DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

NATIONAL ADVISORY COUNCIL FOR BIOMEDICAL IMAGING AND BIOENGINEERING

Summary of Meeting[1]

September 11, 2009

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 21st meeting on September 11, 2009, at the Bethesda Marriott Suites in Bethesda, Maryland. Dr. Roderic I. Pettigrew, Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), presided as Council chairperson.

In accordance with Public Law 92–463, the meeting was open to the public from 9:00 a.m. to 12:30 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 1:30 p.m. to 2:30 p.m. for discussion and consideration of individual grant applications.

Council members present:
Dr. Philip Alderson, Saint Louis University, St. Louis, MO
Ms. Rebecca M. Bergman, Medtronic, Inc., Minneapolis, MN
Dr. Gary H. Glover, Stanford University, Stanford, CA
Dr. Augustus O. Grant, Duke University Medical Center, Durham, NC
Dr. Percival McCormack, University of Illinois at Chicago, Chicago, IL
Dr. Cherri Pancake, Oregon State University, Corvallis, OR
Dr. David Satcher, Morehouse School of Medicine, Atlanta, GA

Ad Hoc member present:
Dr. David Skorton, Cornell University, Ithaca, NY

Ex officio members present:
Dr. John McGrath, National Science Foundation, Arlington, VA
Dr. Andrew Watkins, Centers for Disease Control and Prevention, Atlanta, GA

Council members absent:
Dr. Richard L. Ehman, Mayo Clinic, Rochester, MN
Dr. Katherine W. Ferrara, University of California, Davis, Davis, CA
Dr. Mae C. Jemison, Biosentient Corporation, Houston, TX

Ex officio members absent:
Dr. Francis Collins, National Institutes of Health, Bethesda, MD
Dr. P. Hunter Peckham, U.S. Department of Veterans Affairs, Cleveland, OH
Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD
Ms. Kathleen Sebelius, U.S. Department of Health and Human Services, Washington, DC
Dr. James G. Smirniotopoulos, Uniformed Services University of the Health Sciences, Bethesda, MD

[1] For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a conflict of interest may have occurred. This procedure only applies to applications that are discussed individually, not to "en bloc" actions.

Executive Secretary:
Dr. Anthony Demsey

Also present:
NIBIB staff present for portions of the meeting:

Ms. Afrouz Auroux
Mr. Angelos Bacas
Dr. Richard A. Baird
Ms. Barbara Cantilena
Dr. Xiaoyuan Chen
Dr. Zohara Cohen
Dr. Richard Conroy
Ms. Nancy Curling
Ms. Chris Ann Davis
Mr. Jeff Domanski
Ms. Angela Eldridge
Ms. Kathryn Ellis
Dr. Zeynep Erim
Ms. Cheryl Fee
Ms. Carol Fitzpatrick
Mr. Ryan Gebbia
Dr. David George
Ms. Marie Gill
Ms. Pam Glikman
Dr. Valery Gordon
Ms. Terry Green
Dr. Ruth Grossman
Ms. Jude Gustafson
Dr. John Haller
Ms. Eunica Haynes
Dr. William Heetderks
Dr. Lori Henderson
Dr. Rosemarie Hunziker
Ms. Mary Beth Kester
Dr. Dale Kiesewetter
Dr. Peter Kirchner
Dr. Brenda Korte
Ms. Truc Le
Dr. Richard Leapman
Dr. Albert Lee
Dr. Guoying Liu
Dr. Hector Lopez
Dr. Alan McLaughlin
Mr. Todd Merchak
Mr. Larry Morton
Mr. Joe Mosimann
Dr. Peter Moy
Ms. Mary Patonek
Ms. Donna Pearman
Dr. Grace Peng
Dr. Karen Peterson
Dr. Roderic I. Pettigrew
Ms. Jessica Ryan
Ms. Stephanie Sabourin
Dr. Belinda P. Seto
Mr. Shaun Sims
Ms. Casey Stewart
Dr. Manana Sukhareva
Ms. Florence Turska
Mr. Mitch Wainberg
Mr. Kwesi Wright
Ms. Li-Yin Xi
Dr. Yantian Zhang
Dr. Ruixia Zhou

