Testimony before Government Oversight Committee

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Mr. Chairman, members of the Committee and staff ~ good afternoon. Thank you for inviting me; it is an honor to speak to you today. I am Peter Pronovost, a practicing anesthesiologist and intensive care physician at The Johns Hopkins Hospital, and a professor in the School of Medicine and the School of Public Health at Johns Hopkins University. I am also a trained researcher involved with national and international efforts to improve the delivery of healthcare.

I want to share with you a story. A rising violin star and mother of a two year old awoke one morning with tingling in her right hand and slurred speech. The next day, she had an xray which revealed a large brain tumor. The surgeons ordered a special test to evaluate the blood flow pattern in her brain to determine which parts of her brain controlled hand motion. The surgeons discovered that a part of her brain which they were going to cut through was important in allowing her to curl her hand. If they removed the tumor as originally planned, the student's promising music career would come to an abrupt end.

As a result of advances in science, the surgeons were able to change their operative plan. They cut through a less active part of the brain and successfully removed the tumor. The young musician awoke with full use of her hands.

This story is one example of the value of our investment in biomedical science. Since 1955, the average American life expectancy has increased from 69 to 78 years. Many terminal cancers are now curable, AIDS has become a manageable chronic illness, and some patients can now go home with mechanical hearts that allow them to live with cardiovascular disease that was once universally fatal. The United States is more productive in biomedical research than the entire European Union. Indeed, the entire world looks towards the United States for major breakthroughs in medical research.

Yet this same American medical system, leaves surgical instruments in patients, overdoses children with blood thinner medications, operates on the wrong side of the body, gives patients appropriate therapies only 50% of the time, and kills nearly a hundred thousand people per year from preventable errors. Perhaps most disturbing, a recent Commonwealth Fund Report ranked the

United States healthcare system dead last among other industrialized nations in terms of quality, access, efficiency, equity, and outcomes. Despite these poor outcomes, our median per capita expenditure for hospital services and drugs is three times larger than the 29 other countries that are part of the Organization for Economic Co-operation and Development (OECD). How can this be?

I believe this dichotomy is the result of our national failure to view the delivery of health care as a science. The majority of federal research funding supports what is often considered "biomedical science"-- principally efforts to understand disease biology and identify promising new therapies for a variety of diseases. Efforts to understand how to deliver those complex therapies safely and effectively are under-funded. For every dollar the Federal Government spends on traditional biomedical research, it spends a penny on research to ensure patients actually receive the interventions identified through biomedical research. Given this imbalance, it is understandable, perhaps predictable, that US has some of the best basic and clinical science research, yet the worst patient health outcomes in the industrialized world. To be certain we need to increase our support for traditional biomedical research. At the same time, patients and other stakeholders pay a substantial price for this myopic view of biomedical research. We need to ensure that we continue to identify effective therapies and make sure we use them safely and effectively.

Let me share with you an example. Over the last 40 years researchers, mostly supported by the National Institutes of Health, have tested more than 25 different therapies to reduce mortality in patients with acute lung injury, a life-threatening condition that usually requires life support therapies in an intensive care unit. This condition kills 40% of affected patients. The net output of this research that has consumed hundreds of millions in taxpayers dollars, is a method to reduce mortality from about 40% to 30%. This research finding, known as lung protective ventilation, involves giving patients smaller-sized breaths from the artificial breathing machine used to provide life support. Yet more than 7 years after publication of this research, more than half of patients do not receive this life-saving therapy. Moreover, it appears that ensuring wide-spread implementation of this therapy is not a priority; the NIH has moved on to identify other new therapies. And they should. Forty percent of patients with this disease die; those who survive suffer substantial disability and costs of care for years. We need to learn how to improve these outcomes.

Yet, to me, and likely to the residents of each of your states, it would seem incredulous to search for additional new therapies without also ensuring that patient are already receiving the only known life saving therapy for acute lung injury. Unfortunately, the Agency for Healthcare Research and Quality does not have resources to support this work and there is limited links between NIH and AHRQ to ensure that patients actually receive therapies that are demonstrated to be beneficial.

Yet there are examples of significant benefit from research aimed at ensuring patients receive evidence-based interventions. In a 2003 project funded in part by the Agency for Health Care Research and Quality (AHRQ), a research team from Johns Hopkins partnered with the Michigan Health & Hospital Association and 127 Michigan intensive care units (ICUs) to eliminate catheter-related blood stream infections (CRBSI) throughout the state. These catheters are large intravenous devices used in ICU patients to delivery important medications and monitor heart function. Although life-saving, these catheters can also cause harm with introducing blood stream infections in critically ill patients. Using guidelines from the Centers for Disease Control and Prevention (CDC), the program to eliminate these hospital-acquired infections had been developed and

implemented at Johns Hopkins where it lead to substantial reduction in these infections. Our team wanted to replicate the Hopkins' results across an entire state.

