial laboratory. Outsourcing has proven more costly than in-house production.

Moreover, reliance on the commercial compounding facility has resulted in delays in the performance of emergency studies. Also, the commercial facility does not do the cell labeling needed for certain molecular imaging protocols. The new radiopharmacy facility was nearly complete when a flood did severe damage to a number of the components of the mechanical systems. Furthermore, new requirements for use of the radiopharmacy for both cell labeling and generation of radiotracers developed over the long period of time. The net result is a design that satisfies the evolving needs and resolves these challenges. The new resource will meet the current and future requirements of all intended users- production of radiopharmaceuticals on site from generator and / or accelerator produced radionuclides and commercial kits as well as the ability to radiolabel biologicals, including cells.

Center for Cellular Engineering

Construction of additional aseptic processing areas is also required for expansion of cell processing capabilities. In a 2016 plan developed by IC Directors focused on the future of the CC, the growing demand for cellular engineering became apparent. The CC's Department of Transfusion Medicine had long experience in this field and efforts have been underway to expand the physical plant and workforce required to meet the requests of the intramural research program. The number of tissue culture rooms available increased from 4 to 11 with the completion of the 2J area for cell processing in early 2018. 2J is an area in the original CC building that served as the intensive care unit and underwent significant facility renovations to enhance cell processing capabilities.

An additional 4 rooms are planned to open in a modular facility to be located on the east terrace of the CC by early 2020. Finally, seven additional tissue culture rooms will be opened on the 12th floor of the E wing with in 2021. This 12 East space is also located in the original CC building and formerly served as a patient care unit and is now undergoing significant facility renovations for added cell processing sites. (Note: DTM will move into the renovated E wing in 2021 and is not scheduled to move into the planned new SRLM Wing.)



A rendering of the B1 FAES teaching laboratory (left) and the cellular processing facility (far left), part of the Center for Cellular Engineering.

Enhanced Simulation Center

As an institution focused on rare and especially stubborn medical issues committed to preventing lapses and errors whenever possible, improving our simulation capabilities is of high importance. Our clinical operations all too frequently involve high-risk and low-volume procedures. Although current simulation training programs have been well used by the Critical Care Medicine Department and Nursing Department for some time, the simulation capabilities of the two departments need to be coordinated. Also, we need to add training for contingencies in pediatric patients to our current simulation capabilities as soon as possible. The current Simulation Laboratory is inadequate for the expanded mission. A new location will need to be identified and resourced.

Our clinical operations involve high risk and low volume procedures on an all-too-frequent basis.

Space Allocation

The inpatient capacity of the CC significantly exceeds requirements. Although increased capacity for cellular engineering will fill some of the empty beds, most programs now on the drawing board require expanding the outpatient footprint. A recent space inventory indicated very little unused space in the CC. A plan to convert a portion of the unused in-patient space to outpatient use is a near-term deliverable that will ensure that important new programs involving pain research, opiate use disorders, healthy pregnant women, and dementia can be accommodated. Whenever possible, space redesign will be crafted with flexibility and modularity in mind, so the space can be used for different purposes without extensive modifications.

Summary

Clinical research involving rare and refractory diseases in the 21st century requires highly trained personnel meeting exacting standards in very specialized facilities. This plan, when resourced, provides world-class facilities worthy of our extraordinary patient-partners, and intrepid intramural researchers. Furthermore, these facilities meet the standards necessary to fulfill our commitment to high reliability and safety in the care of our patients.



A pediatric patient receives the first clinical treatment for a rare genetic disease, GM1.

As part of our responsibility and, indeed, honor to work in the world's largest hospital dedicated solely to clinical research, all CC staff at every level of the organization are committed to exemplary service to our patients, families, researchers and the larger global community. At a local level and through stewardship of all CC departments as well as collaborative oversight of IC clinical research, efforts are sustained in promoting increased scientific integrity, public accountability, and social responsibility in the conduct of science at the CC. These efforts are reinforced greatly with a newly-established CC Research Support & Operational Compliance Office as a resource to investigator efforts to ensure rigor and reproducibility of research, reduce administrative burden, and engage in proactive risk management practices. Quarterly Morbidity & Mortality (M&M) Conferences for all CC and IC clinical staff engaged in patient care were introduced in 2017. M&M Conferences in U.S. hospitals originated more than 100 years ago. They have evolved to address various aspects of patient care such as complications, adverse events, death, medical errors, omissions and system problems. At the CC, unique patient care aspects related to clinical research studies are also included in M&Ms. Since 2017, these CC sessions have been extremely well attended and have promoted excellent dialogue and follow up among multidisciplinary professionals throughout the organization.

Pediatric Patients

Contemporary and anticipated advances in gene therapy and cellular engineering will drive new assessments of our ability to take care of younger and smaller pediatric patients. The science necessary to diagnose inherited rare diseases has progressed significantly. The ability to intervene early in the natural history of those disease processes is advancing rapidly as well.

As the world leader in rare disease research, the NIH is positioned to apply the principles of precision medicine early in the natural history of the disease, thereby allowing the child to avoid many of the complications and sequelae that accrue over time. Caring for these younger and smaller patients can only be done if patient safety can be assured. A thorough gap analysis between current capabilities and those required to care for younger patients safely is a near term goal. Subsequent steps will be determined by the results of this analysis.

