

**MORE THAN 1,000 PREVENTABLE DEATHS A DAY
IS TOO MANY: THE NEED TO IMPROVE
PATIENT SAFETY**

HEARING

BEFORE THE

SUBCOMMITTEE ON PRIMARY HEALTH AND AGING
OF THE

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE NEED TO IMPROVE PATIENT SAFETY AND REDUCE
PREVENTABLE DEATHS

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JULY 17, 2014
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**MORE THAN 1,000 PREVENTABLE DEATHS A
DAY IS TOO MANY: THE NEED TO IMPROVE
PATIENT SAFETY**

THURSDAY, JULY 17, 2014

U.S. SENATE,
SUBCOMMITTEE ON PRIMARY HEALTH AND AGING,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:02 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Bernard Sanders, chairman of the subcommittee, presiding.

Present: Senators Sanders, Whitehouse, Murphy, and Warren.

OPENING STATEMENT OF SENATOR SANDERS

Senator SANDERS. Let me begin by thanking all of our distinguished panelists for being with us this morning. In a sense, the discussion we're going to have today is personal, I think, for people all over this country in the sense that many of us, myself included, have seen folks go into a hospital for one problem or another and end up coming out a lot sicker than when they went in and, in some cases, dying as a result.

What is widely known is that the major cause of death in the United States today is heart disease, a serious problem. The second leading cause of death is cancer. According to the 2010 CDC report, more than 597,000 people died of heart disease and 574,000 died of cancer.

But what is not widely known and, in fact, what this hearing is about—and I hope to do my best with the help of my fellow Senators and members of this panel—is to start focusing attention on the third leading cause of death in the United States of America, and that will come as a great surprise to most people. The third leading cause of death in this country has to do with preventable medical errors in hospitals.

A recent article published in the *Journal of Patient Safety* estimates that as many as 440,000 people a year may die from preventable medical errors in hospitals—440,000 a year. That could be more than 1,000 a day. Tens of thousands also die from preventable mistakes outside the hospital, such as deaths from misdiagnoses or injuries from medications.

Nearly 15 years ago, the Institute of Medicine published a report—it is a well-publicized report—entitled, “To Err is Human,” which found that as many as 98,000 people die in hospitals each year due to preventable medical errors. According to a 2010 report,

a more recent report, from the Department of Health and Human Services, 180,000 Medicare patients alone, just Medicare patients, die from preventable adverse events in hospitals.

According to the CDC, 1 in 25 hospital patients gets an infection from being in the hospital. In 2011, these hospital-acquired infections caused 700,000 people to get sick and 75,000 people to die.

Clearly, these errors cause an immense amount of human suffering. But they are also—from a financial point of view—very, very expensive to the government and to individual families. Medical errors cost the U.S. healthcare system more than \$17 billion in 2008, and when indirect costs are taken into account, such as lost productivity due to missed work days, medical errors may cost nearly \$1 trillion each year.

Now, in the midst of this situation, which we will be discussing today—and I think we agree, it's not just an American issue. This is an issue that's taking place all over the world. Countries' healthcare systems all over the world are trying to combat it. The good news is that there has been progress made in recent years. We're going to hear from our panelists about the kinds of progress that has been made and, more importantly, where we have to go.

I think the horror here is that we all understand that tragedies occur. People die for all kinds of reasons. But the tragedy that we're talking about here are deaths taking place that should not be taking place, and that's what we are going to be focusing on.

Some of the advances that we have seen—and we'll be discussing these this morning—come from following practices, interestingly enough, that have been established in other high-stakes fields like aviation and nuclear safety by people who are obviously dealing with very dangerous situations. For example, through the implementation of checklists, infection rates in our country have dropped dramatically. Advances in technology, such as electronic prescribing, can catch medication errors, and robotic tools, which create smaller incisions during surgery, can reduce the risk of an infection.

Further, there has been increased attention to something that seems pretty obvious, the need to wash hands on a regular basis in hospitals. One would assume that would be pretty obvious.

Medical harm in this country is a major cause of suffering, disability, and death, as well as a huge financial cost to our Nation. This is a problem that has not received anywhere near the attention that it deserves. Today, I hope we can begin the process of focusing a spotlight on this matter of such grave consequence.

Senator Warren.

STATEMENT OF SENATOR WARREN

Senator WARREN. Mr. Chairman, I don't have an opening statement. I'm eager to get to the testimony and to the questions.

Senator SANDERS. Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you, Chairman, very much for holding this hearing, and I want to thank Chairman Harkin for allow-

ing this to go forward, because this is really an extraordinarily important issue.

For all the work and all the fuss and all the fighting that has surrounded the Affordable Care Act, there remains a very large fundamental problem in the American healthcare system, which is that it costs about 50 percent more than the most inefficient other industrialized countries' healthcare systems in the world. We have an inefficiency premium of about 50 percent over the major economies that we compete with. The price of that inefficiency is paid also in hundreds of thousands of American lives. For all the good that the Affordable Care Act did, those two problems remain before us.

I am delighted to be here. I, in particular, want to welcome Dr. Pronovost. We have never met before, but he is the architect of what many years ago was called the Keystone Project in Michigan, and I established—

Senator SANDERS. That's a different Keystone Project.

Senator WHITEHOUSE. A different Keystone Project.

[Laughter.]

Senator SANDERS. I want to make it clear.

Senator WHITEHOUSE. And many years ago, I established something in Rhode Island called the Rhode Island Quality Institute, which took the Keystone-Pronovost principles and applied it in our intensive care units and dramatically reduced the hospital-acquired infections in our intensive care units. Interestingly, it also had the side effect of making the nursing staff in the intensive care units empowered enough that nursing turnover experienced a considerable drop-off, because they were so excited about what they were doing.

So there are wonderful ways that we can do this. Obviously, when you're talking about saving people's lives, saving money is a secondary concern. But here, we have a very fortuitous alignment between saving lives and saving money. This is a very important topic, and I applaud you for having brought this wonderful group of witnesses together and for holding this hearing.

Thank you.

Senator SANDERS. Thank you very much, Senator Whitehouse.

OK. Let's get to work. Dr. John James is the Founder—what I'm going to do is just introduce you, and you'll go, and then we'll go on down the line.

Dr. John James is the Founder of Patient Safety America. In September 2013, Dr. James published an article in the Journal of Patient Safety which found that somewhere between 210,000 and 440,000 Americans die each year from preventable medical harm in the hospital. Dr. James retired in early 2014 as NASA's chief toxicologist. He received his Ph.D. in pathology from the University of Maryland.

Dr. James, thanks very much for being with us.

STATEMENT OF JOHN T. JAMES, Ph.D., FOUNDER, PATIENT SAFETY AMERICA, HOUSTON, TX

Mr. JAMES. The counter didn't start. Who starts the counter?

Senator SANDERS. This is not NASA. We don't have to—5,4. All right. We'll start the count. This is a NASA guy. OK.

Mr. JAMES, I thank Chairman Sanders for inviting me to testify about patient safety. I speak today on behalf of hundreds of thousands of Americans whose voices have been silenced forever by preventable adverse medical events.

By way of background, the seminal event that turned me into a patient safety activist occurred in the late summer of 2002. My son Alex was 19 years old and had returned for his junior year at Baylor University. While running in the evening of August 20th, he collapsed on the university campus, self-recovered, but was taken to a local hospital.

He was evaluated there for 4 days by cardiologists and underwent an electrophysiology test at another hospital. Five days after his discharge, he had a followup visit with a physician-in-training who gave him a clean bill of health. In a week, he returned to running.

On September 15th, approximately 2 weeks after he resumed running, I received a call late in the evening that he had collapsed again while running, but this time his heart had stopped and he was in a deep, unresponsive coma. He died 3 days later in the hospital where he was first taken for evaluation. Once I was able to get his medical records, I discovered that my suspicions about the cause of his death were borne out.

During his first hospitalization, I had noted to his lead cardiologist that his potassium was low and this might have been the cause of his initial collapse. He discounted this possibility, and so potassium replacement was never administered. In fact, as I deduced much later, at least three catastrophic errors were made by his doctors: (1) they failed to apply a guideline from the National Council on Potassium in Clinical Practice, (2) they failed to diagnose acquired long QT syndrome, and (3) they knew he should not return to running, wrote this in his medical record, but never warned him not to run. Alex's only discharge instructions in writing were not to drive for 24 hours.

I've written about the details of his poor-quality care in a book that I published in 2007. Many physicians have read that book and none have disputed my analysis. In fact, an electrophysiologist, after reading my book, affirmed to me in an e-mail that she too had been frustrated in attempts to get her cardiologist colleagues to pay more attention to potassium. Apparently, I gained a measure of credibility in the cardiology community, because in the past few years, I have completed 25 invited reviews of cardiology manuscripts for a cardiology journal.

As I unraveled the errors made in my son's care, and then discovered that his cardiac MRI was never done properly, I began to realize that medical errors like those that ended his life were not uncommon. I saw that the Institute of Medicine had estimated that up to 98,000 Americans die each year from medical errors in hospitals. Other reputable estimates at that time were as high as 284,000 deaths. Remarkably, if the harmed patient does survive, then, with few exceptions, the hospital will be paid to fix the harm.

So how much harm is there, really? By 2011, I had noticed four new studies that had used the Global Trigger Tool to identify adverse events in medical records. Two were peer-reviewed studies, and two were from the Office of the Inspector General. This tool

was much more efficient at identifying adverse events than unguided physician reviews.

I noted that the individual studies gave a remarkably consistent picture of the prevalence of lethal adverse events. In addition, other studies had been published showing that medical records often do not contain evidence that is discoverable of harm even when the patients know they were seriously harmed.

In 2013, I published the study in the *Journal of Patient Safety*. The math behind my calculation is rather simple. There's no voodoo statistics here. There were 34 million hospitalizations in 2007, of which approximately 0.9 percent involved lethal adverse events, and of those, approximately 69 percent, on average, were judged to be preventable. This yields an estimate of 210,000.

However, the Global Trigger Tool, while good at detecting errors of commission, misses many errors of omission, communication, context, and diagnosis. It would not have detected any of the catastrophic errors made by my son's doctors. Furthermore, it misses events for which no evidence appears in the medical record. Correcting for these limitations yields an estimate that more than 400,000 lives are shortened by preventable adverse events each year.

What are the solutions? No. 1, the Senate should establish a standalone committee on improving patient safety. No. 2, it should establish a National Patient Safety Board. And No. 3, it should pass a national patients' bill of rights to include legally defined and enforced rights to give genuinely informed consent; to know the safety record of their physician, outpatient clinic, nursing home, and hospital; to know costs for tests and elective procedures beforehand; to transparent accountability; to evidence-based care; to know when drugs are prescribed off-label; to be warned about bad lifestyle choices; to have care by teams of professionals that build individual and team excellence through 360-degree performance reviews. These are anonymous reviews by patients, subordinates, colleagues, and leaders—anonymously.

In my opinion, patient safety is not going to improve substantially until the playing field between the ill patient and the healthcare industry is leveled by an enforced bill of rights. Despite our high per capita expenditures on healthcare, our industry ranks last overall when compared to systems in other developed countries. Please, that needs to change.

I thank you for your attention.

[The prepared statement of Mr. James follows:]

PREPARED STATEMENT OF JOHN T. JAMES, PH.D.

I thank Chairman Sanders for inviting me to testify about patient safety. I speak today on behalf of hundreds of thousands of Americans whose voices have been silenced forever by *preventable* adverse medical events.

Background: The seminal event that turned me into a patient safety activist occurred in the late summer of 2002. My son Alex was 19 years old and had returned for his junior year at Baylor University. While running in the evening of August 20th he collapsed on the university campus, self-recovered, but was taken to a local hospital. He was evaluated there for 4 days by cardiologists and underwent an electrophysiology test at another hospital in Waco. Five days after discharge he had a followup visit with a physician-in-training who gave him a clean bill of health. In a week he returned to running. On September 15th, approximately 2 weeks after he resumed running, I received a call late in the evening that he had collapsed again while running, but this time his heart had stopped and he was in a deep, un-

responsive coma. He died 3 days later in the hospital where he was first taken for evaluation.

Once I was able to get his medical records, I discovered that my suspicions about the cause of his death were borne out. During his first hospitalization, I had noted to his lead cardiologist that his potassium was low and this might have been the cause of his initial collapse. He discounted this possibility, and so potassium replacement was never administered. In fact, as I deduced much later, at least three catastrophic errors were made by his doctors: (1) they failed to apply a guideline from the National Council on Potassium in Clinical Practice, calling for potassium replacement if heart arrhythmias are present, (2) they failed to diagnose acquired long QT syndrome, and (3) they knew he should not return to running, wrote this in his medical record, but never warned him not to run; Alex's only discharge instructions were not to drive for 24 hours.

I have written about the details of his poor-quality care in a book that I published in 2007. Many physicians have read my book and none have disputed my analysis. In fact an electrophysiologist, after reading my book affirmed to me in an e-mail that she too has been frustrated in attempts to get her cardiologist colleagues to pay more attention to potassium. Apparently, I gained a measure of credibility in the cardiology community because in the past few years I have completed 25 invited reviews of cardiology manuscripts for a cardiology journal.

As I unraveled the errors made in my son's care, and then discovered that his cardiac MRI was never done properly, I began to realize that medical errors like those that ended his life were not uncommon. I saw that the Institute of Medicine, had estimated that up to 98,000 Americans die each year from medical errors. Other reputable estimates at that time were as high as 284,000. If the harmed patient survives, then, with few exceptions, the hospital will be paid to fix the error.

