Comments for Senate HELP Committee
Patient Safety Hearing
Peter Pronovost, MD, PhD, FCCM
July 17, 2014

Mr. Chairman and committee members, thank you for hosting this hearing on patient safety and inviting me to testify, and for your dedication and determination in drafting legislation to keep this country great. My family recently returned from Yellowstone National Park and experienced firsthand that Congress can do great things that help America thrive and ensure it remains a global leader. In 1872, Congress created Yellowstone, the world's first, finest, and largest national park. It was and remains the envy of the world; people from around the world visit every year.

Today, we have the opportunity to discuss another area where Congress can help save lives, improve our standard of living, and set a standard for the world. America medicine performs miracles every day and patients benefit from your investments in biomedical research. Yet medicine today falls far short of what is possible.

Medicine today has preventable harm as the third leading cause of death. We do not know exactly how many people die needlessly, but we should. My colleague, David Bates, and I used published literature to estimate that over 220,000 preventable deaths occur from health care; that is over 600 deaths daily, which is far more than from mining or faulty automobiles yet receiving far less attention. This estimate is conservative and does not include more than 120,000 deaths from teamwork failures, 80,000 deaths from misdiagnosis, or thousands of deaths from sepsis.

Medicine today squanders a third of every dollar spent on therapies that do not get patients well, that result from treating preventable complications, and that result from administrative inefficiencies and fraud. This is about $9000 per U.S. household,[1] money that could be better spent on preschool education and STEM, on innovation, and on securing a better tomorrow for all Americans.

Medicine today invests heavily in information technology. The Federal government and health care organizations have spent hundreds of billions of dollars on health information technology with little to show for it. The promised improvements in safety have not been realized and productivity has decreased rather than increased. A recent report by McKensey [2] demonstrated that health care productivity decreased by 0.8 percent since 1990. When you have a health care industry that consumes 17% of the GDP with negative productivity, all Americans suffer. There is strong consensus among economists that improvements in our standard of living come largely through improved productivity from innovation, with improvements in one sector spilling over into others. The University of California Berkley economist, Enrique Monti, estimates that every new innovative job creates seven additional service jobs. [3]

We need to improve patient safety and reduce costs. Once we get pricing right, like in any industry, we can lower costs by reducing services or improving productivity. Our policy debate has focused almost exclusively on reducing services. While we may overuse services, outside of fraud and services that are clearly harmful or result from preventable complications, whether services are needed is a value judgment, with one person's overuse being another person's essential use. Yet no one is discussing how improving productivity can reduce costs, a discussion every other industry has.

Our main policy effort to improve safety and quality is to pay for quality. Although economic incentives have a role in improving quality, their impact to date has been mixed. Incentives must be coupled with efforts to ensure we have valid measures of safety, research investments to ensure we have trained scientists to discover how to improve safety, and collaborative efforts to partner with provider organizations and professional societies to use professionalism and peer norms to guide improvement.

We do have a success story that could inform our efforts. Central line-associated bloodstream infection (CLABSI), a type of healthcare-acquired infection that used to kill approximately 30,000 people per year–about as many people that die as annually from breast or prostate cancer. The story begins on a snowy night in 2001 when an adorable 18-month-old girl, Josie King, was taken off life support and died in her mother's arms. Josie had been burned and the clinicians saved her, but a bloodstream infection sacrificed her. Shortly after, her mother asked if health care was safer. She wanted to know what we were doing to prevent another unnecessary death like Josie's from happening to her other children and patients across America. She looked me in the eyes and asked, "Peter, what are you going to do." That moment is etched in my memory.

At the time I was one of the doctors causing those infections. I did not want to harm patients, no clinician does. Yet we just told ourselves that complications were inevitable; it was the cost of caring for sick patients. Back then, infection rates at Johns Hopkins were very high.

We could not give Sorrel an answer, so we created an intervention to our efforts to provide a positive answer. We did three things. We used the Centers for Disease Control and Prevention (CDC) guideline and made a five-item checklist. We created a program called the Comprehensive Unit-based Safety Program to improve teamwork among doctors and nurses to ensure the checklist was always used and caregivers questioned each other when it was not. And, we reviewed and reported infection rates using the valid CDC definition. Infection rates were reduced from over 11 per 1000 catheter days to zero.[4]

We then applied and received a grant from the Agency for Healthcare Research and Quality (AHRQ) for $500,000 per year for two years to implement the intervention throughout Michigan. Bloodstream infection rates plummeted nearly 70% across

the state,[5] mortality among Medicare patients admitted to a Michigan ICU was 10% less than similar patients in surrounding states,[6] we estimated the program prevented over 1500 deaths per year, and saved the average hospital over $1 million and saved employers 150,000 to 200,000 million.[7] With continued support from AHRQ and in partnership with the American Hospital Association, we spread this program state by state across the United States.[8] As a result of these efforts and the combined efforts of many others, especially the CDC, these deadly infections have been reduced by 60% since 2000, the year *To Err is Human* was first published by the Institute of Medicine.[9]