Members of the public present for portions of the meeting:
Dr. William Casarella, Emory University School of Medicine
Ms. Renee Cruea, Academy of Radiology Research
Mr. Khien Nguyen, Event Technology Solutions
Mr. Vhic Mata, Event Technology Solutions
Mr. Jason Michelitch, National Capital Captioning
Dr. Allison Okamura, The Johns Hopkins University
Mr. Michael Peters, American College of Radiology
Ms. Heather Rawls, NOVA Research Company
Ms. Marian Rothstein

I. Call to Order: Dr. Anthony Demsey

Dr. Demsey called to order the 21st meeting of the National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB). He reminded attendees that the morning session of the meeting is open to the public, welcomed attendees, and introduced Dr. Pettigrew, who formally welcomed all participants.

II. Director's Remarks: Dr. Roderic Pettigrew

A. New Members

Dr. Pettigrew introduced an incoming member of Council, Dr. David Skorton. Dr. Skorton has been the president at Cornell University for the last 3 years, following his 4-year term as president of the University of Iowa. He also currently holds appointments in the Departments of Internal Medicine, Pediatrics, and Biomedical Engineering at Cornell. He earned both his bachelor and medical degrees at Northwestern University and completed his medical residency and cardiology fellowship at the University of California, Los Angeles. Dr. Skorton is also co-founder and former co-director of the University of Iowa Adolescent and Adult Congenital Heart Disease Clinic. He has published numerous articles and book chapters and authored two major texts on cardiac imaging and image processing.

B. New NIBIB Staff

Dr. Pettigrew introduced the following new NIBIB staff members: Leah Baskin, Administrative Fellow; Richard Conroy, Nuclear Medicine Program Officer; Jessica Ryan, Management Analyst; Mary Pitonak, Ethics Specialist; Stephanie Sabourin, Biomedical Engineer; Manana Sukhareva, Scientific Review Officer; and Kwesi Wright, Grants Management Specialist.

C. American Recovery and Reinvestment Act/NIBIB Budget Update

The National Institutes of Health received approximately $10 billion of American Recovery and Reinvestment Act (ARRA) funding. Approximately $80 million of those funds were granted to the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The Institute awarded 16 Challenge grants, including 5 comparative effectiveness research awards, funded through the Office of the Director, in addition to the grants funded directly from NIBIB's appropriation.

The NIBIB allocated approximately 50 percent of its ARRA funds to support R01 and R21 applications that were already in the system and that were poised to make significant progress with 2-year funding.

Two funding opportunities of particular interest to NIBIB are the Small Business Catalyst Initiative and the New Technologies Pilot Initiative, and NIBIB received many applications for both. The Catalyst Initiative promotes high-impact research among small businesses that have not received previous NIH funding. The New Pilot Initiative is intended to bridge the gap between technical discovery and development of a technology, translating it into a commercialized product.

The NIBIB budget is not expected to change substantially in 2010. The $313 million in the President's budget would represent an approximately 1.5 percent increase over 2009 appropriations.

D. NIBIB Intramural Program Expansion

In support of its intramural program focus on Imaging Molecules to Cells, the NIBIB has recruited three principal investigators to play key roles. Shawn Chen is a radiochemist who has been working on development of novel probes for use in cancer and neurological disease; his work at NIBIB will focus on PET radiochemistry. George Patterson, a molecular biologist and biophysicist, has been active in developing techniques aimed at fluorescence imaging; he will lead the biophotonics work. Hari Shroff pioneered tools to study cell activities in real time (e.g., looking at fast cellular processes), focusing on photon-activated light microscopy; he will lead the high-resolution optical imaging section.