Estimating Harm: By 2011 I had noticed four new studies that had used the Global Trigger Tool to identify adverse events in medical records. Two were peer-reviewed studies published in medical journals, and two were from the Office of the Inspector General. This tool was much more efficient at identifying adverse events than unguided physician reviews. I noted that the individual studies gave a remarkably consistent picture of the prevalence of lethal adverse events. In addition, other studies had been published showing that medical records often do not contain discoverable evidence of serious patient harm even when the patients know they were seriously harmed. In 2013 the *Journal of Patient Safety* published my study on the prevalence of preventable adverse events in hospitals. It has been supported by leading doctors in the patient safety community.

The math behind my calculation is rather simple. There were 34 million hospitalizations in 2007 of which approximately 0.9 percent involved lethal adverse events, and of those approximately 69 percent on average were judged to be preventable. This yields an estimate of 210,000; however, the trigger tool, while good at detecting errors of commission, misses many errors of omission, communication, context, and diagnosis. It would not have detected any of the catastrophic errors made by my son's doctors. Furthermore, it misses events for which no evidence appears in the medical record. Correcting for these limitations yields an estimate that more than 400,000 lives are shortened by preventable adverse events each year.

Proposed Solutions: The Senate should establish a stand-alone committee on improving patient safety. It should establish a National Patient Safety Board (like the National Transportation Safety Board) to investigate patient harm.

Congress should also pass a national patients' bill of rights containing rights like those enjoyed by workers and minorities. The law must include the following rights for patients:

- Legally defined and enforced right to give *genuinely informed* consent.
- To know the safety record of their physician, outpatient clinic, nursing home, and hospital.
- To know costs for tests and elective procedures before hand.
- To transparent accountability in the case of an adverse event.
- To evidence-based care.
- To know when drugs are prescribed off-label.
- To be warned about bad lifestyle choices.
- To have an advocate present while hospitalized.
- To care by teams of professionals that build individual and team excellence through 360-degree performance reviews. These are anonymous reviews by patients, subordinates, colleagues, and leaders.

Patient safety is not going to improve substantially until the "playing field" between the ill patient and the healthcare industry is leveled by an enforced bill of

rights. Despite our high per capita expenditures on healthcare, our industry ranks last overall when compared to systems in other developed countries.

Senator SANDERS. Thank you very much, Dr. James.

Senator Warren, I think you were going to introduce our next panelist.

Senator WARREN. I am. I have the honor of introducing Dr. Ashish Jha. Dr. Jha is a Professor of Health Policy and Management at the Harvard School of Public Health. He is also a practicing physician of internal medicine at the Boston VA.

Dr. Jha received his undergraduate degree from Columbia College and his medical degree and his master's degree in the master's of public health from Harvard University. Dr. Jha founded the Initiative on Global Health Quality at the Harvard School of Public Health, and his research focuses on improving the quality and reducing the cost of healthcare in the United States and around the world. In 2013, Dr. Jha was elected as a member of the Institute of Medicine. His work has been groundbreaking, and it is a great honor to have him here today.

Thank you, Dr. Jha.

Senator SANDERS. Dr. Jha, thank you very much for being with us.

STATEMENT OF ASHISH K. JHA, M.D., MPH, PROFESSOR OF HEALTH POLICY AND MANAGEMENT, HARVARD SCHOOL OF PUBLIC HEALTH, BOSTON, MA

Dr. JHA. It's my pleasure. Thank you, Senator Sanders.

And, Senator Warren, thank you for that very warm introduction.

It has been 15 years since the IOM estimated that about 100,000 Americans die each year from preventable medical errors. When they first came out with that number, it was so staggeringly large that most people wondered, "Could it possibly be right?" Fifteen years later in hindsight, evidence is in, and the evidence is very clear that the IOM probably got it wrong. It was clearly an underestimate of the toll of human suffering that goes on from preventable medical errors.

Beyond the problem with the estimate and exactly how many people are suffering from these injuries, there's a second pressing question, which is it has been 15 years, and a reasonable person might ask, "So how much progress have we made in the last 15 years? What have we done?" You're going to hear from Dr. Pronovost and others about areas where I think we have had progress.

But if the fundamental question is, "If I walk into an American hospital today, am I demonstrably clearly safer than I would have been 15 years ago?" the unfortunate answer is no. We have not moved the needle in any meaningful, demonstrable way overall. In certain areas, things are better. In certain areas, things are probably worse. But we are not substantially better off compared to where we were.

The last sort of piece of distressing news in my mind is that, as Senator Sanders alluded to, I often am asked is this a uniquely American problem? Is this something that other countries struggle with? And when we have looked across the globe, what we find is

no matter where you look, the size, the scope, the complexity of the problems are remarkably similar.

The United States, when we compare ourselves with other high-income countries, is right in the middle of the pack. We're better in some areas, worse in others, but there is no country I can point to that I can say, "They really get it right consistently." So I think there is a tremendous opportunity for leadership here.

But beyond all that distressing stuff, let's talk a little bit about some of the progress that has been made. I want to begin by talking about preventable infections, because that is probably the place where we've made the greatest progress. When I talk about that topic, I usually point to two agents that I think have had a central role in reducing infections.

One of them is the speaker two seats down from me, Dr. Pronovost. Peter's work has probably saved tens of thousands of lives, if not more. And I'm not going to talk about it, because he will do a much better job of explaining it.

But the other agent worth talking about is the CDC through its surveillance programs. Its surveillance programs around healthcare associated infections have been, I think, fundamental to the improvement that we have seen. And the reason is if you take a step back and ask, "How is it that we improve? How do we get better in anything in our lives?" The key element in my mind is data and metrics that are valid and credible.

If you don't have data and metrics, you don't know how you're doing, you don't know how you compare to anyone else, and you have no way to judge whether your efforts are making a difference or not. The CDC has been a leader in this area in helping develop validated metrics of infections and feeding that information back to hospitals. I think that has been fundamentally important in the kinds of improvements that we have seen.

So here we are 15 years later, and the question we should ask ourselves is, "How do we avoid another hearing 5 or 10 years down the road, where we say, 'oh, we're 25 years after the IOM report and we still have not made much progress?'" None of us want to be at that hearing.

So how do we avoid that? How do we begin to make real progress? I have three suggestions that I think are very doable. First is I think we need to expand the efforts of the CDC. There is no reason to think that what they have been able to do around healthcare associated infections, they can't do in other areas, such as venous thromboembolism, such as medication errors. They can partner with the FDA. The CDC has a phenomenal track record. This is a public health problem. The CDC is our public health agency. I think they have a central role to play.

The second is around electronic health records. The country is in the midst of digitizing our records system. We have seen phenomenal progress in adoption and use of electronic health records. I think that has a lot of potential. But the potential is not going to be realized unless those tools are really focused on improving patient safety. The tools themselves won't automatically do it, and I think we need to make that a priority. There are very specific things the administration and Congress can do in that area.

The third is around incentives. We can't continue to have unsafe medical care be a regular part of the way we do business in healthcare. Payers have a very important role to play. Medicare has a very important role to play. I think the ACA takes important steps in this area, but we can do so much more.

To finish up, we have a cadre of physicians and nurses in this country who are incredibly well-trained, dedicated, caring individuals who go to work every day trying to do the best for their patients. We have a system that fails them, and we have a system that fails the patients who expect and really deserve healthcare that is not only effective but safe and improves their health, not harms it.

Thank you very much.

[The prepared statement of Dr. Jha follows:]

PREPARED STATEMENT OF ASHISH K. JHA, M.D., MPH

Chairman Sanders, Ranking Member Burr, and distinguished members of the subcommittee, thank you for inviting me to testify today. My name is Ashish Jha, and I am a professor at the Harvard School of Public Health in the Department of Health Policy and Management. I am also a practicing general internist at the VA Boston Healthcare System. My research focuses on quality and safety of medical care, and it is for that reason that I am here today.

PROGRESS IN PATIENT SAFETY, BUT A LONG WAY TO GO

It has been 15 years since the landmark report by the Institute of Medicine (IOM), *To Err is Human*, which found that as many as 100,000 people die every year in the United States as a result of preventable medical errors. IOM estimated that medical errors have a total annual cost of between \$17 billion and \$29 billion in additional care, lost income, and disability.¹ As a physician, I took the oath to "first, do no harm" and yet, *To Err is Human* revealed to me and to doctors, nurses, and patients a simple truth: we do a staggering amount of harm every day. So here we are, 15 years after *To Err is Human* and it is critical to ask a simple question: how much progress have we made?

First, I want to start off with some good news. We have dramatically increased our awareness of patient safety issues and changed how we think about medical errors. In the past, medical errors were thought to be the result of individuals behaving badly. We blamed the doctor who ordered the wrong treatment, the pharmacist who dispensed the wrong dose, or the nurse who gave the medication to the wrong patient. This idea that adverse events were due to bad people led to a "deny and defend" culture among healthcare professionals and prevented progress on patient safety.

Today, we know better. We know that medical errors are largely the result of bad systems of care delivery, not individual providers. When a physician orders the wrong medication because two drugs might sound alike or when a patient develops a central line infection because a rushed surgeon didn't use proper sterile technique, we now understand that we need to focus on the system that produced the errors. Yes, we still hold individuals accountable, but we also know that humans make mistakes. It is part of the human condition. Asking for a healthcare system where doctors and nurses and other healthcare professionals are free of error is not only unrealistic but also naïve. And it is a set up for failure.

This change in thinking—that providing safe care is fundamentally a systems problem—is a very important step forward and is increasingly accepted by the medical community. And this, Mr. Chairman, is progress. But it is, of course, not enough. Now that we know that unsafe care is largely a systems problem—that is, we have systems that allow errors to occur and fail to safeguard patients, the next question is: What are we doing about it? And, most importantly, has this newfound knowledge made care safer? Here, the news is not so good.

Four years ago, the *New England Journal of Medicine* published a terrific study from North Carolina hospitals that found that between 2002 and 2007, there had been little or no progress in reducing harm from unsafe medical care.² A recent study led by Dr. John James found that between 200,000 and 400,000 Americans die each year from unsafe medical care, which makes it the third leading killer in the United States, behind only heart disease and cancer.³ Finally, in an eye-opening

November 2011 report on adverse events in hospitals, the Office of the Inspector General (OIG) in the Department of Health and Human Services found that 13.5 percent of Medicare patients suffered an injury in the hospital that prolonged their stay or caused permanent harm or death. An additional 13.5 percent of Medicare patients suffered temporary harm such as an allergic reaction or hypoglycemia. Together, the data suggest that more than one in four hospitalized Medicare beneficiaries suffers some sort of injury during their inpatient stay, much higher than previous rates. The OIG report also found that unsafe care contributes to 180,000 deaths of Medicare beneficiaries each year, and that Medicare pays at least \$4.4 billion to treat these injuries.⁴

Despite all the focus on patient safety, it seems we have not made much progress at all.

The news is not all bad, of course—and there are areas where we have made meaningful gains. The area of safety that has seen the biggest improvement is healthcare-associated infections. And there are two important actors to mention in this space. The first is Dr. Peter Pronovost of Johns Hopkins University. He developed a simple, five-item checklist, which was implemented in over 100 intensive care units in Michigan to reduce rates of central line infections. Each of these infections can cost up to \$50,000 to treat and requires an average of 7 additional days in the hospital.⁵ Though the problem of central line infection is complex and expensive, Pronovost's checklist intervention was not. By implementing this checklist, participating Michigan hospitals reduced their rate of central line infections to essentially zero in 3 months.⁶ Rather than targeting individual providers, the checklist improved the system of care and brought tremendous improvement in outcomes. The checklist program has now been implemented in over 1,100 intensive care units across the country, and is saving lives and resources every day.⁷

The other key player is the Centers for Disease Control and Prevention (CDC). In 2005, the CDC established the National Healthcare Safety Network (NHSN). NHSN is a voluntary, online system that tracks healthcare-associated infections nationwide. The CDC has established standard metrics for assessing and reporting healthcare-associated infections (HAIs) and allows providers to collect their own data and report it anonymously and directly to the CDC. NHSN allows providers, healthcare executives, and policymakers to track infection rates and ensure that necessary preventive procedures are being followed.⁸ Thanks to NHSN, hospital leaders are able to compare their facilities with others to see where improvement is needed.

NHSN is based on the idea that good metrics, provided in a timely fashion, can have a profound impact on provider performance. Between 2008 and 2012, rates of central line infections decreased by 44 percent, and rates of infection linked to the 10 most common surgical procedures fell by 20 percent.⁹ In short, we have made significant progress in reducing the number of infections caused by the healthcare system.

Despite important strides on healthcare-associated infections, recent data on medical errors indicate that we have a long way to go. And, in many ways, the problems that have been described above do not capture the totality of the problem.

While much attention in patient safety has been paid to acute hospitals, we have generally paid far less attention to what happens when patients are discharged. In a different report, the OIG at HHS found that 22 percent of Medicare beneficiaries in skilled nursing facilities (SNF) suffered a medical injury that prolonged their stay or caused permanent harm or death. An additional 11 percent suffered temporary medical injury. All told, OIG estimates that adverse events cost Medicare roughly \$2.8 billion per year, and about half of these events are preventable. The OIG report is particularly alarming given that about 20 percent of hospitalized Medicare patients go to a SNF after discharge.¹⁰ We need a renewed call to improve patient safety as a national priority.

INTERNATIONAL COMPARISONS

It is instructive to compare our progress on patient safety to other developed countries. The Organization for Economic Co-operation and Development (OECD) Health Care Indicators group measures and compares quality of health services in 20 developed countries. They look at several types of hospital errors including post-operative sepsis, postoperative blood clots (venous thromboembolism), and failure to remove foreign bodies during a medical procedure. For all of these metrics, the United States does about average, maybe slightly better (see figures 1–3). While average is OK, given that we spend more on healthcare than any other country, we should be a lot better.¹¹ Our high spending is not buying us particularly safe care. In addition, it is hard to say how accurate these rankings are given the variation

in how countries report, code and calculate patient safety. Nonetheless, the OECD scores show that hospital errors are not only a domestic issue, but also an international one. With targeted policy efforts, we can become a world leader in patient safety.