So why did it work? We had clear goals and valid measures, using CDC definitions. We had a supporting infrastructure to collect infection rates, summarize evidence-based interventions, and encourage local innovation in how to implement the evidence. Every hospital had their own version of the checklist and everyone thought theirs was the best, and it was for them. We engaged clinicians and connected them through clinical communities, supporting peer-to-peer learning and social norms to drive improvement.[10] Finally, we transparently reported infections and created accountability systems, both through hospital governing boards and through economic incentives.

Yet CLABSI is one type of harm, and outpatients and hospitalized patients are at risk of a dozen others. So we reflected on the stories that were holding us back. Stories are powerful forces for change. They can pin us to current preferences or they propel us to new pinnacles. The stories we tell influence how we act in the world and what we achieve. Stories coupled with action can move mountains. Stories like John F. Kennedy's, "we will put a man on the moon," Martin Luther King's, "I have a dream," and Ronald Reagan's, "tear down that wall."

So what new stories and actions are needed? We need to declare right now that preventable harm is unacceptable and work to prevent all types of harm, including harm from care that patient's feel is disrespectful care, not just one harm. We need to start viewing the delivery of health care as a science. We need to stop relying on the heroism of our clinicians to ensure safety and start relying on well-designed systems, just as every other high risk industry has done.

Given the number of preventable deaths, the limited ability to routinely measure these deaths, and the small investment in applied research to reduce these deaths, policy action is needed. Outlined below are some policy recommendations.

Charge the Centers for Disease Control with developing, monitoring, and transparently reporting the incidence rates of the top causes of preventable harm. The CDC has a model for accomplishing this through its National Nosocomial Infection Surveillance (NNIS) program. In this program, the CDC coordinates efforts among professional societies to develop valid and reliable measures and widely disseminates these measure definitions. Hospitals have trained infection prevention staff who understand epidemiology and have mechanisms to collect infection data. The CDC

has mechanisms to collect these data from provider organizations and the Centers for Medicare and Medicaid Services (CMS) transparently reports some infection rates.

This approach can be expanded to other common causes of harm. The CDC can convene a similar process as they did for healthcare-acquired infections. Infection prevention staff could also undertake outcome or harm prevention, and the CDC can expand its data infrastructure to collect and report other types of harm.

Invest more in career development awards for patient safety improvement. To reduce harm, science must guide the way but there are too few people trained in the science of safety to lead this effort. To improve safety requires an understanding of epidemiology or health services research to measure harm and make inferences about whether harm was reduced; social sciences to design and implement interventions to reduce harm and make inferences regarding how and why harm was reduced; and engineering and informatics to efficiently collect the desired data and design interventions. There are limited resources to support the transdisciplinary research teams need to make improvements in patient safety. AHRQ can be supported to fund both individual career development awards (new investigator and mid-career) and program projects to support the convening of all the disciplines required into a cohesive program.

Support AHRQ to coordinate collaborative implementation science efforts to reduce harm. Central line-associated bloodstream infection is one of the few examples of the national reduction in a preventable harm. There should be many more. Nonetheless, these efforts should be robustly designed and evaluated using valid measures. If we are to tell Sorrel King and the American people if care is safer, we need valid measures and well done research. AHRQ could coordinate efforts to reduce other harm types using the newly developed CDC definitions. In areas where health care lacks clinical evidence for therapies to reduce harm or evidence for how to implement evidence to reduce harm, the NIH and AHRQ should support research to eliminate that gap.

Create standards for the reporting of health care quality and cost measures by creating the equivalent of the Securities and Exchange Commission and Federal Accounting Standards Board for health care. There are no standards for publically reporting performance measures or using them in pay for performance programs. There should be standards. For example, The Johns Hopkins Hospital was criticized and congratulated for its performance on CLABSI by two separate state agencies for the same time period: congratulated when measured using the CDC definitions, and criticized when using billing data that CMS uses to measure complications and withhold payment when one occurs. When we examined the billing data, it agreed with the more accurate CDC data 13% of the time. Johns Hopkins now has 4% of its revenue at risk in pay for quality programs. Yet with 13% accuracy, this is not a quality of care issue, it is a coding issue. Given the money at risk, we will have to

hire an army of nurses to improve our coding. Nurses who we all agree would be better utilized providing care and preventing complications.

