PREPARED STATEMENT OF RODERIC I. PETTIGREW, PH.D, M.D.
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Mr. Chairman and Members of the Committee: I am pleased to present the President's Fiscal Year (FY) 2017 budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH).

The mission of NIBIB is to improve human health by leading the development of biomedical technologies and accelerating their application. NIBIB supports research that integrates engineering with the physical and life sciences to develop emerging technologies that can be applied to a broad range of biomedical and health care problems. The scope of NIBIB-supported research is vast, from innovations to address paralysis to novel ways to deliver vaccines.

NIBIB is a leader in bringing together many disciplines to solve great biomedical challenges, with a mission that spans all diseases. To achieve that mission, NIBIB supports researchers from every field of medicine and gathers teams of scientists and engineers from diverse backgrounds. These researchers work to develop innovative approaches to advance scientific discovery and address real-world health issues through new knowledge and new technologies. I am pleased to share a few highlights from the breadth of NIBIB-funded research efforts that are working toward our shared goal of improving public health.

DELIVERING A VACCINE WITHOUT A NEEDLE OR NEED FOR REFRIGERATION

NIBIB's Quantum Grants Program is designed to have a profound, or quantum, impact on a particular health care problem. In keeping with NIBIB's mission, projects in this program take an approach that is highly collaborative and interdisciplinary with a focused goal that is achieved through technological innovation. In one Quantum Grant example, researchers have developed a microneedle patch to deliver vaccines without the traditional "shot in the arm." This technology could lead to self-administered vaccines with an easy-to-use, more widely available device that is about the size of a quarter.

The first targeted application is flu vaccination. Influenza is a major cause of illness and death worldwide. While vaccines are effective in preventing infection, access in rural and medically underserved areas is a challenge. A new microneedle patch addresses these challenges in that it can be self-administered, does not require refrigeration, and could be delivered in the mail. The single-use patch is also painless and research has indicated that all of these benefits could lead to higher rates of immunization and reduce flu-related deaths and hospitalizations.

A clinical trial is underway to assess the use of microneedle patches in vaccinating against influenza. The patches contain very thin and short microneedles, which are barely visible to the eye. As the patch is applied to the skin, these microneedles painlessly penetrate the upper layers of the skin and deliver the vaccine. The study includes 100 healthy adults and seeks to assess the safety of the microneedle patch, how the body's immune system responds to the vaccine delivered through the patch, and participants' opinions about using the patch. Initial results indicate that influenza vaccination using the microneedle patch generates immune responses at least as good as conventional injection, that the microneedle patch has a very good safety profile, and that study participants strongly prefer vaccination by the microneedle patch over a traditional flu shot.

USING IMAGING TECHNOLOGY TO BOTH DIAGNOSE AND TREAT DISEASE

For decades, imaging technologies such as magnetic resonance imaging (MRI), ultrasound, and computed tomography (CT) have provided a window for a non-invasive look inside the body to locate and assess tumors or damaged tissue. Increasingly, research in imaging technology is not only discovering improved ways to see inside the body but also developing highly integrated systems to provide rapid feedback to guide treatment.

In another Quantum Grant Program example, researchers are using an improved imaging technology that combines diagnosis and an intervention for acute ischemic stroke. Strokes are a major cause of death and neurological injury. Acute onset of stroke-like symptoms is a medical emergency and rapid diagnosis and treatment are critical to saving as many brain cells as possible. This novel method is estimated to save from one to two hours per patient, and therefore save considerable brain tissue.

Currently, stroke diagnosis and monitoring is performed with imaging in dedicated CT or MRI imaging suites separate from where stroke is treated, requiring the patient to be moved and costing precious time while brain tissue is damaged through loss of blood supply. The treatment of stroke caused by blocked blood vessels involves specialized catheter-based angiography to restore blood supply to the affected brain area. The breakthrough of this Quantum Grant award is the integration of angiography with advanced imaging capabilities into a time-saving and cost-efficient platform that is housed on a single machine. This is possible through a revolutionary image acquisition and reconstruction technique that fundamentally challenges the traditional methods now in use. For the first time, this new technique produces rapid, high resolution CT images and enables immediate treatment of strokes caused by blood vessel occlusion (blockage).

Advances to current imaging technologies such as this could lead to more rapid and personalized treatment of occlusion stroke, potentially resulting in better neurological outcomes for patients.

FINDING RARE CELLS AMONG BILLIONS FOR EARLY DETECTION OF CANCER

Cancer tumors shed tiny fragments that can enter the blood stream. Capturing these obscure traces of cancer allows them to be analyzed so that treatment can be designed specifically for each patient. Similarly, the technology can be used to monitor treatments for effectiveness. This individualized approach, which identifies and targets the specific genetic features in each person, is the hallmark of the President's Precision Medicine Initiative.

In an initial phase of an ongoing NIBIB Quantum Grant Program, researchers developed the iChip, a microfluidic device that can capture one circulating tumor cell (CTC) among one billion red blood cells. This means that in a small vial of blood there could be from 1–100 CTCs among 80 billion red-blood cells. In one study, human cancer cells were captured using this technology and analyzed, then tested in animal models to see which treatment was most effective. Researchers are also working to make the device so small that it can be used at the point-of-care to deliver results rapidly. This real-time measurement of CTC numbers could one day allow doctors to promptly change or stop ineffective treatments, such as when cancer cells become resistant to a particular chemotherapy drug.