E. NIH Update

Dr. Francis Collins was appointed NIH Director in August and shortly thereafter announced five themes as the focus for future NIH efforts: (1) employing genomics and other high-throughput technologies to understand fundamental biology and causes of specific diseases; (2) translating basic science discoveries into new and better health treatments; (3) putting science to work for the benefit of health care reform; (4) encouraging a focus on global health; and (5) reinvigorating and empowering the biomedical research community. Comparative effectiveness research, funded with $400 million in ARRA funds, will specifically contribute to health care reform. NIBIB is already active in many of these areas, specifically comparative effectiveness research, personalized medicine, health disparities, and health information technology, and NIBIB's point-of-care technology collaboration with India demonstrates the Institute's efforts to address global health issues.

Human Stem Cell Research Guidelines

On March 9, 2009, President Obama issued Executive Order 13505, entitled "Removing Barriers to Responsible Research Involving Human Stem Cells," which states that the Secretary of Health and Human Services, through the NIH Director, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. NIH was charged with drafting and issuing guidelines to implement the Executive Order as it pertains to extramural NIH-funded stem cell research and to establish policies and procedures under which NIH funds such research. The guidelines were released July 6, 2009.

The guidelines state that the NIH may not fund derivation of stem cells from human embryos. Creation and destruction of embryos specifically for medical research were already prohibited under the Dickey-Wicker Amendment. Existing stem cell lines may be used, including approximately 700 lines beyond the 60 lines previously allowed. Cells derived from human embryos must be donated with voluntary written consent for their use in research and must be listed on the NIH registry, which will be available via the Web. The policy also restricts NIH from funding research that uses human embryonic stem cells introduced into non-human primate blastocysts or that involves animal breeding in which cells may contribute to the germlines.

F. NIBIB-Supported Scientific Advances

Dr. Pettigrew outlined three examples of scientific advances that have occurred through NIBIB-supported research. The first is a thermos bottle-sized device that can extract DNA without requiring refrigeration. Dr. Katherine Clapperich developed the point-of-care device, which is operated by a bicycle pump and can be used in remote and low-resource settings. The device represents a tremendous advance toward delivering modern medicine to underserved and rural

communities. The second advance is a hand-held device that can detect tuberculosis within 30 minutes; the device was created by Dr. Ralph Weissleder. Current procedures used to detect tuberculosis generally take up to 6 weeks for a definitive diagnosis. Dr. Michael Goldfarb developed the third advance, a prosthetic device for above-the-knee amputations. The battery-operated device powers both the knee and the ankle joint in a way that mimics natural movement. Sensors detect the level of torque and pressure within the joints, enabling them to respond appropriately to walking speed and the surface on which the individual is walking.

The Program for Appropriate Technology in Health (PATH), an NIBIB grantee, has received a $1.5 million award from the Conrad Hilton Foundation. Each year the Foundation recognizes an organization that has made significant humanitarian contributions. PATH will receive this award at a ceremony in Washington, DC.

III. Summit on Imaging Overutilization: Dr. William Casarella

Dr. Pettigrew introduced Dr. William Casarella, a professor of radiology and Executive Associate Dean for Clinical Affairs at Emory University. Dr. Casarella is a pioneer in interventional radiology and immediate past chair of the American Board of Radiology Foundation (ABRF).

Dr. Casarella reported on a summit that sought to address the problem of overutilization of medical imaging. The summit was co-sponsored by ABRF and NIBIB. To present a broad-based view of the problem and possible solutions, professionals from many disciplines were invited to participate in the August 2009 event. Attendees included representatives from insurance companies, governmental organizations, and hospitals as well as professional societies. Speakers included Jim Borgstedt, University of Colorado; Robert Kocher, Special Assistant to the President; Bernard Rosoff, National Quality Forum; Jim Thrall, Chief of Radiology at Massachusetts General Hospital; and Paul Wallner, radiologist and Executive Associate Director of the American Board of Radiation.

The Growth of Imaging Utilization—History and Contributing Factors

Prior to the summit, ABRF had gathered relevant U.S. health care statistics and examined the implications of increasing health care costs. Health care is the largest sector of the economy, representing 16 percent in contrast to housing (10 percent), food (9 percent), and national defense (4.8 percent). It is projected that, between 2007 and 2015, the national health expenditure will increase by 70 percent, and health care will account for approximately 20 percent of the gross domestic product.