POLICY RECOMMENDATIONS

Given the tremendous amount of work that still needs to be done, the Federal Government has a responsibility to take meaningful, effective action on patient safety. In most industries, the payer of a service ultimately holds providers of that service accountable for safety and quality. In that way, the Federal Government, as the Nation's largest payer of healthcare, needs to lead on improving patient safety. I believe there are important, bipartisan actions that Congress can and should take to improve the safety of care that Americans receive. In 2011, Dr. David Classen and I published an opinion piece in the *New England Journal of Medicine* that outlined several concrete steps that the government could take to improve patient safety.¹²

The strategy for improvement has to focus on three main areas: metrics, accountability, and incentives. Getting the metrics right may be the most important.

The fundamental problem is that most healthcare organizations don't track the safety of their care.

First, we should ask the CDC to expand its patient safety efforts in the model of NHSN. The 2012 NHSN budget was just \$19 million and with small additional funding, NHSN could expand its monitoring efforts beyond infections to other types of adverse events.¹³ The resources required would be small change compared to the potential savings to the Medicare program. If there is one area of healthcare where simple interventions can save money, it is in patient safety. For example, blood clots cost the U.S. healthcare system somewhere between \$5 billion and \$10 billion per year.¹⁴ If expanded efforts by the CDC reduced the incidence of blood clots by just 1 percent, our country would save between \$50 million and \$100 million annually, not to mention the benefit of increased health for our citizens. This is an opportunity for us to make a small investment that is likely to have huge returns and pay for itself over time.

Next, there are currently a variety of safety metrics being used by different Federal agencies. It would be beneficial for Medicare to take the lead, as it did in the creation of the Hospital Quality Alliance, to bring together stakeholders and use a standardized set of safety metrics.

In addition, I believe that health information technology has a critical role to play in improving patient safety. Health IT is a key tool for improving care. All the evidence to date suggests that the passage of the Health Information Technology for Economic and Clinical Health (HITECH) in 2009 has led to significant increases in the percentage of hospitals with electronic health record (EHR) systems. In the first year that HITECH incentives were available, we found that the proportion of hospitals with basic EHR systems nearly doubled.¹⁵ In order to receive HITECH incentives, providers must demonstrate that they are "meaningfully using" their Health IT systems. The criteria for Meaningful Use is determined by the Centers for Medicare and Medicaid Services (CMS), with input from the Office of the National Coordinator.¹⁶ Despite recent progress in adoption of Health IT, most healthcare organizations are not using this tool to maximize its impact on patient safety.

One key role that EHRs can play is helping track adverse events. Most hospitals, even those with EHR systems, do not know their own rates of adverse events. They don't know how often they harm patients. However, there are now tools available that automatically track these events and these tools are generally quite good. Yet, most EHR vendors have not put these tools into their EHR systems. I believe that if we made automated patient safety monitoring a key part of certification for meaningful use, it would have a dramatic effect on the EHR vendor industry. The EHR products now being built would scan clinical data and provide real-time surveillance information to doctors, nurses, pharmacists and other healthcare providers about potentially bad events that might be happening to patients. It would allow hospitals to intervene quickly, and track their own progress over time. As we have seen with the NHSN program, good metrics provided to stakeholders in a timely fashion can drive systems improvement.

But metrics and reporting alone will not be enough. We also need to make safe care part of the business of providing healthcare. And this requires incentives. In the current system, hospitals with high rates of medical injuries receive nearly the same compensation from Medicare as hospitals that cause fewer injuries. There is little to no incentive for hospitals to spearhead patient safety efforts. My own research suggests that engaging hospital leadership—from boards of directors to CEOs—may be an important target of policy efforts to improve quality and safety.

In 2010, I led a study of leadership at 1,000 U.S. hospitals and found that only a minority of board chairs had received training in quality, focused on quality, or believed that quality was even an important priority.¹⁷ As the largest hospital payer in the country, Medicare can do a lot.

One idea that has been suggested is that hospital Boards should receive training in patient safety, and that can be a condition of participation in the Medicare program. Beyond training requirements, CMS must implement robust incentives for hospitals to avoid medical errors.

Some would argue that these incentives already exist under Medicare's Value-based purchasing program (VBP). VBP ties a hospital's payment to its performance on a variety of quality metrics, from avoiding blood clots to correct antibiotic selection for pneumonia patients.¹⁸ This system was designed to move Medicare away from the fee-for-service system, which rewards high volume of care rather than high quality care. I believe that this is a good start, but it is not nearly enough. VBP payments account for only 1 to 2 percent of total Medicare hospital payments and the incentives are diffusely spread out across many metrics. Congress has also authorized 1 percent payment cuts for the hospitals in the top quartile of HACs—Hospital Acquired Conditions. This is also a step in the right direction. However, much of the HAC measure is built on metrics that rely on billing information, and likely measure patient severity and coding variations as they do patient safety. Medicare should put both bigger incentives on the table and use high quality metrics that truly capture unsafe care. One idea would be for Medicare to simply not pay for hospitalizations where patients suffer a preventable adverse event that inflicts real harm.

CONCLUSION

In conclusion, I believe we are at a crossroad. Fifteen years after IOM's *To Err is Human*, we have made some progress, but we have so much further to go. Hundreds of people are dying every day in U.S. hospitals because of unsafe care. We are not alone—this is truly a global problem. However, with smarter metrics, greater transparency, more accountability and the right set of incentives, we can make big progress. With the right leadership, we can lead the world in patient safety—and the biggest beneficiaries of such an effort would be the American people.

Figure 1: Post-operative sepsis after abdominal surgery. Adjusted rates per 100,000 hospital discharges. (Source: OECD HCQI Program)

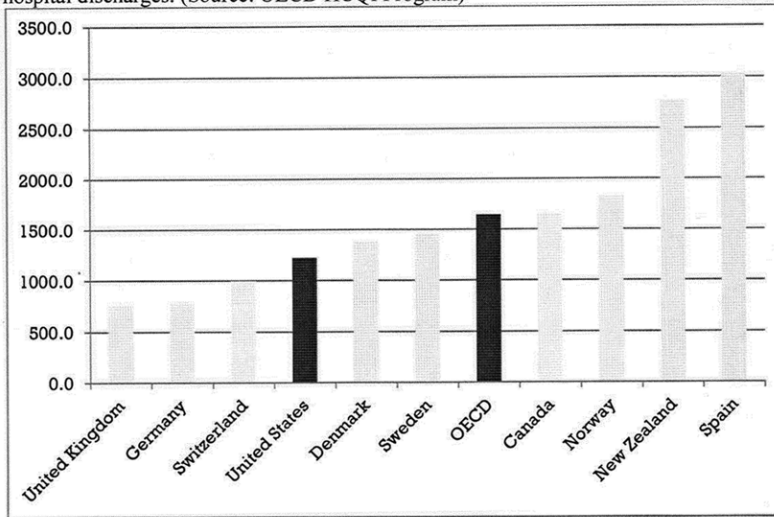


Figure 2: Post-operative venous thromboembolism after hip/knee replacement. Adjusted rates per 100,000 hospital discharges. (Source: OECD HCQI Program)

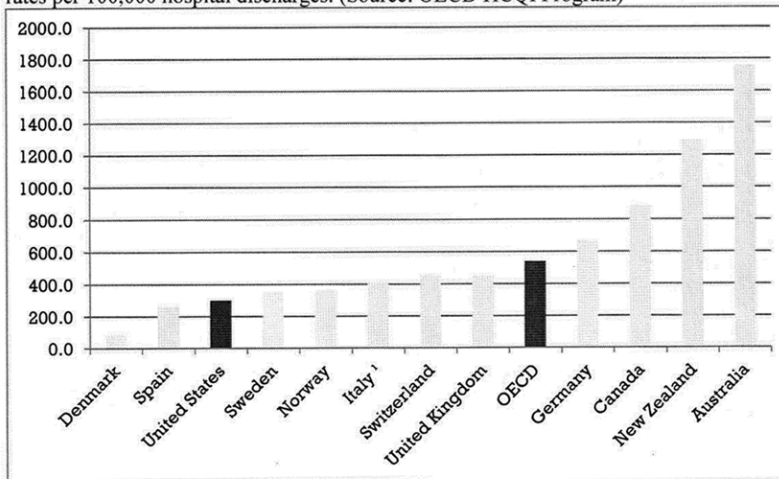
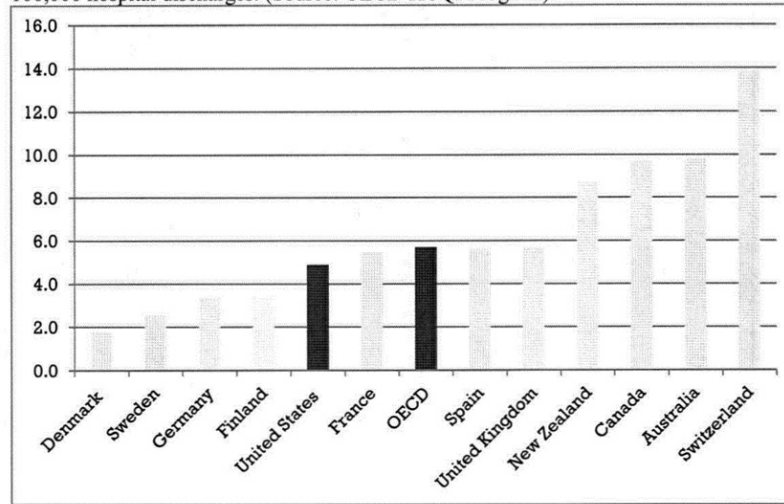


Figure 3: Foreign body left in patient during surgical procedure. Adjusted rates per 100,000 hospital discharges. (Source: OECD HCQI Program).



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Senator SANDERS. Thank you very much.

Senator Warren, you are going to introduce Dr. Gandhi?

Senator WARREN. I am. This time I'll introduce Dr. Gandhi. Dr. Tejal Gandhi is an Associate Professor of Medicine at Harvard Medical School, and she is the President of the National Patient Safety Foundation. She received her undergraduate degree from Cornell University and her medical degree and her master's of public health degrees from Harvard University.

Before serving on the National Patient Safety Foundation, Dr. Gandhi was the Chief Quality and Safety Officer at Partners Healthcare, and she served as executive director of Quality and Safety at Brigham and Women's Hospital. Dr. Gandhi's research has focused on patient safety and on how using information technology can help reduce errors in healthcare.

In 2009, she received the John M. Eisenberg Patient Safety Award in recognition of her research on the epidemiology and prevention of medical errors. So, again, we have someone who has done extraordinary research and put it into practice.

Thank you for being here this morning, Dr. Gandhi.

Senator SANDERS. And not only that, but from Massachusetts as well.

Senator WARREN. Well, that goes without saying.

Senator SANDERS. Dr. Gandhi.

STATEMENT OF TEJAL K. GANDHI, M.D., MPH, CPPS, PRESIDENT, NATIONAL PATIENT SAFETY FOUNDATION; ASSOCIATE PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. GANDHI. Thank you, Senator Warren, and thank you, Chairman Sanders, for the invitation to speak today on a really critical topic, the topic of patient safety. I would like to talk to you today about ambulatory patient safety and the priorities and challenges that we currently face.

The focus of patient safety efforts over the past 15 years, as you've heard a bit about, has been on improving patient safety in the hospital setting. However, it is important to remember that most healthcare is given outside of hospitals in diverse ambulatory settings such as primary care and specialist practices, nursing homes, rehabilitation centers, dialysis centers, ambulatory surgical centers, and that just names a few.

The safety issues in each of these settings differ, and little is known about what those distinct safety issues are. We need better data in all of these settings to understand the risks and opportunities for improvement.

The ambulatory setting that we do know the most about in terms of safety issues is primary care. I will touch on three areas, in particular, medication safety, missed and delayed diagnosis, and transitions of care. Studies have shown that medication errors are common in primary care and that adverse drug events or injuries due to drugs occur in up to 25 percent of patients within 30 days of being prescribed a drug.

In addition, a key medication safety issue in ambulatory that's not an issue in hospitals is the issue of non-adherence. One out of four prescriptions never gets filled by patients, and these are prescriptions for important conditions such as hypertension or diabetes. Better strategies are needed to both reduce medication errors, but also to improve adherence.

Missed and delayed diagnosis is a key issue as well. In the malpractice world, this is the most common type of outpatient malpractice claim, usually missed and delayed diagnosis of cancer in primary care. Missed and delayed diagnosis is complex. Some of the most common breakdowns that occur include failing to order an appropriate test as well as failure to followup on test results.

We cannot just tell clinicians to try harder and think better. We need better systems to minimize cognitive errors, to minimize failing to think to order a test, such as computerized algorithms also known as decision support. Better systems are needed to manage test results to ensure that every test that gets ordered is completed, the provider receives the result, acts on it, and notifies the patient.

Last, transitions of care. Transitions occur all the time in healthcare. For example, patients move from hospitals to home, from nursing homes to emergency departments, from rehabilitation centers to home or to visiting nursing. We know transitions are high-risk times when key pieces of information can be lost.

For example, one study found that after hospital discharge, within 3 to 5 days, one-third of patients were taking their medications differently than had been prescribed in the hospital. And another study showed that 40 percent of patients are discharged with test results that are pending, that have not come back yet, and these results are often not seen by their subsequent primary care provider.

Efforts have been underway across the country to improve transitions, such as having post-discharge followup phone calls to patients and better electronic systems to ensure complete information transfer. But there's much work that still needs to be done for all these varied transitions.