Upgraded Network

The upgraded network is key to a number of future initiatives. Improvements in medication safety involve greater use of barcoding technology, robotics, and automated dispensing cabinets that are networked with our electronic health record. Extending the reach of the CC requires a comprehensive evaluation of the current and future potential of telemedicine and telehealth. In the past, extending the reach of the CC typically involved collaboration with outside investigators. The UO1 and Bench-to-Bedside programs facilitated collaboration between NIH and extramural investigators. Although these programs have resulted in important scientific accomplishments, efforts to increase use of the CC through these mechanisms have not been successful. If the CC is to be a national resource, it must become a more robust virtual resource. The CC will develop a new initiative, "CC Without Walls," that will leverage technology to extend the reach of the CC to more patients, more families, more clinicians, and more scientists.

The upgraded network is a key to a number of future initiatives.

Electronic Health Record

While developing new initiatives that rely on technology, every effort will be made to keep the CC's bread-and-butter information systems current and robust. Our current electronic health record, Clinical Research Information System (CRIS), is flexible and adaptable to many patient care and patient safety applications. Increasing the duration and frequency of training for users would reduce a significant number of the shortcomings noted in a recent in-depth evaluation by an outside contractor.

This study did recommend starting procurement planning for a major upgrade or replacement of CRIS in 3 to 5 years. The landscape of electronic health records is expected to evolve during this period. The CC needs to keep abreast of new developments if the major procurement is to meet the CC's needs for many years into the future.

Cellular Engineering

The CC will continue to expand cellular engineering capabilities. While capacity has nearly tripled in the last year, requests by investigators for more and varied products continue to grow. By the time 12E opens in 2021, the number of cell culture rooms will be doubled yet again. As our experience in the construction and maintenance of these facilities matures, the ability to provide hope to sufferers of even the most challenging and rarest of diseases will continue to grow as well.

Summary

Renewed investment by the NIH in clinical research facilities, new capabilities, and expanding old capabilities portend a bright future for the CC. The improved capabilities and facilities are key recruiting and retention tools that ensure the CC will remain the leader in first-in-human clinical research well into the 21st century.

A capability in the CC context of strategic planning is a tool that enables research or research support. A new investigator who has unique expertise, a specialized piece of equipment that facilitates groundbreaking insights into clinical science, or a renovated suite of rooms that allows us to provide better care for a subset of CC patients are all examples of capabilities.

The CC has added or expanded a number of capabilities during the last three years. Some of these capabilities have been discussed in other parts of this plan, but several have not:

- Hospice suites – **NEW**
- Cellular engineering – **TRIPLED CAPACITY**
- Pediatrics observation beds – **NEW**
- Pediatrics hospitalist service – **NEW**
- Internal medicine service preoperative evaluation clinic – **NEW**
- Urgent transport capability – **NEW**
- Digital patient tracking – **NEW**
- Primary nurse model for out-patients – **NEW**
- Resources for research compliance and support – **AUGMENTED**



The Capital Investment Fund has also provided support for facility renewal that will serve us well over the coming years:

- Over the next two years, all in-patient rooms will be upgraded
- Nursing stations in the ACRF outpatient clinics will be remodeled to improve workflow
- Major investments have been made in electrical and mechanical (HVAC) systems to improve performance and mitigate the consequences of infrastructure failure
- Phased refresh of the Department of Laboratory Medicine

Additionally, through the well-established processes for prioritizing capital expenditures and leveraging the Capital Investment Fund provided by the NIH, major equipment purchases that would have been nearly impossible a few years ago are in process:

- CT scanning equipment to be located in the Critical Care Unit
- New mass spectrometer for the Department of Laboratory Medicine
- Next generation sequencing equipment for the Department of Transfusion Medicine
- Hybrid imaging suite for interventional radiology
- Positron Emission Tomography / Magnetic Resonance Imaging equipment
- Network upgrade



Conclusion

It's impossible for this brief strategic plan, which is designed for all of our stakeholders including our patients, their families, Congress, NIH staff, health researchers and professionals, and the public, to provide a comprehensive description of all the major activities currently underway or those planned for the next few years. For instance, this document contains no information about the ongoing efforts to establish the CC as a more active partner among the important healthcare interests in the National Capital Region. The intramural clinical research program of the NIH will always be in a state of evolution. Capabilities present in the past such as cardiac surgery are no longer present here.

As diseases like childhood leukemia have yielded consistently to therapeutic regimens pioneered in the CC, children afflicted with this malady are most often treated closer to where they live. Only the most unusual and hard to treat cases find their way to the CC. The CC is not, and presumably never will be, a general hospital capable of providing all services and subspecialties. Thus, partnerships with other institutions, both commercial and those connected with other government agencies, will remain of significant strategic importance. Great progress has been made in the development of these relationships in the last few years but there is still much work to do.

In a similar vein, current and planned efforts to more fully engage our patient-partners in their care have not been discussed herein to any significant degree. The most significant near-term effort in this regard is the plan to provide progress notes to most patients through the Patient Portal beginning in July 2019. Only notes written on or after July will be available initially. This effort to engage patients

in their own care is just one of a number of efforts to improve patient engagement as a way of improving patient safety, making progress toward the goal of high reliability in the clinical research environment.

While the strategic plan may not be exhaustive, it does highlight the areas where changes will be the most numerous and have the most impact. Enabled by a series of increases in the overall NIH budget and a renewed commitment to intramural clinical research, the CC at 70 will be significantly different than the CC at 65 – improved facilities and infrastructure, a host of new or updated capabilities, and a new generation of staff members prepared to tackle the tough biomedical research issues that face us domestically and globally.

The improved capabilities and facilities are key recruiting and retention tools that ensure the CC will remain the leader in “first-in-human” clinical research well into the 21st century.



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