In the early 1980s, imaging was extensively used, but by 1986, high-tech imaging was being used in approximately 10 million exams per year. By 2006, this rate had risen to over 60 million exams per year. Between 1999 and 2004, imaging increased by 62 percent, twice the overall growth rate of any other physician service covered by Medicare.

A major reason for increased imaging utilization has been development of new technology and the capital investment required to acquire this technology. Each advance renders some existing technology, equipment, and training obsolete, leading to a cycle of continued development and capital expenses. Because imaging innovations such as magnetic resonance (MR), computed tomography (CT), and positron emission tomography (PET) are expensive, the insurance industry has assigned high reimbursement values on procedures requiring their use.

Psychosocial issues have contributed to increased imaging utilization; patients expect doctors to order imaging procedures for diagnosis, and physicians, in turn, have come to rely on the diagnostic accuracy and certainty afforded by imaging. Lack of awareness of the proper use of imaging also contributes to the increased use of imaging procedures. A study published in *Academic Radiology* found that less than 50 percent of internal medicine residents knew one-half or more of the appropriate criteria for the proper use of imaging in a series of clinical scenarios; these criteria simply are not taught at an effective level to residents and medical students.

In addition, physicians' concerns about liability encourage the practice of defensive medicine, which is the tendency to make decisions—such as ordering expensive procedures—in order to prevent criticism or possible lawsuits. There is a consensus that approximately 25 percent of medical imaging orders result from the practice of defensive medicine, adding $150 to $190 billion to health care total costs annually.

Other factors contributing to the growth of imaging include financial incentives from self-referrals. Because a loophole in the Stark Laws allows self-referral "for facilities that are internal to someone's practice," many practices have added high-end imaging to their facilities, paying off the capital investment with the income self-referrals generate. An article in the *Journal of American College of Radiology* estimated that self-referral accounts for $16 billion of imaging costs.

In addition to rising health costs, radiation dose exposure is another negative result of imaging overutilization. Studies have shown that one CT scan is equivalent to 100 to 200 chest x-rays, a significant amount of radiation. An article in the *New England Journal of Medicine* by Fazel, et al., cites a six-fold increase in radiation exposure to the population over the past 25 years and calls for more comparative effectiveness research and other clinical research to verify the need for the high degree of dose rates in individuals.

Reducing Inappropriate Imaging

One of the summit's primary goals was to determine how much of imaging's rapid growth is due to overutilization versus how much actually contributed to improved patient outcomes and patient care. In addition, the summit considered efforts to reduce inappropriate imaging. For example, the "Image Gently" campaign has proven effective in working with manufacturers to reduce the dose rate needed, particularly in children, to obtain a diagnostic result. The campaign was developed and conducted by a group of radiology societies, including the American College of Radiology and the Society for Pediatric Radiology.

The Radiology Benefit Management Companies (RBMC) is a group of organizations that works on behalf of insurance companies to review and oversee the utilization of imaging, determine which individual physicians are overutilizing or utilizing imaging more than average, and attempt to determine which procedures will or will not be covered.

Summit attendees agreed that radiology order entry (ROE) systems could help ensure appropriate imaging use. ROE systems attached to decision support systems would allow for the pre-certification of procedures, improve primary care efficiency, and decrease medical costs. This type of system has been shown to decrease the yearly growth rate of CT scans at Massachusetts General Hospital from 12 percent to 1 percent. It is unknown whether the mandates related to these systems will be included in the final version of a health care reform bill.

The American College of Radiology has led the development of the appropriateness criteria, which would be built into ROE systems. These evidence-based criteria are dedicated to quality, safety, and appropriateness.

Recommendations from the summit included payment reform, decision support systems, patient involvement, and examination of real costs for imaging procedures. The recommendations encourage more appropriate use of imaging and development of quality standards, and emphasize the need for certification of personnel who perform imaging procedures. The recommendations offer solutions to the contributing factors that are controllable. Physician and patient education about the long-term effects of improper imaging will address psychosocial factors and the practice of defensive medicine. Additionally, electronic sharing and ROE systems will allow physicians to determine when imaging procedures are necessary or whether a colleague has already conducted the procedure.