There are over 1500 procedures and thousands of diagnoses; everyone one should have performance measures. Despite broad bipartisan support to pay for value, policy makers did not create a mechanism to produce the many measures of quality (the numerator in the value equation with cost as the denominator) that patient's deserve, clinicians' want, and America needs. The reporting of costs is just as fragmented.

In 1934, Congress once again did the good great thing that made America prosper and served as the model for the world–they passed the Securities and Exchange Act. Before this act, , financial statements from businesses were not standardized, limiting the ability to evaluate the value of business, making markets less efficient and the country less well off. This changed in 1934. Though some may debate the effect of the SEC as a regulator, its effect as a truth teller and a transparency agency is largely agreed upon. The SEC delegates authority to the Federal Accounting Standards Board (FASB). The SEC has public sector rule setting, private sector transparency and auditing, and private sector re-analyses, working from a common book of transparent truth, combining data with commentary to make the reports meaningful to multiple audiences.

This process is similar to how the CDC develops measures and how we reduced CLABSI. The CDC partners with professional societies to make measures, they create mechanisms to collect the data, although they lack an auditing function, and our team used the CDC data to produce specialized reports of infection rates for the states and hospitals participating on our program.

The public would be well served if Congress repeated what it did in 1934. By creating a process to produce valid measures of quality and cost, hospitals could focus efforts on improving care rather than coding, patients and payers could make purchasing decisions on actionable data rather than anecdote, and health care markets would compete on truth and transparency.

Invest in systems engineering learning labs to improve productivity and safety in health care and ensure patient data belongs to the patient not the health information technology (HIT) companies. Johns Hopkins just built a beautiful new hospital. The outside is artwork and the inside is more dangerous than a hospital that was built 30 years ago. We bought the best intensive care unit (ICU), operating room (OR) and emergency room (ER) settings possible. Yet the best is backed with scores of pieces of equipment that do not communicate. As a result, our nurses answer a false alarm every 90 seconds, we spend two FTEs of nursing time in every unit of every hospital, $8 billion across the U.S. annually, having two nurses manually double check pain medication changes. This is a heroic process that is error ridden, when there is an electronic order in the medical record and in the medication infusion pump, yet these two devices do not talk. If they did we could automatically

double check, improving safety and productivity, as every other industry has done with technology.

CLABSI is one type of harm from over a dozen harms. Every type of harm has a checklist, every checklist has 5 to 10 items, and every item may need to happen 3 or more times per day. Add it up and patients need between 100 and 200 things done every day to keep them safe and well. None of the electronic medical record vendors, despite spending billions, displays this information. With a grant from the Gordon and Betty Moore Foundation, our team has produced an application to display compliance with checklists for seven types of harms.

Moreover, the usability of most HIT is poor. For example, to obtain the "meaningful use incentives," Johns Hopkins implemented a technology approved by ONC. Shortly after it was turned on, clinicians raised concerns that it made care less safe. After thousands of hours of work, we essentially turned all the supposed "safety" functions for the tool off and had the doctors type the patient's medications into the tool, allowing us to receive the financial incentives for meaningful use, hurting clinician productivity, failing to improve safety.

Patients, providers and all Americans would be well served by investing in a learning laboratory in which academic health systems collaborate with a systems integrator to build an integrated ICU, OR , ED or clinic. This would stimulate innovation and reduce costs like it has in aviation and submarines. What we have now equates to Boeing building a plane with many subcontractors and the manufacturer of the landing gear telling Boeing they would not have the capability to send a signal to the cockpit that the landing gear was up or down. Imagine Boeing saying no problem, if you do not want to send a signal that is fine; planes will crash, people will die, we will waste tons of money, but the signal data is yours and if you do not want to send it, okay.

We learned the power of systems integration from our work with the Applied Physics Lab at Johns Hopkins. They conduct integration work for the Department of Defense for space flight, and submarines. Their engineers estimate that we can improve health care productivity by 40%, let alone improve safety by designing an integrated care system. Given the thousands of hospitals being built around the globe, we still cannot buy an integrated hospital. If the U.S. produced one, safety would improve, productivity would improve, and the standard of living of the American people would improve.

Congress, you are aligned in wanting the best health care for our citizens, in reducing health care costs, and in improving the standard of living for all Americans. Once again do that great thing:

- Invest in patient safety.
- Ensure we can measure safety and develop other measures.
- Invest in training researchers to bring Engineering to Medicine.

- Invest in the science of health care delivery, including supporting learning labs to make the Boeing or Lockheed Martin of health care.

You see, Sorrel King is not specifically asking Peter, *what are you going to do to make sure care is safer*, she is asking everyone of you. She deserves an answer.

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