The results of this project were breath-taking. They were published in the *New England Journal of Medicine* and later described in the *New Yorker*. Within three months of implementing our program, which included simple interventions like using a checklist to ensure doctors followed recommended practices, these infections were nearly eliminated. More than 50% of participating ICUs, reduced their rate of catheter-related blood stream infections to zero and that rate has persisted for four years. The overall rate of these infections was reduced by two-thirds. If implemented nationally, this program could substantially reduce the 28,000 deaths and 3 billion dollars in excess costs attributed to these preventable hospital-acquired infections.

Individual states, including California and Ohio, are seeking funding to replicate the Michigan project. In addition, clinicians in Michigan want to develop a program to eliminate two very serious healthcare-acquired infections that are becoming an increasingly common and expensive problem in the U.S. health care system and a growing concern with the public, methicillin resistant *staphylococcus aureus* (MRSA), and vancomycin-resistant *enterococcus* (VRE). These bacteria are among the most common healthcare-acquired infections that affect one in ten patients, kill approximately 90,000 individuals, and cost between 5 and 11 billion dollars annually in the U.S. Many, although not all, of these infections are preventable by the use of known interventions. Most of these infections could likely be prevented if we invested in ways to identify and implement effective preventative therapies. Yet, as a country, there is neither funding nor an infrastructure to create and implement such programs. To improve the ranking of our healthcare system from dead last among industrialized nations, there is an urgent need for such programs.

Beyond the development of these programs, there are far too few people with the training required to conduct rigorous quality improvement research. Neither medical nor nursing schools provide the requisite skills to lead this type of research. Formal degree programs from schools of public health are required in the area of quality improvement. Unfortunately, there are few programs to support this type of formal training.

The efforts by the Center for Medicare and Medicaid Services (CMS) to stop paying for preventable complications in hospital is an important step to align payment policy with quality of care. Yet, the politics have far outpaced the science. As designed, this new CMS policy will be neither wise nor just. For all but two of the complications included in the CMS plan, we are not able to accurately diagnose them and we have no evidence regarding how many of these complications are truly preventable. Without investment in research, we likely never will know the potential for preventing these complications.

Why are efforts to improve the delivery of healthcare and prevent medical errors not a national funding priority? If patients are to receive the full benefits of our national investment in biomedical research, we must invest in studies directly aimed at understanding how to efficiently and effectively ensure that patients receive the beneficial therapies discovered by biomedical research.

Not only do we lack federal leadership to support the development and implementation of such programs, official interpretations of existing federal regulations have, perhaps inadvertently, imposed barriers to this type of work.

The Office of Human Research Protection (OHRP), within the U.S Department of Health and Human Services (HHS), charged that the Michigan project, which resulted in dramatic reductions in t catheter-related blood stream infections, violated regulations to protect patients who participate in human subjects' research. Though ultimately the office indicated that the work could continue in Michigan, there is great concern across the country regarding whether doing the same project in California or Ohio, or implementing new quality improvement programs, would violate federal regulations. The healthcare community wants clarity regarding the ethical oversight of quality improvement efforts.

Just as research funding supported our ability to look at blood flow in the brain, and changed how we cut out a tumor so that a young musician is not harmed, research funding is needed to identify effective methods to ensure patients receive those beneficial therapies without causing harm. The Michigan project to eliminate blood stream infections is one such program. We need leadership at the federal level to support wide-spread implementation of this program, develop future programs, and provide appropriate methods of ethical oversight for these efforts.

If we are committed to improving quality and reducing costs of healthcare, establishing a foundation of research in this area must be a priority.

Specifically, I ask the committee to consider the 4 recommendations:

1. Provide support to AHRQ to replicate the Michigan project in every state, to build capacity to address patient safety problems, and to develop and implement new safety programs.

2. Urge HHS to promptly clarify government oversight requirements for quality improvement projects and remove barriers to implementing and evaluating quality improvement efforts.

3. Substantially increase funding for research aimed at identifying and delivering effective therapies.

4. Support training for physicians, nurses and other clinicians in quality improvement methods in order to improve the delivery of healthcare across the U.S.

Through these efforts, your committee can save more lives this year alone than we have in the last decade while also dramatically reducing the cost of healthcare. I hope as courageous leaders, you can make wise investments that change the rhetoric of high quality low cost healthcare into reality. Improvements in quality of care over the last decade have been disappointing: patients continue to suffer harm that is preventable and costly. To alter this reality, we must invest in research which will identify and reliably delivery effective therapies. There is no short cut.

Thank you.