Discussion

A Council member stressed the importance of researching ways to upgrade current medical devices rather than replacing them with new technology; this should also be encouraged among colleagues in the medical device industry. He also pointed out that many radiological procedures have been put into practice without their efficacy having been proven through multiple high-quality randomized trials. Dr. Casarella agreed, but commented that many procedures give such extraordinary images and provide such a clear diagnosis that their use is assumed to be appropriate.

Another Council member mentioned that current Health Insurance Portability and Accountability Act (HIPAA) guidelines already restrict hospitals from self-referral and wondered whether HIPAA could be strengthened to restrict self-referrals within physicians' offices. Dr. Casarella responded that the medical profession as a whole has resisted any attempts to restrain physician self-referrals; politically, this would be a large issue to tackle.

IV. Review of Council Procedures and Regulations

Dr. Demsey noted for the record that a quorum was present for this Council meeting. Council Members Drs. Dick Ehman, Kathy Ferrara, and Mae Jemison and Ex Officio Members Drs. Anne Plant, P. Hunter Peckham, and James Smirniotopoulos were unable to attend today's meeting.

G. Council Regulations, Policies, and Procedures

Dr. Demsey summarized elements of the Government in the Sunshine Act and the Federal Advisory Committee Act that govern all Advisory Council meetings. These Acts require the U.S. Department of Health and Human Services to open Advisory Council meetings to the public except when proprietary or personal information is discussed. To comply with these regulations, the NACBIB meeting is open to the public for all but the review of individual grant applications. Dr. Demsey reviewed the guidelines regarding conflict of interest, confidentiality, and lobbying.

H. Future NACBIB Meeting Dates

The next NACBIB meeting is scheduled for January 22, 2010, with the site to be determined. Dr. Demsey asked Council members to inform him of major conflicts with upcoming meeting dates.

I. Approval of the May 15, 2009, NACBIB Meeting Minutes

A motion was made and seconded to approve the minutes of the May 15, 2009, NACBIB meeting. The minutes were approved unanimously.

V. Overview of New Scoring Procedures

Dr. Demsey explained that a new scoring system is in place for peer review meetings effective for the October 2009 Council Round. These changes include a new 1–9 scoring scale, the scoring of individual core criteria, and templates for structured critiques.

Under the 1–9 system, a score of "1" is the highest possible score, and "9" is the lowest. Only whole numbers are used. Under the previous system, there were 41 different possible scores, which translated to 401 possible overall priority scores. Under the new system, there are only 81 possible overall priority scores. As a result, there will likely be more tied scores than under the previous system.

Adjectival descriptors will be used to define the nine possible scores. The new descriptors will be as follows: (1) exceptional, (2) outstanding, (3) excellent, (4) very good, (5) good, (6) satisfactory, (7) fair, (8) marginal, and (9) poor. The previously used term *unscored* will be replaced by *not discussed*.

Reviewers will receive structured templates to list strengths and weaknesses for each individual core criterion, the overall impact, and any other relevant review consideration for a particular application. Criterion scores will not be mandatory; reviewers can enter scores for any of the five individual core criteria they choose. Criterion scores will not be averaged; however, the preliminary overall impact scores from assigned reviewers will be averaged to determine a discussion cut-off point.

Beginning with the October 2009 Council Round, the all-CSR percentile base will be recalculated. Percentiling will be calculated in whole numbers, with all tenths rounded up to the next highest integer.

VI. Strategic Plan Workgroup Report

Dr. William Heetderks summarized the Strategic Plan Workgroup's meeting prior to the NACBIB meeting. The group discussed three main topics: strategic plan experiences members have had, the implementation plan for NIBIB's strategic plan, and the need for a revision of the strategic plan as it currently exists.