A major theme throughout ambulatory safety is patient engagement, partnering with patients to achieve safer care. Clinicians need to be better engaged with patients to ensure that patients understand and agree with their care plan. For example, ensure patients understand why the medication or test is being ordered and why it's important and understand what the plan is after leaving the hospital. This needs to be a true partnership in order to really ensure that the goals of the patient are being met.

To summarize, there are numerous ambulatory settings, all with unique safety issues that need more focused attention. We need to first develop a more robust ambulatory infrastructure with mecha-

nisms for error reporting, culture change, and process redesign across all of the settings that I've mentioned.

Second, we need to identify better measures, metrics of ambulatory safety, and conduct more research to understand what the safety risks are in these settings and how they can be improved. You heard a bit about metrics and the metrics that do exist. There are very few, if any, that exist for the ambulatory setting.

And, last, we need to continue to redesign care from a systems and human factors approach and ensure that we are engaging patients in this process so that we can deliver the safest care. Thank you.

[The prepared statement of Dr. Gandhi follows:]

PREPARED STATEMENT OF TEJAL K. GANDHI, M.D., MPH, CPPS

Thank you Chairman Sanders and members of the subcommittee for the invitation to speak today on a critical topic that I have spent my career working to address—patient safety. My name is Tejal Gandhi and I am a board-certified internist and president of the National Patient Safety Foundation, a non-profit that has been a leading voice in patient safety since 1997. I am also associate professor of Medicine at Harvard Medical School and was formerly the Chief Quality and Safety Officer at Partners Healthcare, a large health system based in Boston.

I would like to talk to you today about ambulatory patient safety and the priorities and challenges that we currently face. Much of the effort of the patient safety movement over the past 15 years, since the Institute of Medicine report *To Err is Human* (http://www.nap.edu/catalog.php?record_id=9728), has focused on improving patient safety in the hospital setting. However, it is important to remember that most care is given outside of hospitals, and there are numerous safety issues that exist in other health settings that are quite different from those we face in hospitals (<http://www.nejm.org/doi/full/10.1056/NEJMp1003294>).

The setting that we know the most about, in terms of ambulatory safety issues, is primary care. I will touch on three areas in particular—medication safety, missed and delayed diagnoses, and transitions of care. Studies have shown that medication errors are common in primary care, and that adverse drug events, or injuries due to drugs, occur in up to 25 percent of patients within 30 days of being prescribed a drug (<http://www.ncbi.nlm.nih.gov/pubmed/12700376>). In addition, a key medication safety issue in ambulatory care, that is not an issue in hospitals, is non-adherence. Patients do not fill one out of four prescriptions—and these include prescriptions for important, highly prevalent chronic conditions such as high blood pressure and diabetes (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842539/>). Better strategies are needed to reduce medication errors and improve adherence to medications. Of note, studies indicate that electronic prescribing systems show promise in the ability to significantly reduce errors, and much attention has been focused on expanding implementation of these systems.

Missed and delayed diagnosis is a key issue as well—this is the most common type of outpatient malpractice claim (usually missed and delayed diagnosis of cancer in primary care). Missed and delayed diagnosis is complex—in one study, a single malpractice case had on average three steps in the diagnostic process that broke down and led to the missed diagnosis (<http://www.ncbi.nlm.nih.gov/pubmed/17015866>). Some of the most common breakdowns include failing to order an appropriate test, as well as failure to followup on test results. The answer is not simply to tell clinicians to try harder or think better. Better systems are needed to help minimize cognitive errors—failing to think to order a test—such as computerized algorithms (also known as decision support). Better systems are also needed to manage test results—ensuring that every test that gets ordered is completed and the provider receives the result, acts on it, notifies the patient, and engages them in their plan of care. This is called closing the loop, and electronic health records show promise in helping to do this, but there is much work still to be done to design these systems optimally.

Last, we know that patients are vulnerable during transitions in care. These transitions occur all the time in health care—hospital to home, nursing home to emergency department, rehabilitation center to visiting nurse. Transitions are high-risk times, when key pieces of information (such as medication changes, pending test results, additional workups that need to happen) can be lost. For example, one study found that after hospital discharge, within 3 to 5 days, one-third of patients were

taking their medications differently than how they were prescribed at discharge (<http://www.ncbi.nlm.nih.gov/pubmed/16534045>). Another study showed that 40 percent of patients are discharged with test results that are pending (the final result has not come back) and these results are often not seen by the patients' primary care providers (<http://www.ncbi.nlm.nih.gov/pubmed/16027454>). Efforts are underway across the country to improve transitions, particularly with the focus on reducing re-admissions, such as having post-discharge followup phone calls with patients and better electronic discharge systems to ensure complete documentation and transfer of information. But there is much work that still needs to be done to address all of these varied transitions.

A major theme throughout ambulatory safety is patient engagement—partnering with patients to achieve safer care (see *NPSF Lucian Leape Institute whitepaper at http://www.npsf.org/wp-content/uploads/2014/03/Safety_Is_Personal.pdf*). Clinicians need to be better engaged with patients to ensure that patients understand and agree with their care plan—understand why the medication or test that is ordered is important for their care and understand what the plan is after leaving the hospital. This needs to be a partnership in order to really ensure that the goals of the patient are being met, and clinicians need to be trained to be better partners with patients.

It is also important to realize that the ambulatory setting is incredibly diverse. There are primary care practices, specialist practices, nursing homes, rehabilitation facilities, dialysis centers, ambulatory surgical centers, the list goes on and on. The safety issues in each of these settings differ, and not very much is known about what those distinct safety issues are, though some recent studies have been eye opening, such as a recent report from the Office of the Inspector General on adverse events in skilled nursing facilities, which found that approximately 16 percent of Medicare beneficiaries in nursing homes experienced preventable harm (<http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>). We need better data in all of these settings to fully understand the risks and opportunities for improvement. Most of these settings do not have the type of quality and safety infrastructure that exists in hospitals, nor do they have robust mechanisms to identify errors or measure errors and adverse events. Many of these settings do not have dedicated quality and safety personnel with expertise to create a culture of safety (where staff feel comfortable talking about errors) or expertise to redesign processes of care to try to prevent errors.

A final point is that health information technology (HIT) is becoming ubiquitous in inpatient and ambulatory settings. We need to design better HIT systems to maximize patient safety benefits while minimizing new risks that can be introduced from these technologies, as outlined by reports from the Institute of Medicine (<http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx>) and the Office of the National Coordinator (http://www.healthit.gov/sites/default/files/safety_plan_master.pdf).

To summarize, there are numerous ambulatory settings, all with unique safety issues that need more focused attention, especially because most health care is delivered in these settings. Three key recommendations are as follows:

- We need to develop a more robust ambulatory infrastructure, with mechanisms for error reporting, culture change, and safety expertise across all of these settings.
- We need to identify better measures of ambulatory safety and to conduct more research to understand what the issues are and how they can be improved.
- For the safety issues we do know about, we must redesign processes of care and further engage patients and families to ensure that we are delivering the safest care.

Senator SANDERS. Dr. Gandhi, thank you very much.

Our next panelist is Dr. Peter Pronovost. He is a practicing anesthesiologist and critical care physician and director of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins. He also serves as Johns Hopkins Medicine's senior vice president for Patient Safety and Quality.

Dr. Pronovost has developed a scientifically proven checklist method for reducing the deadly infections associated with central line catheters, and he serves in an advisory capacity to the World Health Organization's World Alliance for Patient Safety. In 2008, he won a MacArthur Fellowship Genius Grant award for his work on patient safety.

Now you make us all very nervous here.
Dr. PRONOVOST. Tell my daughter that.
[Laughter.]

Senator SANDERS. Dr. Pronovost received his M.D. and Ph.D. from Johns Hopkins University.

Dr. Pronovost, thanks so much for being with us.

STATEMENT OF PETER PRONOVOST, M.D., Ph.D., FCCM, SENIOR VICE PRESIDENT FOR PATIENT SAFETY AND QUALITY AND DIRECTOR OF THE ARMSTRONG INSTITUTE FOR PATIENT SAFETY AND QUALITY, JOHNS HOPKINS MEDICINE, BALTIMORE, MD

Dr. PRONOVOST. Mr. Chairman and Senator Whitehouse and Senator Warren, thank you, and you should all take comfort to know that your States are actively using the checklist and have dramatically reduced their infections. Thank you for hosting this important hearing and for inviting me to testify. And, importantly, thank you for the great work you do to keep this country strong.

Our family just returned from vacation in Yellowstone, the world's first national park created by an inspired act of Congress in 1872. I believe today with this hearing, Senators, we have an opportunity to do that good great thing to also keep this country great.

You heard the numbers of deaths, and it's important to recognize that medicine does perform miracles every day. There's hard-working, well-intentioned doctors and nurses who work hard every day. But what underlies these numbers of deaths, I think, are two important questions for you to answer.

No. 1 is: Why is it that 15 years after "To Err is Human," we still have to guess how many people die? Why is it that the public doesn't have a routine way of monitoring these numbers of harm? Outside of healthcare acquired infections, we do not have an accurate monitoring system to routinely look at, or let the public look at, how often harm happens, and we should.

Also, I ask you: Why is it that when a death happens, one at a time, silently, it warrants less attention than when deaths happen in groups of five or tens or thousands? You see, what these numbers say is that every day, a 747, two of them, are crashing. Every 2 months, 9/11 is occurring. And we would not tolerate that degree of preventable harm in any other form, because the suffering of people who lose to death one at a time is just as real as those who lose to it in groups of tens or thousands.

Our collective action in patient safety pales in comparison to the magnitude of the problem today. Medicine today invests heavily in information technology, yet the promised improvements in patient safety and productivity have frankly not been realized. Productivity in healthcare, indeed, has been negative since 1990.

But we have a success story to guide us. Luckily, I have been blessed to be part of that. These central line infections used to kill as many people as breast or prostate cancer each year. That's the scope of it—30,000.

Now, with collective effort from the CDC on how to measure CLABSI, with work from NIH to understand the science of how to improve it, with funding from AHRQ to pull groups together and

work to reduce it, these infections are down 70 percent since “To Err is Human” was reported. AMCs have reduced their infection rates from 6 to 1.3 per 1,000 catheter days, non-teaching hospitals from 4.1 to 1.1, saving lives, saving money, producing more productive Americans.

So why did it work, what did we learn, and what policies should we implement? Well, it worked, I think, because we had clear goals and valid measures. It worked because we had good science to guide us about what to do. It worked because we engaged clinicians through professionalism. And it worked because we transparently reported infections and had accountability.

Yet on a deeper level, when we partnered with our anthropologists and sociologists to find out why, what we found was that it worked because clinicians told a different story. You see, prior to this, we all said, myself included, that these infections are inevitable. But with this work, we said, “No, they’re preventable, and I can do something about it.”

Stories are powerful forces for change, whether it’s JFK saying, “I want to put a man on the moon,” Martin Luther King saying, “I have a dream,” Ronald Reagan saying, “Tear down this wall.” Change the story, and we change everything. So what are the stories that are holding us back, or where do we need stories? I think we need to say, first, that harm is preventable and not tolerable, that patient safety is a science and science must guide it, and safe systems must be designed to deliver safe care not based on the heroism of our clinicians.

So what might we do for policy things? First, as Ashish said, charge the CDC with developing monitoring and transparently reporting the incident rates of the top causes of harm. They do it for HAI. They know how to do it for others.

Second, create standards for the reporting of healthcare quality and cost measures similar to what you did in 1934 when you created the Securities and Exchange Act so that we now know—we can look at financial statements and make sure they’re accurate. Right now, we have no guarantee that the measures that we’re reporting are accurate.

Indeed, Johns Hopkins Hospital was both congratulated and criticized for its performance on the exact same measure for the exact same time period for bloodstream infections. And when we looked, the one we’re paid on, using administrative data, got it right 13 percent of the time. So what do we do? We will hire an army of nurses to code better, not to improve care.

And, frankly, that is not what these incentives should be driving our hospitals to do. It is disrespectful of our loved ones to not have accurate data, and billing data just isn’t up to the task for this, or at least we ought to be transparent about how accurate it is and not saying it’s good enough or it’s not good enough.

Third, we need to support AHRQ to advance the science of patient safety; to make sure we have a workforce who has the training, like Tejal and Ashish, to have the skills to do this; and to make sure we implement programs.

Finally, we need to invest in systems engineering and learning labs to improve productivity and safety. We rely too much on heroism. Our nurses answer a false alarm every 90 seconds. We spend

two FTEs of nursing on every unit of every hospital, \$8 billion, manually double checking pain medicines because the devices don't talk to each other, and it's completely inaccurate.

We had success with the checklist, but bloodstream infections are one harm. Patients with chronic diseases, patients in hospitals are at risk for a dozen harms. Every harm has a checklist. Every checklist might have 5 or 10 items. Every item may need to happen three or four times a day. You add it up, and you have clinicians expected to do 100 to 200 things every day, and no information system lists them.

What we have now, Senators, would be the equivalent of Boeing building a plane with many subcontractors, as they do, and the maker of the landing gear saying to Boeing, "You know, I don't want to send a signal to the cockpit to tell you if the landing gear is up or down. You're going to have to guess," and Boeing says, "No problem. We will still buy it, even though it will cause deaths."

We need to start doing another good great thing, because the reality is 25 patients died during this hearing.

[The prepared statement of Dr. Pronovost follows:]

PREPARED STATEMENT OF PETER PRONOVOST, M.D., PH.D., FCCM

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 \$9,000 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 McKensey² demonstrated that health care productivity decreased by 0.8 percent since 1990. When you have a health care industry that consumes 17 percent 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 1,000 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 2 years to implement the intervention throughout Michigan. Bloodstream infection rates plummeted nearly 70 percent across the State,⁵ mortality among Medicare patients admitted to a Michigan ICU was 10 percent less than similar patients in surrounding States,⁶ we estimated the program prevented over 1,500 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 percent 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 percent of the time. Johns Hopkins now has 4 percent of its revenue at risk in pay for quality programs. Yet with 13 percent 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 1,500 procedures and thousands of diagnoses; everyone one should have performance measures. Despite broad bipartisan support to pay for value, policymakers did not create a mechanism to produce the many measures of quality (the numerator in the value equation with cost as the denominator) that patients 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 United States 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 three 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, OK.”

