



Testimony
Before the Committee on Oversight and
Government Reform
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NIH Emergency Care Research

Statement of

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Mr. Chairman and Members of the Committee, I am Dr. Walter Koroshetz, an internist, neurologist/neurointensivist, and, since January of this year, the Deputy Director of the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I am also a member of the Trans-NIH Emergency Medicine Task Force. This group is developing a coordinated NIH response to the relevant concerns raised by the Institute of Medicine (IOM) Report on the Future of Emergency Care in the United States Health System. Prior to coming to NIH, I directed the emergency neurology, stroke, and neurointensive care services at Massachusetts General Hospital and Harvard Medical School. I also worked over a 17- year period with the emergency medicine societies in the Brain Attack Coalition to improve emergency care of stroke victims.

The mission of the NIH, in emergency care as in other areas of medicine, is to make biomedical discoveries that improve health and save lives. Essential to emergency medicine is the emphasis on ultra-rapid diagnosis and treatment to save the critically ill emergency patient. NIH research continues to push for discoveries that will improve the outcomes for patients with these life, or quality of life, threatening conditions in which time to treatment is so critical. In this discussion it is important to see this mission as separate, though linked by the site of care, to the problem of supplying optimal medical care for the wide spectrum of conditions that bring millions of Americans to emergency departments across the country.

It is also important to note the vital contribution of basic biomedical research to emergency medical care. Basic biomedical research yields critical insights into the fundamental

mechanisms of cell response to injury, and into pathways of cell recovery and regeneration. While not classified as emergency medical research *per se*, these and other avenues of basic research provide the foundation for the translational and clinical research I will be highlighting today.

STROKE AND OTHER NEUROLOGICAL EMERGENCIES

The stroke story, which I know best, illustrates how NIH research plays a critical role in developing new emergency interventions and working with emergency medicine to improve treatment. It is replicated in many areas of emergency medicine, including treatment of acute coronary syndromes, cardiac arrest, trauma, burns, sepsis, and toxic exposures, to name just a few.

About a decade ago, an NINDS clinical trial revolutionized acute stroke treatment by demonstrating that the clot-busting drug tPA (tissue plasminogen activator), administered within a critical time window to carefully diagnosed patients, improved the outcome from stroke. This was the first proven treatment for stroke, and it was the culmination of many advances from basic biomedical research that were then tested for years in animal models, followed by careful pilot studies in patients. Its success has opened entirely new areas of patient care and research on emergency care of stroke and other neurological disorders in academia and industry. Building on this first acute stroke treatment, the Brain Attack Coalition, which includes government, voluntary, and professional societies, has energized the public and the medical community to regard stroke as a treatable emergency. The Coalition developed guidelines for certifying primary stroke centers, and there are now more than 250 stroke centers across the United States.

No doubt, these advances in stroke care added to the complexity of emergency medicine because they introduced an entire new set of responsibilities into the responses provided by already strained emergency departments.

To further improve emergency care of stroke victims, the NINDS instituted a competitive process to establish Specialized Programs of Translational Research in Acute Stroke (SPOTRIAS) centers across the country. To qualify for this national network of research centers, institutions must demonstrate a strong commitment to the rapid treatment of acute stroke patients and an active collaboration between emergency medical services, emergency physicians, neurologists, and radiologists. Promising interventions developed at SPOTRIAS centers, such as the use of ultrasound to enhance the clot busting effectiveness of tPA, are now in clinical trials. SPOTRIAS centers, which are at large academic medical centers, are now reaching out with telestroke programs to address the need of all hospitals, no matter their size or location, to have rapid access to on-call stroke specialists necessary to carry out treatments such as tPA safely. Access to specialists was one of the issues that the IOM report highlighted, and we are exploring whether telemedicine can supply a solution. SPOTRIAS sites are also committed to training emergency medicine physicians in clinical neurological research.