Workgroup members shared several experiences, with emphasis on lessons learned and best practices. Dr. Gary Glover described his experience with the International Society for Magnetic Resonance in Medicine of organizing a standing committee that met for half a day annually to consider how well objectives had been met and what changes were needed; the committee then focused on specific objectives of the strategic plan. Other suggestions by members were related to the importance of determining the purpose of the strategic plan and the role it has within the Institute. Emphasis was also placed on the need for all stakeholders to be involved.

The Workgroup then discussed implementation of the existing plan and the need to identify measurable components for future assessment of the plan's effectiveness. There was a suggestion to ensure that the implementation should be compatible with the goals of the Department of

Health and Human Services relating to health disparities and quality of life, with measurable outcomes for the objectives.

Revising the strategic plan was also a focus of the Workgroup's meeting. One revision to the existing plan would be to modify the language of the plan to be directed more to the community.

Copies of the current strategic plan are available to the public.

Dr. Pettigrew commented that the strategic plan outlines NIBIB's areas of focus and reflects in very broad terms the direction of the Institute. The current plan was drafted with an eye to the future, but the future often goes in unanticipated directions. For that reason, the strategic plan is and likely always will be something of a living document.

VII. Haptics in Medical Robotics—Surgery, Simulation, and Rehabilitation: Dr. Allison Okamura

Dr. Allison Okamura was trained in mechanical engineering at the University of California, Berkeley, and received her master's and doctoral degrees in mechanical engineering at Stanford University. She is currently at The Johns Hopkins University Engineering Research Center (ERC), where she is engaged in research on haptics in medical robotics.

Johns Hopkins is one of the leading institutions in robotics research, with emphasis on the fundamentals of robotic systems and human-machine interaction. Robotics projects at Johns Hopkins include using robotics in extreme environments, surgery, radiology, and various areas of biology and bioengineering. The ERC works in collaboration with other institutions (e.g., Carnegie Mellon University, Massachusetts Institute of Technology, Harvard University, Morgan State University, Columbia University, Georgetown University, University of Washington, University of Pennsylvania, Technische Universität München, Queen's University), industry affiliates (e.g., Siemens, Philips, General Electric, Medtronic, Intuitive Surgical, Hologic Ikona, Acoustic Medsystems, Northern Digital), and the Applied Physics Lab and other departments at Johns Hopkins. For example, the ERC is collaborating with the Johns Hopkins Radiation Oncology department on prostate brachytherapy. Dr. Okamura reported that they recently were able to insert brachytherapy seeds in the prostate in a desired configuration.

Dr. Okamura defines robotics as systems that use computation or computers in order to guide their interaction with the physical world; robotics is the physical connection computers have to the real world. Dr. Okamura's work focuses on haptics (i.e., touch) in robot-assisted surgery. She is conducting an NIBIB-funded project on how haptics and modeling simulation can be used for robot-assisted procedures.

Dr. Okamura believes that using robotics within a medical setting will provide many advantages. Robots have been shown to improve treatment practices because they are accurate, precise, and untiring, and many times can be remotely operated. For example, robotics can help over-scheduled physical therapists assist stroke patients as they take the thousands of steps necessary to regain the ability to walk. Robots provide physical assistance and increased dexterity that allow clinicians to perform more difficult and new procedures. Robotics also can provide information enhancements to a surgeon during surgical procedures.

Dr. Okamura described three main areas of haptics research: (1) understanding human haptics through the use of robotic devices, (2) giving robots the sense of touch, and (3) haptic

feedback—giving a human operator in a virtual world a sense of touch as if he or she is interacting with the physical world.

Haptic feedback enables physicians to make more natural motions when using robots to perform medical procedures. These human-robot interactions differ according to the procedure and the person performing the task. To test feasibility of human-robot interactions in real procedures, Dr. Okamura and her colleagues utilized the da Vinci® surgical system, a clinical robot that is commonly used in the United States.