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 percent, 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 United States 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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Senator SANDERS. Dr. Pronovost, thank you very much.

Dr. Joanne Disch is a Professor ad Honorem at the University of Minnesota School of Nursing. She has provided leadership to several national organizations working to improve patient safety. This included past terms as president of both the American Association of Critical Care Nurses and the American Academy of Nursing, as well as board chair for AARP.

For the past 12 years, she has been a faculty leader for the Quality and Safety Education for Nurses Initiative, which has educated more than 1,500 nursing faculty in safety science. Dr. Disch received her B.S. in Nursing from the University of Wisconsin Madison, her MSN from the University of Alabama in Birmingham, and her Ph.D. from the University of Michigan.

Dr. Disch, thanks very much for being with us.

**STATEMENT OF JOANNE DISCH, Ph.D., RN, FAAN, PROFESSOR
AD HONOREM, UNIVERSITY OF MINNESOTA SCHOOL OF
NURSING, MINNEAPOLIS, MN**

Ms. DISCH. Good morning. Thank you, Chairman Sanders and other members of the subcommittee, for hosting this very important hearing.

I would like to begin my comments by providing some context. First, while the subcommittee is to be commended for tackling this challenging issue, I believe that the title understates the problem. We are not only dealing with 1,000 preventable deaths a day, but 1,000 preventable deaths and 10,000 preventable serious complications a day, which can result in a quality of life that might be comparable to death for some, such as the woman from Minnesota who underwent a bilateral mastectomy for cancer only to find out shortly after surgery that there had been a mix-up in the biopsy reports and she had not had cancer.

Second, this is possibly the most bipartisan issue that exists today since most of us have either been patients or family members or will be in the future. It affects all of us.

Third, this is one of the few issues that money alone cannot solve. As I often say when I lecture to nursing students, even Bill Gates cannot guarantee safe care for himself or his family.

This morning, I will highlight some of the key factors influencing patient safety and make three recommendations for action. First, we know the factors that compromise safety. Many have been mentioned: the complexity of healthcare, the patchwork nature of our healthcare system, the perverse financial incentives, and the growth of technology which can be a blessing and a curse.

In addition, system barriers make doing the right thing hard, and time pressures reinforce doing things quickly without fixing underlying problems. We also have strong traditions in healthcare that discourage people from speaking up or examining problems from a system viewpoint.

Interestingly, the Joint Commission has found three factors to be most commonly involved in serious preventable events. No. 1, human factors, which includes things like staffing mix, the levels, inadequate orientation, fatigue, distraction, complacency, bias. No. 2, communication errors, whether they be oral, written, electronic. Again, technology can help, but it does add burden. And then, No. 3, leadership.

This suggests that rather than fixing individual problems, we must take a systems approach and adopt fundamental changes in our healthcare organizations. I propose three strategies that, when taken together with those of my colleagues, will make a difference.

First, we must ensure that we have an adequate number of registered nurses, appropriately educated, with a voice for decision-making about staffing and patient care at the bedside. This may seem obvious. Registered nurses are the cornerstone of the American healthcare system. They form the largest element with 2.7 million. They are there 24/7 and are on the ground floor of care delivery.

It is the nurse who sees a skin breakdown that will lead to a bed sore. It's the nurse who notices the older women's unsteady gait and puts in place strategies to prevent a fall. The nurse is often the last line of defense. Unfortunately, the Bureau of Labor Statistics anticipates a shortage of 1 million nurses by 2022 due to the growing demand and the need to replace those retiring.

The good news is that more people are entering nursing, and older nurses are working longer. But these increases are insufficient to meet projected demands. Of great concern is that U.S. nursing schools turned away at least 80,000 qualified applicants in 2012 due to inadequate resources. More than just preparing more nurses, however, research shows that we need registered nurses with a minimum of a baccalaureate degree and at adequate staffing levels in hospitals, which has been shown to decrease patient mortality.

However, only 50 percent of nurses have a baccalaureate or higher degree in this country. So we need an adequate number of nurses with a minimum of a baccalaureate degree and who are ac-

tively involved—as Dr. Pronovost mentioned at Johns Hopkins—in making decisions and determining safe levels of staffing.

The second recommendation is that we must engage the patient and family as full partners in care. Some would say source of control and full partner. Actually, that is what the IOM would say. As they noted, practice still is usually organized around what is most convenient for the provider, the payer, or the healthcare organization and not the patient.

Yet we know that better outcomes can be achieved at lower costs when patients partner with their care providers and assume responsibility for helping manage their own healthcare. And we know that while clinicians have the medical expertise and know the science, the patient and/or family knows the individual best and what works for him or her.

Third, we must change the culture of healthcare to one committed to safety. Again, this might be obvious. Aren't all hospitals concerned about safety? Of course, they are. But the extent to which this becomes a priority and adequate resources are allocated varies tremendously. We must shift from a bureaucratic, patriarchal model based on professional autonomy and independence to one of interdependence and a relentless focus on safety.

We also need leaders who are passionate advocates for preventing harm, who commit resources for process improvement, and actually leaders who know what they don't know and invite others to help solve problems.

In conclusion, this is enormous change. It would be easier if we could just throw money at it. To start, though, we can use the principles and encourage organizations to adopt the principles of high reliability organizations, where everyone has a laser focus on safety; where there are systems in place to improve processes; and where everyone, including patients and families, is encouraged to speak up and report errors and unsafe conditions. There are those organizations. We should make sure they get visibility and are emulated.

Thank you.

[The prepared statement of Ms. Disch follows:]

PREPARED STATEMENT OF JOANNE DISCH, PH.D., RN, FAAN

Chairman Sanders and the Subcommittee on Primary Health and Aging are to be commended for examining the current crisis of preventable deaths (PDs) that occur each year in the United States and for developing the compelling title of this hearing. The estimate by James (2013) that possibly 400,000 PDs occur each year is more accurate than the previous Institute of Medicine (IOM) projection of 98,000/year (1999). However, I would respectfully suggest that the title of this hearing understates the problem—and the title of the hearing should be changed to “*More than 1,000 preventable deaths—and 10,000 preventable serious complications a day—is too many . . .*” While PDs are certainly to be avoided, I would note that serious preventable complications (SPCs) can result in a quality of life that might be comparable to death for some, such as the woman from Minnesota who, approximately 10 years ago, underwent a bilateral mastectomy for cancer, only to find out shortly after surgery that there had been a mix-up in the biopsy reports—and she had not had cancer.

My points are three: (1) the impact of preventable events—death and serious preventable complications—is even more extensive than the gripping title of this hearing suggests (James, 2013); (2) it is possibly the most bi-partisan issue that exists today—since many, if not most, of us here have likely had the experience of being a patient or family member who experienced one of these events, or will in the future; and (3) it is one of the few issues that money alone cannot solve. As I have

often said when lecturing on this topic: “Even Bill Gates cannot guarantee safe care for himself or his family.”

This morning, I will highlight some of the key factors influencing patient safety, and make three recommendations which I know, from my 46 years as a nurse, make a difference: (1) assuring an adequate and appropriately educated supply of registered nurses at the bedside; (2) actively engaging patients and families as partners in their care; and (3) moving hospitals and other health care settings to embrace a safety culture and become *high reliability organizations*. My comments focus on the hospital setting since that is where we have the most data, although the principles apply to other settings.

Factors Compromising Patient Safety

The factors that contribute to these events have been extensively outlined, and range from the minor to the most comprehensive. They include the complexity of health care, the rapid generation of new knowledge and interventions, the patchwork nature of our health care system, the incentives to do too many interventions and not enough assessment and prevention, and the use of technology (both too much and too little).

ECRI, an “independent, nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care” has begun to compile an annual Top Ten list of technology-related issues that jeopardize safety. Table 1 includes the list for 2013.

Table 1: The Top 10 list of technology-related issues that compromise patient care:

1. Alarm hazards that result in fatigue and inadequate response by care providers.
2. Medication administration errors using infusion pumps.
3. Unnecessary exposures and radiation burns from diagnostic radiology procedures.
4. Patient/data mismatches in EHRs and other health IT systems.
5. Interoperability failures with medical devices and health IT systems.
6. Air embolism hazards.
7. Inattention to the needs of pediatric patients when using “adult” technologies.
8. Inadequate reprocessing of endoscopic devices and surgical instruments.
9. Caregiver distractions from smartphones and other mobile devices.
10. Surgical fires.

Some factors relate to health care providers (HCPs) themselves, such as fatigue, disruptive behavior (Rosenstein & O’Daniel, 2008), lack of adequate preparation, and either failure to keep up with current practice or persistence in following outdated practices (Disch, 2012). Amalberti and colleagues (2005) identified five system barriers that would prevent unsafe professional behavior, among them, the (1) the need to abandon status and self-image in exchange for inclusion and respect for the contributions of all providers; and (2) the need to reduce provider autonomy, i.e., doing what one chooses to do over evidence-based practices. Makary (2012) described inadequate levels of transparency and outright concealment of certain results in his riveting book *Unaccountable: What hospitals won’t tell you and how transparency can revolutionize health care*.

With all of these factors contributing to preventable deaths and complications, it can be over-whelming to know where to focus first and with the greatest impact. The Joint Commission has created a list each year of the most frequently identified root causes of sentinel events derived from Root Cause Analyses of the serious events that must be reported whenever they occur. There are 28 of these events, and include serious medication errors, falls that result in significant harm or death, hospital-acquired infections, decubitus ulcers (bed sores). Over the years, the analyses have found that the majority of events have several root causes. In 2013, the most frequently identified root causes of 887 sentinel events are listed in Table 2:

Table 2: Most frequently identified causes of sentinel events reviewed in 2013:

- Human factors (635)
- Communication (563)
- Leadership (547)
- Assessment (505)
- Information management (155)
- Physical environment (138)
- Care planning (103)
- Continuum of care (97)
- Medication use (77)

Operative care (76)

It is important to note that the first three factors relate to people:

- Human factors—staffing levels, staffing skill mix, staff orientation, in-service education, competency assessment, staff supervision, resident supervision, medical staff credentialing and privileging, rushing, fatigue, distraction, complacency, and bias.
- Communication—oral/written/electronic, among staff, with/among physicians, with administration, with patient or family.
- Leadership—organizational planning and culture, community relations, service availability, priority setting, resource allocation, complaint resolution, collaboration, standardization and best practices, inadequate policies and procedures, non-compliance with policies and procedures.

This is not to suggest that the cause of preventable deaths are the people involved. The challenges facing HCPs are complex; system barriers make doing the right thing hard; time pressures reinforce doing things quickly without fixing underlying problems; long standing traditions that demand errorless performance and discourage examination of systems' fallibility create a chilling environment; and the whole field of safety science is unknown to most HCPs who graduated more than 10 years ago. The point here is that the changes that are needed will require changes in behavior and mindset—and these are the most difficult to achieve. It would be easier if we could just allocate more money. Common wisdom used to be that those of us in health care just needed to be vigilant to prevent mistakes. There is still a role for vigilance but that is woefully inadequate in today's health care environment. There are certainly responsibilities that we as care providers have, but safety science suggests that we must also fix the underlying system issues for sustainable change which requires significant change from all of us.

The Critical Role Of The Nurse In Patient Safety

Nurses are the cornerstone of the American health care system. Registered nurses form the largest element (2.6 million), with more than half (58 percent) working in medical and surgical hospitals (BLS, 2013). They provide care 24/7 and are on the “ground floor” of care delivery. They are the eyes and ears of patients and their families, as well as physicians and other HCPs who are interacting with the patient intermittently. The nurse's role is to assess the patient's condition and response to treatment; perform indicated treatments; prevent complications; assist the patient and family in adjusting to the treatment or impact of chronic illness; and create a safe environment within which health, healing or a peaceful death can occur. It is the nurse who sees a skin breakdown that will lead to a bedsore; it is the nurse who notices the older woman's unsteady gait and puts in place strategies to prevent a fall; it is the nurse who notices that the dose of the drug ordered is not relieving the pain and who initiates a conversation with the physician to get the order changed. Individuals who have been hospitalized, or have had a family member hospitalized, understand the essential role of the nurse. Actually, nursing care is the reason for hospitalization . . . and it is the nurse who is the “last line of defense” against error.

Who could argue with this point of view? Our current health care system is built on the belief that the physician is the captain of the ship and needs to be in charge in every setting and situation. However, given the complexity of health care today, that is impossible, may be dangerous—and is actually unnecessary. Rather, today we need interprofessional teams of caregivers who can each contribute their own expertise and perspectives. Sometimes the physician would be in charge, at other times the nurse or social worker or pharmacist, depending on the patient's needs.

The elderly are particularly vulnerable to complications and the consequences can be more serious when errors occur. Older individuals are often less physically stable, have chronic conditions for which multiple drugs and treatments are ordered, can have sensory deficits, and memory impairment. If they are unsteady on their feet, they are more prone to falls; if they are not active, they are prone to bedsores and other complications. Inadequate levels of RN staffing in hospitals and nursing homes decrease the nurse's ability to prevent complications. It is vital that nurses—and really any HCP—be respected for their knowledge and skills, and be encouraged to actively speak up when they think that something can be improved or a problem prevented. But that is not common practice in every setting today.