Stroke, brain trauma, spinal cord injury, continuous seizures, and other neurological events together constitute 5 to 10% of all medical emergencies, and the NIH continues its research programs to develop better interventions. Ongoing emergency neuro-clinical trials, for example, focus on whether patient outcome can be improved by cooling children with head injury; on ultra-rapid administration of magnesium sulfate by paramedics in the field to stroke

patients; and on removal of clots that block blood flow to the brain in stroke. To expedite the development of emergency interventions, the NINDS recently developed the Neurological Emergency Treatment Trials (NETT) network. The NETT is led by experts in emergency medicine who are designing a system of testing new therapies for neurologic emergencies. The first NETT clinical trial is testing the use of the drug midazolam for emergency treatment of continuous seizures, such as those that chemical nerve agents from a terrorist attack might provoke.

The NETT/midazolam trial is part of the CounterACT (Countermeasures Against Chemical Threats) program. CounterACT is a major effort, from basic research to clinical trials, through which the NIH is working together with other agencies, including the Department of Defense, to address potential terrorist chemical challenges. As this Committee has heard in the past, the NIH, through the leadership of its National Institute of Allergy and Infectious Diseases, is also developing emergency countermeasures and diagnostics for nuclear and biological terrorist agents, as well as for emerging infectious diseases that may pose a public health threat.

NIH EMERGENCY CARE RESEARCH

I have used a few examples from neurologic emergencies to illustrate how NIH research lays a scientific foundation for improving emergency care. As the IOM report noted, emergency care research is a very broad field of inquiry, involving many disciplines and cross-cutting themes. The Trans-NIH Emergency Medicine Task Force reflects this range, with 23 NIH Institutes and Centers participating.

To understand the scope and nature of NIH supported research and training that underpin emergency care, the NIH is conducting a targeted internal review of its current research portfolio as it relates to the key scientific questions that need to be addressed to improve emergency medical care. This will include research in pediatric emergency care, pre-hospital acute care, and research training opportunities. A few other examples illustrate NIH activities:

- The National Heart, Lung, and Blood Institute's (NHLBI) National Heart Attack Alert Program Coordinating Committee addresses multiple aspects of emergency medical service (EMS) care for acute cardiac syndromes.
- NHLBI's Resuscitation Outcomes Consortium (ROC) conducts collaborative clinical trials of new treatments for cardiac arrest and severe traumatic injury. Along with EMS agencies, ROC will involve public safety agencies, regional hospitals, community healthcare institutions, and medical centers in 11 regions in the United States and Canada and as many as 15,000 patients over a 3-year period.
- The research and training programs in Trauma, Burn, Perioperative Injury, and Wound Healing of the National Institute of General Medical Sciences improve understanding of the biological processes invoked after traumatic or burn injury; bring basic scientific observations and principles into the clinical arena; and foster interactions and communications within institutions and throughout the trauma community by outreach efforts that promote trauma, burn, perioperative injury, and wound healing research at the institutional level.

The IOM report emphasized the importance of research into the efficacy, safety and health outcomes of treatments for infants, children, and adolescents. The NIH supports many

projects focused on the needs of pediatric populations. The National Institute of Child Health and Human Development, for example, supports the Pediatric Pharmacology Research Units (PPRU) Network, whose overall goal is the safe and effective use of drugs in children. PPRU activities include studies on the action, absorption, and elimination of drugs in children, pre- and post-marketing clinical trials in children, and an advisory body to industry, regulatory agencies, health professionals, and the public on the appropriate use of drugs in pediatric populations. NIH will pay special attention to pediatric issues as it reviews its current portfolio for gaps and opportunities in research.

In consultation with experts, we will continue to identify emergency care research issues and explore ways to address barriers to conducting emergency care research. The NIH will also explore opportunities for leveraging existing and developing new partnerships that can promote research and training in this area, both within NIH and in the academic and privately funded research community.

Finally, the IOM raised several key issues about overcrowding of emergency and trauma centers, the fragmentation of emergency medical services, unmet needs for access to specialists, and the challenges of preparation for major disasters. Although the structural issues in U.S. health care system do not fall within the purview of the NIH, the same problems that complicate the quality and timeliness of emergency care also hamper research in this important clinical care setting. The NIH will continue to work with HHS's Office of the Assistant Secretary for Preparedness and Response and with other appropriate agencies to improve the treatment of patients with medical/ surgical emergencies.

Thank you for providing me with the opportunity to present this information to you. I will be happy to answer any questions you may have.