Various force feedback techniques are being studied, including estimating force, graphical display, and force sensors. Estimating force is challenging because, although robots move according to instructions, they have their own complex dynamics. Force sensors are usually bulky and tend to be expensive. Graphic displays give surgeons an instantaneous idea of how much force they are applying; this technique tends to be more straightforward to implement compared to directly applying haptic feedback to the surgeon's hand.

In a study of the performance of the da Vinci surgical robot in actual human surgeries, cases that incorporated haptic feedback had significantly lower error than those that utilized graphical feedback or no feedback at all. Haptic feedback reduced the force used by surgeons, specifically when locating an artery.

Studies have indicated that different types of haptic feedback are optimal for different types of tasks. In some cases, graphical feedback was more useful to surgeons with little experience using the da Vinci surgical robot than those who were experienced. Determining the right haptic feedback to utilize according to the level of experience of the surgeon is the key to utilizing robots to their fullest potential.

Modeling and simulation are very useful tools in driving a surgical procedure or an interventional radiology procedure, as well as for training. Surgeons can use general and patient-specific models for training. Currently, however, there are no good models that can be used to drive surgery. Models under study include (1) haptic scissors to cut tissue and acquire data and (2) needle insertion to track deformation and understand tissue properties. These advancements are key to understanding complex medical issues that may not otherwise be understood through general surgery techniques.

Dr. Okamura described several new projects that use haptics in rehabilitation and prosthetics. A project sponsored by the Defense Advanced Research Projects Agency (DARPA) has developed prosthetics that offer a high degree of freedom, approximately 20 degrees, for artificial arms and hands. In order to make these prosthetic limbs work, they must be brain-controlled, utilize a mental model of the arm, and incorporate and process feedback. Research is also being conducted on people's ability to use proprioception—awareness of one's position and movement of the body—when using a robotic device. This is especially important when developing prosthetic devices that enable users to perform simple tasks such as holding a cup. Another project is driven by the need to rehabilitate patients who have experienced damage to the cerebellum, the part of the brain that controls movement. This project will focus on using robotics to expand understanding of how the cerebellum works.

Current research on haptics in medical robotics has contributed to a list of ideal characteristics for future research projects. These include incorporating human input and a quantitative description of patient state, which allows physicians to use models to plan an intervention and

design devices and systems that connect information to action. Although the ability of robotic systems to operate autonomously may not exist for many years, the ultimate goal is to use these systems to improve health and quality of life overall.

Discussion

An NIBIB staff member inquired about variability of individual reactions in conducting motion studies and whether the correlation with the vestibular system was incorporated into the study on proprioception. Dr. Okamura explained that individual reactions varied when using the training simulators for surgery; some individuals experience motion sickness with the simulator, yet not with the tele-operator surgical systems in which they control its motion. Current robotic system studies have not incorporated the vestibular system into the proprioception; this will be investigated once the prosthetic limb is attached to the body. Differences in proprioceptive capability across subjects are small; however, great variation in tactile-sensing capabilities exists.

Dr. Pettigrew inquired about the use of robotics in training surgical residents. Dr. Okamura responded that quite a bit of work is being done with surgical simulators at Walter Reed Army Medical Center to train physicians. However, this type of training has not been shown to translate well to real procedures.

VIII. Adjournment

The open session of the NACBIB meeting was adjourned at 12:30 p.m.

IX. Closed Session

The grant application review portion of the meeting was closed to the public in accordance with provisions set forth in Section 552b(c)(4) and 552b(c)(6) Title 5, U.S. Code and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2). The closed session was adjourned at 2:30 p.m.

Certification

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and complete.[2]

_____ Anthony Demsey, Ph.D.

Executive Secretary,
National Advisory Council for Biomedical Imaging and Bioengineering
Director,
Office of Research Administration
National Institute of Biomedical Imaging and Bioengineering

_____ Roderic I. Pettigrew, Ph.D., M.D.

Chairperson,
National Advisory Council for Biomedical Imaging and Bioengineering
Director,
National Institute of Biomedical Imaging and Bioengineering

[2] These minutes will be approved formally by the Council at the next meeting on January 22, 2010, and corrections or notations will be stated in the minutes of that meeting.