The Institute of Medicine (2011) has recommended that “Nurses should be full partners, with physicians and other health professionals, in redesigning health care in the United States.” In most instances, physicians are actively involved in decisionmaking. And the focus in improving health care has often been to assure enough physicians are educated. However, this crisis will not be solved by focusing only on

an adequate supply of physicians, both in the pipeline and in practice. Registered nurses and other HCPs are equally essential and need to be actively funded and included. This issue of nurses being involved and engaged in individual patient and systemwide decisionmaking is not simply a matter of *parity*, i.e., that nurses should be included because physicians are. Rather it's a matter of *perspective*, i.e., that nurses bring a vital viewpoint to safety concerns that is often absent yet essential if workable solutions for safe care are to be put in place.

The question that nurses often ask is "Does this work at 2 am?" We have a very pragmatic appreciation for what works round the clock, and on weekends. We often have solutions for seemingly intractable system issues, or personal situations. One recent example: A nurse and physician were talking with a patient with congestive heart failure who was needing his medications adjusted. The doctor provided detailed instructions and asked the patient to weigh himself daily, and to call back if he gained more than 3 pounds. After the physician left, the nurse asked the patient if he had a scale on which to weigh himself, recalling his housing situation and that he was homeless. To adapt the directions to his situation, she asked him to carefully note whether his shoes became tighter—and to call back if that happened. That is an example of a nurse personalizing care to prevent a complication and needless hospitalization.

In considering what can be done to reduce preventable deaths, we must redirect our efforts. First, rather than continuing to work at the margin we must now turn toward fundamental change in our health care organizations; and second we have to focus on three crucial strategies that are often overlooked because they seem so simple and apparent—and yet they are essential if we are to make progress.

1. Assure an adequate number of appropriately prepared registered nurses.

For nurses to make their optimal contribution to improving the safety of health care, there have to be enough nurses and they have to be equipped with the right educational preparation. According to the BLS (2013), the Registered Nurse is listed among the top occupations for job growth through 2022, with an expected increase from 2.71 million in 2012 to 3.24 million in 2022 (19 percent increase). The BLS also projects the need for 525,000 replacement nurses, so that the total number of job openings for nurses from both causes would be 1.05 million by 2022. The good news is that more people are entering nursing—in 2013, there was a reported 2.6 percent enrollment increase in entry-level baccalaureate programs in nursing (AACN, 2013), yet this increase is insufficient to meet projected demands for nursing services in all settings. More than 32 million Americans are gaining access to healthcare services provided by registered nurses and advanced practice registered nurses (APRNs). Of great concern is that U.S. nursing schools turned away 79,659 qualified applicants from baccalaureate and graduate nursing programs in 2012 due to insufficient number of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints (AACN, 2013). Also the most recent information indicates that the average age of today's nurse is 47 years (HHS, 2010).

There is a significant body of research, both here and abroad, that shows that registered nurses with a minimum of a baccalaureate degree, and at adequate staffing levels in hospitals, have a positive impact on patient safety, including mortality rates (Needleman, ET al., 2006; Aiken, et al., 2014). Key implications are that nursing staffing cuts to save money jeopardize patient safety and hiring more nurses with baccalaureate degrees could decrease the number of preventable deaths. However, the most recent data indicate that only 50 percent of nurses have baccalaureate or higher degrees (HRSA, 2010); and if we look at the percentage of nurses in baccalaureate programs as their first educational program, it is only 35 percent (IOM, 2011). The IOM has recommended that it be 80 percent by 2020. [There is currently a bill being proposed in Congress called the Registered Nurse Safe Staffing Act to assure an adequate number of nurses with baccalaureate degrees be hired. This would have significant impact on patient safety].

In addition to formal education, however, nurses and all HCPs need to be knowledgeable and competent in the IOM's required competencies for achieving safe patient care: patient-centered care, teamwork and collaboration, informatics, safety, evidence-based practice and quality improvement. Many nurses, physicians and other HCPs received their educational preparation more than 10 years ago when health professions' curricula did not contain this content so that both health professionals' students and practicing HCPs need to be educated in these competencies.

2. Engage the patient and family as partners in care.

Another vital partner in assuring safe patient care is the patient and his/her family. Whereas health care has traditionally been offered in a well-intentioned, yet patriarchal fashion, with the physician knowing best, today's health care delivery re-

quires that the patient and his/her family become “the source of control and full partner” (Cronenwett, et al., 2007). This is distinctly different from the way health care has traditionally been provided, and in most settings, is currently provided today. As the IOM report *The Future of Nursing: Leading Change, Advancing Health* noted:

“Practice still is usually organized around what is most convenient for the provider, the payer, or the health care organization and not the patient” (2011, p.51).

Patient-centeredness is actually not a new concept. Barnsteiner (2014) notes that Hippocrates taught the first medical students to “provide by listening to the patient” and prior to the establishment of hospitals, individuals were routinely cared for in their homes by family members. However, many contemporary factors have altered this relationship: professional autonomy, the medical model of health care, the education of health professionals, technology, the pressures of time, the complexity of the options available, and the perverse incentives for financing of health care.

Increasingly, the consumer movement (Disch, 2014) and the patient movement belief of “Nothing about me without me” are creating pressures for active engagement by individuals and their family members in health care decisions. This is a good thing: It has become increasingly apparent that better quality outcomes are achieved when patients partner with their care providers and assume responsibility for managing their own health (Balik, Conway, Zipperer & Watson, 2011). While HCPs know the science best, the patient and/or family know the individual best. Appendix A includes a true story of the powerful impact and positive change that can occur when including a patient’s preferences in managing her medications.

3. Institute a safety culture with High Reliability Organizations (HROs).

Over the past 15 years, the quality and safety (Q/S) literature has included findings from hundreds of studies examining strategies for improving Q/S, such as rapid response teams; rounds; patient safety audits; checklists; and patient safety officers. However it has become increasingly clear that while these efforts can improve safety at the margin, a more systemic, upstream approach is needed—an entire culture dedicated to safety.

According to the Agency for Healthcare Research and Quality (2010), a safety culture of an organization is:

“the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.”

[from Organising for Safety: Third Report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations) Study Group on Human Factors. Health and Safety Commission (of Great Britain). Sudbury, England: HSE Books, 1993]

Sammer and colleagues (2010) conducted a comprehensive review of safety literature within U.S. hospitals and identified seven sub-cultures essential for a safety culture: leadership; teamwork; evidence-based; communication; learning; a commitment to justice; and patient-centered. High-reliability organizations (HROs)—or settings with “consistent performance at high levels of safety over long periods of time”—share several key characteristics but most importantly they provide “a collective mindfulness” which is embodied by everyone throughout the organization (Chassin & Loeb, 2011, 2013).

In these organizations, everyone is clear that even small failures in process or systems can result in catastrophic outcomes, and that everyone has a role to play in identifying errors and near-misses. Everyone is actively encouraged to be part of the problem-finding and solution-generating models of shared governance and patient engagement are thriving. Everyone includes patients and their families. Of particular importance in HROs is the need for a “greater reliance on [interprofessional] teams and increased complexity in terms of team composition, skills required, and degree of risk involved” (Baker, Day & Salas, 2006) Also in HROs, the leaders are passionate advocates for preventing harm and alter their roles from the traditional one of focusing on the financial bottom line to one of being equally concerned about the Q/S bottom line.

At the core of high reliability organizations are five key concepts, which are essential for any improvement initiative to succeed (AHRQ, 2008):

Sensitivity to operations. Preserving constant awareness by leaders and staff of the State of the systems and processes that affect patient care. This awareness is key to noting risks and preventing them.

Reluctance to simplify. Simple processes are good, but simplistic explanations for why things work or fail are risky. Avoiding overly simple explanations of failure (unqualified staff, inadequate training, communication failure, etc.) is essential in order to understand the true reasons patients are placed at risk.

Preoccupation with failure. When near-misses occur, these are viewed as evidence of systems that should be improved to reduce potential harm to patients. Rather than viewing near-misses as proof that the system has effective safeguards, they are viewed as symptomatic of areas in need of more attention.

Deference to expertise. If leaders and supervisors are not willing to listen and respond to the insights of staff who know how processes really work and the risks patients really face, you will not have a culture in which high reliability is possible.

Resilience. Leaders and staff need to be trained and prepared to know how to respond when system failures do occur.

CONCLUSION

A great deal of work has been done over the 15 years since *To err is human* was published (IOM, 1999), and progress is being made. A phenomenal amount of resources have been made available through AHRQ, the Department of Defense, Department of Veterans Affairs, and organizations such as the Institute for Health Improvement. Patient safety networks and consumer groups have been formed; surveys have been developed; incentive programs have been created. A lot of people are doing good work.

However, to increase the rate of improvement and reduce preventable deaths and serious implications, we must move upstream and implement some of the more challenging, yet fundamental strategies for a safe healthcare system. We must change the systems of care and how we fundamentally think about and work together to reduce preventable deaths and serious complications.

I have highlighted here three strategies that, from my perspective as a nurse for more than 45 years, yield the greatest benefit:

1. Assuring an adequate number of appropriately educated registered nurses.
2. Engaging patients and their families in the care process.
3. Establishing a safety culture where every hospital is a High Reliability Organization.

Thank you for this opportunity to comment on this vital topic.

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APPENDIX A

[HealthLeaders, April 2012]

PATIENT-CENTERED CARE REDISTRIBUTES RESPONSIBILITY

(By Betty A. Marton)

In 2008, a 23-year-old woman with severe cystic fibrosis (CF) successfully carried and delivered a healthy, full-term baby girl at Long Island Jewish (LIJ) Medical Center, in New Hyde Park, NY. Despite that major achievement, the complex regimen of daily medications that Christina Marie McDonald needed to manage her disease created challenges. “On the maternity ward, no one understood anything about CF,” says Ruben Cohen, M.D., director of the adult CF program and co-director of the asthma center for the 888-bed tertiary teaching hospital. “She didn’t receive her medications when she needed them.”

“After that experience, the patient’s father wrote a letter asking,

‘Why does the hospital tie our hands and put these routine measures in the hands of busy medical personnel when the patients and their families know the illness very well and are experts in their own care?’”

explains Fatima Jaffrey, M.D., director of outcomes research at LIJ Medical Center. The hospital realized they needed a new way of doing things. LIJ Medical Center embarked on a process to explore how to improve the in-hospital delivery of daily medications to CF patients.

In February 2009, Jaffrey began coaching an interdisciplinary team of all the frontline caregivers, including Cohen, and a respiratory therapist, dietician, nurse, pharmacist, CF social worker, and Christina’s father, in how to apply the methods of improvement science to improving CF care. The team focused on how it could support and empower the patient while still meeting regulatory requirements. “The goal,” says Jaffrey, was to go from “a system of care that wasn’t deeply connected to patients’ experiences to one that is incredibly connected.” Six months after it was established, the team met its first two goals of reducing the length of time patients had to wait for the delivery of the medications for which they were admitted—to

2 hours (from 15 or more) for the first breathing treatment and 4 hours (from 18) for IV antibiotics.

The program went live in March 2010, with patients who opt to self-administer receiving special locked boxes containing all of their medications. Patients keep a log of what they take and when and nurses review the log to determine if medications are being taken correctly. The nurses also work with the hospital's pharmacists to keep the box replenished. "The process gives the nurses oversight so we can still manage the documentation," says Margaret Murphy, RN, senior administrative director of patient care services.

"It all seems so simple in retrospect, but at the time it required a lot of coordination and education. It offers a tremendous amount of efficiency while ensuring that the patients who know their medications are administering them correctly."

Having dramatically reduced the time it takes to provide the care CF patients need has reduced the average length of stay in the hospital for CF patients to 7 days from 11. The success of self-administration is also reflected in patient and professional satisfaction surveys: Satisfaction rates for both groups rose from less than 20 percent before the intervention to above 95 percent. "What's remarkable is that this sophisticated work can only be done at ground level," explains Jaffrey.

"People who do the day-to-day work can get through these issues with so much velocity. When we empower them to be the change agents, we're leveraging the largest untapped resource we have in healthcare."

Senator SANDERS. Dr. Disch, thank you very much.

Our next panelist is Lisa McGiffert, who is the director of the Safe Patient Project at Consumers Union, a policy and action division of Consumer Reports. Ms. McGiffert directs a multistate campaign to initiate infection reporting legislation, which has passed in 27 States and Washington, DC, and raise public awareness on the prevention of medical harm.

Ms. McGiffert serves as the consumer liaison to the CDC Healthcare Infection Control Practices Advisory Committee and is a consumer representative on the National Quality Forum Healthcare Associated Infections Steering Committee. Prior to joining Consumers Union, Ms. McGiffert worked for the Texas Senate Committee on Health and Human Services.

Ms. McGiffert, thanks very much for being with us.

STATEMENT OF LISA MCGIFFERT, DIRECTOR, SAFE PATIENT PROJECT, CONSUMERS UNION, AUSTIN, TX

Ms. MCGIFFERT. Thank you, Senator Sanders, for holding this hearing, and to Senators Whitehouse, Murphy, and Warren for being here.

I'm not going to go over the statistics because they've been covered. But I do want to make the statement that the response from policymakers, healthcare leaders, and regulators does not come close to match the scope of this problem, and that is exactly the focus of this hearing, as I understand it.

I want to talk about the patients, because the impacts on patients vary and can be anywhere from minor harm to death. Regardless of the scope of the impact of a medical error, most people's lives are affected, and they're affected beyond the healthcare that they need or the physical response.

People who are harmed lose their jobs. They lose their homes. They lose their health insurance. Many go bankrupt, trying to pay the medical bills that they would not have had had they not been harmed by the healthcare provider they sought help from. These are very real consequences of the failure to take action to eliminate medical errors. They are our sisters and brothers, parents and chil-

dren, and they are disabled, and many of them are dead because of these events.

Patients have been betrayed by the system in which they place their trust, not because we expect perfection from nurses and doctors, but because we trust that they will use the best knowledge; diligent adherence to the best practices; pay attention to what we tell them and ask of them; understand that when we pay for their services, we expect it will include doing all they can to keep us safe from harm; and when they make a mistake, they will realize it, admit it, and correct it.