The technology has also been developed to isolate clusters of CTCs. Clusters are even rarer than single CTCs, but are 50 times more potent in producing metastatic spread of cancer. Identifying and capturing CTC clusters could help identify and study more aggressive cancers.

Building on this research, the investigators are now turning toward a new phase of development that can capture pieces of DNA shed from cancer tumors. Researchers are looking at this new use of the technology as a sensitive method for early identification of prostate and lung cancer. In both types of cancer, detection is challenging and cancers are often discovered when tumors are of a significant size, or the cancer has spread. This technology also has the potential for non-invasive monitoring to determine if the selected treatment is working. The new approach integrates the CTC iCHIP technology with known methods to identify genetic markers for early detection.

USING NEURAL STIMULATION TO ADDRESS PARALYSIS

Each year 12,500 new cases of severe spinal cord injury (SCI) occur (2015, National SCI Statistical Center). Currently, the approach for treating this type of injury is to provide rehabilitation therapy to limit further damage. In these patients, the pathways that send information about sensation from the legs to the brain and from the brain to the legs to control movement are disrupted. For years physicians thought that recovery of function in spinal cord injury was not possible.

Now, after years of basic research and recent developments in a very small number of patients, investigators are working to understand how neurostimulation of the spinal cord might help patients regain function. Recent studies have shown that it might be possible to reawaken the neural pathways along the spinal cord after injury. A small number of patients have received electrical stimulation either implanted under the skin next to the spine (epidural) or placed on top of the skin along the spine (transcutaneous) and have regained the ability for some limb movement and the ability to stand unassisted for a brief period of time. Patients receiving stimulation also report that they have regained other functions important for improved quality of life, such as control of blood pressure, temperature, bladder, bowel, and sexual function. Further study is aimed at understanding how electrical stimulation can most effectively lead to restored function and how stimulation can be customized to work best for individual patients.

NIBIB is also part of the President's BRAIN Initiative and part of this effort is to develop tools and technologies that lead to a better understanding of brain function. Many of the technologies developed for understanding the brain can be used to understand the spinal cord and the peripheral nervous system. Understanding these systems will help us know how to help people overcome these devastating injuries.

CONCLUSION

Advances in technology are catalyzing the development of solutions to previously intractable disorders and improved approaches to biomedical research. As these examples illustrate, this type of research requires many disciplines to work together and this integration of disciplines is what defines NIBIB's approach. NIBIB is committed to supporting such convergent teams of researchers to solve major biomedical challenges that will improve the health of all Americans.

Roderic I. Pettigrew, Ph.D., M.D.
Director, National Institute of Biomedical Imaging and Bioengineering

Roderic I. Pettigrew, Ph.D., M.D., is the first Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the National Institutes of Health (NIH). From 2013-2014, the NIH Director appointed Dr. Pettigrew as the Acting Chief Officer for Scientific Workforce Diversity to establish program oversight of all NIH activities that address the unique diversity and inclusion challenges, to strengthen the national biomedical research workforce.

Prior to his appointment at NIH, Dr. Pettigrew was Professor of Radiology, Medicine (Cardiology) at Emory University in Atlanta, Georgia, Professor of Bioengineering at the Georgia Institute of Technology, and Director of the Emory Center for MR Research at the Emory University School of Medicine. He is known internationally for his pioneering work at Emory University involving four-dimensional imaging of the cardiovascular system using magnetic resonance (MRI). His current research focuses on integrated imaging and predictive biomechanical modeling of coronary atherosclerotic disease.

Early on at NIBIB he jointly led a national effort with Howard Hughes Medical Institute to create new interdisciplinary graduate training programs, and established the Quantum Projects program to achieve “medical moon shots” by pursuing high-risk, high-impact projects designed to solve major healthcare problems. Under Dr. Pettigrew’s leadership, national collaborative and international initiatives have been issued to develop low-cost and point-of-care medical technologies and at present, he leads an effort to reduce CT radiation dose to background levels. He also leads a recent U.S.-India collaboration to develop unobtrusive technologies for frequent recording of blood pressure to address the world wide problem of hypertension.

Dr. Pettigrew has been elected to membership in two components of the U.S. National Academies: the National Academy of Medicine (formerly the Institute of Medicine and the National Academy of Engineering. His awards include Phi Beta Kappa, the Bennie Award for Achievement, Morehouse College, the Most Distinguished Alumnus of the University of Miami (1990), the Hall of Fame of the Miller School of Medicine at the University of Miami, the Herbert Nickens Award of the ABC, the Pritzker Distinguished Achievement Award of the Biomedical Engineering Society, the Distinguished Service Award of the National Medical Association, the Pierre Galletti Award of the American Institute of Medical and Biological Engineering, and the Inaugural Gold Medal Award of the Academy of Radiology Research. He also has been awarded Honorary Professor of the South China University of Technology in Guangzhou on the occasion of commencing their first medical school class.