For 10 years, my project at Consumers Union has conducted a national campaign to eliminate hospital infections and medical errors. A major strategy for us in reaching this goal is to improve public transparency. In 2003, we developed model legislation to create hospital acquired infection reporting and took it across the country, recruited people who had been harmed to help us pass these bills, and now 31 States and Washington, DC have these laws. And as most of you know, a Federal program requires reporting of infections.

The creation of the CDC National Healthcare Safety Network was essential to making this happen. That was created right around the time when we were going across the country, and many of the States adopted that as the way that they would report infections. So it is true that we have this system in place that is a standardized system that we could use to collect information about more infections as well as medical errors. That is really essential in moving us forward.

Public disclosure is a critical element to preventing these events from happening, because it informs people about healthcare outcomes and motivates providers to do more to prevent errors. Our work also includes working with people who have been harmed, and I'm very grateful for all that they have taught me. I wish they all could be here with me today. I know many of them are watching, and many of them sent letters to Congress last week urging them to create a national patient safety board and to step up their efforts to address this national crisis.

I'd like to touch quickly on three things: transparency, oversight, and accountability. We have an infrastructure for oversight of healthcare provided by hospitals and physicians and others. But it doesn't work very well for consumers seeking reliable information or for patients trusting that oversight agencies will respond promptly when standards of care are not followed.

Public transparency can address some of these issues. I want to be clear that we're talking about transparency of the events, not patient-related information. But our system is very secretive, and it needs to change. The government holds lots of information about harm that's being done that is not readily available to the public, and they could make it more easily available.

The oversight system does not work for patients. We have this network of oversight at the State level and at the Federal level, and it is not responsive. Our healthcare system does save lives every day, and we all know that that happens, but it's also rife with dishonesty and stonewalling when patients are harmed.

Linda Carswell, whose husband died suddenly in a Texas hospital, had to fight in court for years to get his heart back, an organ that early on could have revealed that he died due to medications given in the hospital. Alicia Cole, who barely survived infections following routine surgery, discovered that photos from her hospital records were not submitted to the medical board when they asked for information.

Hospital boards and leaders of hospitals regularly choose to spend their money on things that will bring in profits rather than activities that will improve the safety of patients. We need someone on our side to look over this system, and that is why we're asking for an independent national patient safety board. We need someone to listen to patients, because they offer real insights to what needs to be done, and we need someone to make this network of systems work for us.

I'd be happy to talk to you more about this through the question and answer.

[The prepared statement of Ms. McGiffert follows:]

PREPARED STATEMENT OF LISA MCGIFFERT

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to speak to the Subcommittee on Primary Health and Aging about an urgent health care crisis—medical errors and health care-acquired infections that kill as many as 440,000 people¹ and harm an estimated 8.5 million² every year in this country.

The impact on patients varies—from minor harm that is addressed quickly to permanent disability to years of recovery to death. People who are harmed lose their jobs, their homes, their health insurance. Many go bankrupt trying to pay the medical bills that they would not have had if they had not been harmed by a health care provider. These are the very real consequences of the failure to take action to address the problem of medical errors. They are our sisters and brothers, parents, and children. They have been betrayed by the system in which they placed their trust. Not because we expect perfection from nurses and doctors, but because we trust that they will use the best knowledge, diligent adherence to the best practices, pay attention to what we tell them and ask of them, understand that when we pay for their services we expect it will include doing all they can to keep us safe from harm, and when they make a mistake they will realize it, admit it, and correct it.

Since 2003, Consumers Union's Safe Patient Project has conducted a national campaign to eliminate hospital acquired infections and medical errors. A major strategy for reaching this goal is to improve public transparency about these mostly preventable events. We developed model legislation and initiated debates in nearly every State on whether hospitals should disclose their infection rates. Thirty-one States passed laws based on our hospital infection model before a Federal program required such reporting for most U.S. hospitals. Public disclosure is a critical element to preventing these events from happening—it informs people about health care outcomes and motivates health care providers to do more to prevent errors.

Our work includes organizing patients and their families who have been harmed by medical care and who are working to improve the health care system to prevent harm from happening to others—in their communities and nationally. Many of them sent letters to their congressional members last week urging them to create a National Patient Safety Board and to step up efforts to address this national crisis.

We acknowledge that many individuals, hospitals and other health care institutions are working to eliminate medical errors. Their work and progress is often the subject of congressional hearings. But today's hearing, highlighting this national tragedy, is a call to action for a very big problem—millions of Americans are at risk for death and serious injury but the response by our leaders fails to match the scope of this epidemic.

¹James JT, "A new, evidence-based estimate of patient harms associated with hospital care." *Journal of Patient Safety*, 2013 Sep;9(3):122–8. doi:10.1097/PTS.0b013e3182948a69.

²<http://www.aha.org/research/reports/tw/chartbook/2014/table3-1.pdf>. According to the AHA, in 2012 approximately 34 million people were admitted to American hospitals; one in four is calculated as 8.5 million patients.

Consider this headline: “House to push for answers on why GM failed to recall cars despite knowledge of flaws ultimately linked to 13 deaths.” The CDC home page this week highlighted salmonella infections from sprouted chia powder and pet bearded dragons and ecoli from raw clover sprouts—but nothing on infection outbreaks in U.S. hospitals. The VA faces significant actions for delays in care, but is anyone asking about medical errors that occur at the VA and put soldiers in harms way? Diabetes kills nearly 70,000 people each year and there is a significant emphasis in our health care system to eradicate this disease. But what about the third leading cause of death? Where are the programs reaching out to help patients who are suffering from medical errors? Where is the demand for accountability of the deaths caused by preventable hospital-acquired infections?

MEDICAL ERRORS: THE THIRD LEADING CAUSE OF DEATH IN THE UNITED STATES

Many names are given to medical errors and some, like “mishaps” and “misadventures” are offensive to the patients affected. The most used list of medical errors was developed by the National Quality Forum (NQF). These are commonly referred to as “never events” but officially named “serious reportable events.” The never events name was appropriate because these are things that should never be happening to patients in hospitals. The list includes surgical errors (such as surgery on the wrong patient, the wrong body part or leaving a foreign object in the body), care management (such as medication errors, blood errors, maternal or infant deaths during normal deliveries, serious bed sores), product or device-related events (such as contaminated drugs, death due to intravascular air embolism in the use of an IV), environmental events (such as electrical burns, falls, electric shocks), and criminal and patient protection issues (such as abduction of a patient, sexual assault of a patient, suicide).

In 2011, Consumer Reports polled Americans about patient safety and asked them the terms they would use to describe these events. Medical errors and medical mistakes topped the list (48 percent combined). “Adverse events,” a term commonly used by professionals was barely recognized (4 percent). How we refer to these events is critical to raising public and professional awareness. Using understandable terms like hospital-acquired infections rather than “nosocomial infections” is a small but critical step toward creating a culture focused on eliminating them.

While medical harm spans all providers—hospitals, doctors, dialysis centers, nursing homes and outpatient surgical centers—most of what we know is limited to what happens in hospitals. And what we know about hospitals is a very small part of the comprehensive problem.

More than 10 years ago, the Institute of Medicine (IOM) estimated that annually 98,000 patients lost their lives due to medical harm.³ Even then it was contradicted by CDC data that estimated 88,000 deaths from infections alone.⁴ Using 2002 data, CDC updated their estimate to 99,000 deaths from hospital-acquired infections.⁵ And the agency’s 2014 prevalence estimate, based on a 2011 study was 722,000 infections in 648,000 patients and 75,000 deaths. This reflected a change in the incident rate from 5 percent to 4 percent of hospital patients or on any given day, 1 in every 25 patients will get an infection.⁶ Clearly this is very slow progress that cries out for more attention. CDC’s media statement said,

“Although there has been some progress, today and every day, more than 200 Americans with healthcare-associated infections will die during their hospital stay.”

Further, antibiotic resistant infections are on the rise, creating another crisis in the treatment of infections that occur. Even if there were many drug developers working on new antibiotics, the scientists cannot keep up with the bugs. By the time a new drug is on the market, resistances are forming. We cannot research our way

³ Kohn LT, Corrigan JM, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999.

⁴ MMWR Weekly, February 25, 2000; “Fourth Decennial International Conference on Nosocomial and Healthcare-Associated Infections;” <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4907a4.htm>.

⁵ R. Monina Klevens, DDS, MPH; Jonathan R. Edwards, MS; Chesley L. Richards, Jr., M.D., MPH; Teresa C. Horan, MPH; Robert P. Gaynes, M.D.; Daniel A. Pollock, M.D.; Denise M. Cardo, M.D.; “Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002,” *Public Health Reports / March–April 2007 / Volume 122*; PP 160–66.

⁶ Magill, Shelley S., Jonathan R. Edwards, Wendy Bamberg, Zintars G. Beldavs, Ghinwa Dumyati, Marion A. Kainer, Ruth Lynfield, Meghan Maloney, Laura McAllister-Hollod, Joelle Nadle, Susan M. Ray, Deborah L. Thompson, Lucy E. Wilson, Scott K. Fridkin, “Multistate Point-Prevalence Survey of Health Care—Associated Infections,” *New England Journal of Med* 2014; 370:1198–208. DOI: 10.1056/NEJMoa1306801.

out of this problem. The only way out is rigorous infection prevention and aggressive antibiotic stewardship programs throughout the country.

When it comes to tracking medical errors, we don't really know how many hospital patients are harmed because there is no national effort to collect this information or to make it public. But three landmark studies in 2010 and 2011 gave us some solid estimates of how often these errors and infections happen.

The studies rocked the confidence of experts in the field who assumed piecemeal efforts to prevent medical harm were having an overall effect on improving patient safety. All of these studies looked at all harm—from minor to major—and included both errors and infections. All emphasized the need for the system to focus on a broader array of adverse events than the National Quality Forum list and serious adverse events. All used techniques that avoided the underreporting problems common to hospital self-reporting and misleading billing data.

- *U.S. Health and Human Services Office of Inspector General (OIG)* based its study on Medicare data and found that 27 percent of Medicare patients hospitalized in October 2008 were harmed from medical care. One in seven of them endured long-term and serious harm from hospital care (defined as events resulting in prolonged hospitalization, permanent disability, life-sustaining intervention, or death).⁷ The OIG estimated that 44 percent of the harm identified was preventable.

- *New England Journal of Medicine (NEJM)* study revealed similar findings—one in four hospital patients are harmed.⁸ This study was done in North Carolina where there had been a high level of engagement in efforts to improve patient safety during the 6 years covered by the study. Despite this work, the surprising findings showed little evidence that harm had decreased substantially over that 6-year period. At the time, no public reporting of infections or errors was required of North Carolina hospitals. Without information about medical harm, the public cannot hold these hospitals accountable for their errors. The NEJM study found that 63 percent of these events were preventable and made the important point that “preventability” changes over time as new ways to keep patients safe are tried and measured.

- *Health Affairs* study using the Institute for Healthcare Improvement's global trigger tool⁹ found that one in three hospital patients are harmed.¹⁰ The study compared three methods for detecting adverse events in patients hospitalized in three large tertiary care centers—all teaching hospitals with well-established patient safety programs—and found the most common methods used to track patient safety in the United States—self reporting and pulling information from administrative billing documents—missed 90 percent of adverse events.

A 2013 study, “A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care,” translated existing research into a reliable estimate of how many patients die from medical errors each year. Based largely on the findings cited above, the study estimated that the premature deaths of more than 400,000 patients each year was associated with preventable medical errors.¹¹ When undetected diagnostic errors were added to that number, the study estimated up to 440,000 patients are harmed each year. These new estimates established medical harm as the third leading cause of death in the United States.

THE ROLE OF PUBLIC TRANSPARENCY IN IMPROVING SAFETY

Consider if Consumer Reports tested 50 cars and found some performed well and others were unsafe, but refused to reveal which cars fell into each category. The public would not be served by such evaluation and it would seem ridiculous to go to the trouble of looking at this information and then hiding it. But that is how reporting on patient safety issues was traditionally handled. Summaries that do not identify the hospital or physician in charge of patients' care when errors occurred are not useful—the information should be publicly tied to where the harm occurred.

⁷ Department of Health and Human Services, Office of Inspector General, “Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries,” Daniel R. Levinson Inspector General, November 2010, OIG-06-09-00090.

⁸ Christopher P. Landrigan, M.D., M.P.H., Gareth J. Parry, Ph.D., Catherine B. Bones, M.S.W., Andrew D. Hackbarth, M.Phil., Donald A. Goldmann, M.D., and Paul J. Sharek, M.D., M.P.H., “Temporal Trends in Rates of Patient Harm Resulting from Medical Care.” *The New England Journal of Medicine*, November 25, 2010; 363:22.

⁹ <http://www.ihl.org/resources/Pages/Tools/IHGlobalTriggerToolforMeasuringAEs.aspx>.

¹⁰ David C. Classen, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C. Whittington, Allan Frankel, Andrew Seger, and Brent C. James; “Global Trigger Tool Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured.” *Health Affairs*, April 2011, 30:4.

¹¹ James, JT, “A new, evidence-based estimate of patient harms associated with hospital care.” *Journal of Patient Safety*, 2013 Sep;9(3):122–8. doi:10.1097/PTS.0b013e3182948a69.

In recent years, the trend has been changing and it has provided useful tools for improvement—fundamentally, one cannot measure progress unless metrics are being documented.

In the past 10 years, 31 States and the District of Columbia have mandated public reporting of certain hospital-acquired infections and these hospital-specific reporting laws have stimulated more activity around infection prevention than this Nation has seen in previous decades. And, now Federal payment policies have created incentives for reporting infections that hospitals in other States cannot resist. While this infection reporting is still giving us a limited snapshot, new measures are being added each year. Only two States—Pennsylvania and California—require the kind of comprehensive reporting needed to evaluate hospitals' overall infection safety.

However, the reporting of other types of medical harm currently in place fails to create external pressure for change. In most cases hospital-specific information is confidential and under-reporting of errors is not curbed by systematic validation of the reported data. Currently, about half of the States require hospitals to report certain types of medical harm, but only 10 require reporting this information by hospital. At the Federal level, some medical complication information is revealed through the Hospital Compare Web site, but it is limited. Without hospital-specific information, key elements for stimulating change are missing: public accountability and hospitals' awareness of their record and that of their peers.

Another hurdle exists in deciding which events should be reported. A 2010 series in the *Seattle Times* clearly illustrated the problems arising from narrowly defining "harm" in a way that ensures most harm will not be reported. One article told of a man who entered the hospital for a simple outpatient arthroscopic shoulder surgery and, according to State investigation records, sustained brain damage and died due to nursing errors, including a misadministration of pain medication. This was clearly a case of preventable medical harm but the harm did not fit into any definitions under Washington State's reporting law, so was not reported. These are the issues that the previously mentioned studies by the Office of Inspector General and the *NEJM* pointed to in their conclusions—we need a system that identifies all preventable harm, not just those that fit into a narrow definition.

The question often asked is whether public transparency improves safety. While it is impossible to parse out the impact of public reporting mandates from the prevention activities they have stimulated and the programs that followed to tie payments to performance, we do have some evidence that transparency is making a difference.

In a report issued last March, the Center for Disease Control and Prevention (CDC) documented a 44 percent decrease in central line-associated bloodstream infections between 2008 and 2012. This is the one measure that almost every State with an infection disclosure law required to be reported. Further, CDC reported that the rates of other types of infections are coming down: 20 percent decrease in infections related to the 10 surgical procedures tracked between 2008 and 2012; 4 percent decrease in hospital-onset MRSA between 2011 and 2012; and 2 percent decrease in hospital-onset *C. difficile* infections between 2011 and 2012.

Many States have documented similar reductions from year to year in their public reports. For example, in New York, overall surgical site infection rates had decreased by 16 percent between 2007 and 2012, resulting in a cost savings estimated to be between \$12.1 million and \$35.4 million since 2007. And, bigger improvements were made in specific surgical procedures such as coronary artery bypass surgery, a 23 percent–47 percent decrease since 2007.¹² New York is probably the most reliable State, as it has validated the infection data each year.

There are attitude changes that come with public transparency. Minnesota is one State that publishes facility-specific information about medical errors on a State Minnesota Department of Health Web site. Seventy-two percent of Minnesota facilities surveyed in 2008 felt that the Minnesota error reporting law made them safer than they had been when reporting began in 2003. One respondent said,

"(Our) focus was always on patient safety, however now safety efforts are better understood by more of our staff and we prioritize this work ahead of other work. Data is helping us to create more sense of urgency for this work."

Evidence of individual hospital successes to reduce errors abound and Federal programs recently documented a 9-percent decrease in hospital-acquired conditions and an 8-percent decrease in re-admissions, which are often connected to errors or

¹²"Hospital Acquired Infections, New York State, 2012," New York State Department of Health, Albany, NY, September 2013; page 4; https://www.health.ny.gov/statistics/facilities/hospital/hospital_acquired_infections/2012/docs/hospital_acquired_infection.pdf.

infections.¹³ None of this documentation would be possible without public reporting mandates.

ANOTHER KIND OF TRANSPARENCY IS NEEDED

Transparency at the patient level is absolutely critical to ending medical errors. When patients are harmed, they often are subjected to additional harm when caregivers fail to disclose or explain what happened. Medical records are withheld or altered or never documented accurately. Many families have to file lawsuits just to get information about how their loved ones died. This is the underbelly of medical errors—the cover-ups and the insults to injury. We must create a more just and fair system that encourages discussions without requiring patients' rights in exchange, that compensates patients for their losses and that treats them with dignity and respect.

RECOMMENDATIONS

Because of the significant scope of this problem—tens of thousands of service delivery points and hundreds of millions of patient contact points—the solutions can seem overwhelming. Many programs are in place today but they are fragmented and the results of their efforts are difficult to track. Fundamentally, as a nation just as with hospitals and other institutions, a comprehensive, coordinated approach is needed. This is why Consumers Union and many of the advocates with whom we work are supporting the creation of a National Patient Safety Board, modeled after the National Transportation Safety Board. We would welcome the opportunity to work with Members of Congress to develop a plan for creating this oversight agency.

Some additional recommendations are briefly listed below. More information about them can be provided upon request.

- Support the infrastructures needed for public reporting and tracking of infections and errors. For example, the CDC's National Healthcare Safety Network (NHSN) collects information from more than 10,000 providers. We need to sustain this system and ensure that it can grow in capacity into the future. This should include funding to the States to validate data being reported.
- Expand hospital infection reporting so that infections are being documented throughout the hospital and consumers have a clear picture of a hospital's overall infection rate.
- Mandates are needed for antibiotic stewardship. Require hospitals to report on antibiotic usage and resistant infections using CDC-NHSN's new modules for this purpose.
- Require medical error reporting. Electronic billing records could be used as a resource for documenting these events by improving their accuracy. Create a rigorous validation process that includes fines for hospitals that fail to accurately document patient stays.
- Require death certificates to indicate when infections or errors are the cause of death and document the presence of these events preceding or at the time of death.
- Hospital infection outbreaks should be disclosed to the public, the patients in the hospital, and patients being admitted.
- Make the National Practitioner Data Bank public so patients can refer to it to check on physicians that have licenses in multiple States.
- Continue adding measures to Medicare pay for performance programs and consider standardizing how incentives and penalties are calculated. Keep the programs growing but simplify the calculations.

Senator SANDERS. Thank you very much, Ms. McGiffert, for your testimony, and thank you all. I think this has been excellent testimony. Let me begin the questioning.

Dr. Jha, you work for the VA occasionally, right, and I'm chairman of the Senate Committee on Veterans Affairs. We've been hearing a whole lot on the front pages of newspapers throughout the country about problems in the VA, and they're legitimate problems, and we've got to deal with those problems. But I think, as many of the panelists have indicated, we haven't heard a whole lot about this issue.

¹³ <http://innovation.cms.gov/Files/reports/patient-safety-results.pdf>.

I think, Dr. Pronovost, you indicated that we don't know exactly how many people died because of errors. But you used the analogy of two large airplanes a day going down. Is it 500 people a day dying or 1,000 people? We don't know. But it's a lot of people.

So my first question is: How come this story is not on the front pages of the papers every single day? If somebody dies in a VA hospital, it's a big story. It should be. But if 500 people every single day die, that also is a big story. So that's one question.

Well, let's start at that one. Why is this issue not getting the kind of attention that it deserves? Who wants to start that one off?

Dr. Jha.

Dr. JHA. Let me make two quick points. One, to that question, Senator, when people go to the hospital, they are sick, and it is very easy to confuse the fact that somebody might have died because of a natural consequence of their disease versus they died because of a complication from a medical error.

The bottom line is that it has taken work like the work that Dr. Pronovost has done to prove to all of us that many of these deaths are not a natural consequence of the underlying disease. They are purely failures of the system to address the problem. That has been a wake up call for clinicians, for physicians, like me, for nurses to know that we can do so much better.

Senator SANDERS. Good. Let me just run to Dr. Pronovost.

Dr. PRONOVOST. I think there's three reasons that it doesn't get visibility, as Dr. Jha said. The first is that we've labeled so much harm as inevitable—it's the result of being sick—that we now know is preventable. The difference in harm estimates between the IOM report of 1999 and today isn't that care got worse. It's just that all these other deaths that we put in the inevitable bucket we now moved into the preventable bucket, and there's, frankly, probably even more that we should move.

Second is that the deaths occur alone, one at a time, and silently and don't get the media attention. If you look at it compared to the mining in West Virginia or the automobile—the number of deaths are pale—I mean, they're in the tens, not in the hundreds a day. But look at the media attention, because one death at a time doesn't garner it.

Third, if you look at what drives research agendas or your work, it is disease advocacy groups, like the Alzheimer groups, the breast cancer groups. And there's no advocacy group with that power for patient safety, because there are many, many different diseases, and there needs to be. I mean, NIH funding or your work is—you have to answer to those constituents. They're powerful. And we lack that, and we need it.

Senator SANDERS. I apologize for cutting people off, but we only have 5 minutes to ask questions. Let me pick up on a point that Ms. McGiffert raised, and that is the issue of transparency. If I go into a hospital, is there public information—I'm getting surgery—about the level of infection at the hospital or other preventable deaths? I mean, do we have the information that would allow a consumer to make a good choice and say, "whoa, whoa," if too many people have died or gotten sick in that hospital because of preventable problems?

Ms. MCGIFFERT. We are beginning to have information. We don't know if the whole hospital is safe, and we do know that people often are treated in different parts of the hospital. But when it comes to surgery, it probably depends on what State you're in, whether the surgery you're getting is going to be published. In Washington State, they publish hip and knee implant surgery, so you're in luck there. But you're not in luck in Texas. And the Federal Government doesn't require that yet.

So we're getting there. But it's been very slow over the last 10 years, and we really are just getting a small piece of the problem.

Senator SANDERS. Let me just jump in, and I'll go to Dr. Gandhi in a second. A wife has an operation. Clearly, there is a problem. The husband in this case says, "You did something terrible." Maybe there's the threat of a lawsuit. Is it not true that many of these settlements will not be made public, that we don't know how many types of settlements have been made because of poor practice?

Dr. Gandhi, is that an accurate statement?

Dr. GANDHI. That's an accurate statement. So I want to talk about transparency. I think you mentioned other infection rates available for someone going in for surgery, and I think that's getting more available. But there's so many other pieces of information that someone needs to know before they go in. And maybe they're not going for surgery. Maybe they're going to see a primary care doctor. What do they need to know? So I think the amount of good information available to patients is minimal.

But on the transparency front, I think it's important to think of transparency on a couple of different levels. So, first, we need transparency with patients, as we were just talking about, with data, transparency about errors, transparency about why we're doing the care that we're doing.

But then there are other levels of transparency that we really need to think about. One of the things that I think is a huge lost opportunity is transparency across organizations. To your point about a malpractice case, or even an error that didn't lead to malpractice—my hospital fixes it, figures out how to solve it, that does not naturally leave the four walls of my hospital.

Things are getting reinvented, and things are happening constantly around the country. I think we need better mechanisms to ensure that sharing across organizations when these events do occur.

Senator SANDERS. We're going to have other rounds of questioning, but I wanted to get to Senator Warren.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman. According to the CDC, about 75,000 people die annually with infections they get while they're in the hospital. I think it's a shocking number. We should be doing everything we can to drive that to zero. Now, we already know a lot about how to reduce these deaths. Some of the simplest things, like better hand washing, more thorough room cleaning, establishing protocols for catheters and ventilator tubes, have shown to reduce these infections.

I want to brag here just a little bit. Boston Children's Hospital, which treats some of the sickest children in the world, has had terrific success at implementing steps like these. Boston Children's

has not had a single case of ventilator associated pneumonia in the cardiac ICU in nearly 2 years and not a single catheter associated urinary tract infection in the medical ICU for over 2 years.

In other words, I just want to start with what we already know. We know how to make patients safer. Unfortunately, it's not happening everywhere. We need a system in place to promote the adoption of these practices. So my question is this: Can you help us understand why certain healthcare entities have not yet adopted straightforward, proven techniques to reduce these infections?

Dr. Jha, would you like to start?

Dr. JHA. I would be happy to, and it's a terrific question. Fundamentally, the question in front of us is how do we have an industry where you have cheap, easy interventions that save lives, save money, and not every single person is using it every day? It's like there's a disconnect here. Something doesn't make sense.

It strikes me that when I look at places like Boston Children's, when I look at Hopkins, when I look at these leading organizations, what they're doing is driven by passionate leaders who care deeply despite all the incentives in the system that don't give them any rewards for doing this kind of stuff. That's the problem. If we have a system that relies on heroes and great leaders and people like Peter Pronovost to solve all of our problems—I'd love to clone this guy. But that is not a policy solution for the problem we have.

We've done work that has looked at hospital CEOs and what determines CEO pay in nonprofit hospitals. These are the organizations that have a nonprofit status. Quality outcomes, patient safety—none of those things influences the pay of the CEO. So until we get to a point where the CEO of the hospital is lying awake at night worrying about patient safety, I don't think we're going to really, meaningfully move the needle beyond these few leading organizations that are going to do it no matter what incentives we put in place.

Senator WARREN. OK. Good. Dr. Gandhi wants to add to that.

Dr. GANDHI. I just want to add that it's also critical for boards of directors to be better educated about this topic. Often, boards are much more focused on the financial aspects of how the hospital is running, especially, and I understand that these are hard financial times for many hospitals. But having boards of directors that really understand this issue and then can push it through the organization is also really key.

Senator WARREN. Good.

Dr. Disch.

Ms. DISCH. I'd like to add also that there are some very simple procedures, and it seems like we should be able to just say, "Wash your hands." And yet when you get down into even that simple of a basic, which we all know is the No. 1 preventative action you can take, it really becomes complex. So you need the leaders that really will say, "We are as concerned about safety as finance."

But you also need the resources in place. Even for something as simple as washing your hands, you need the right equipment. There's got to be sinks that are accessible. You've got to have the soap that's there—housekeeping making sure the soap dispensers are filled. If the nurse and physician comes with a bunch of equipment, where do they put that down? On the floor to wash their

hands? I don't think so. So it's just such a ripple effect that you need equipment, you need people to understand what's going on.

I was going to mention earlier about transparency. Staff have to understand what's going on with the metrics in their organization. So we can do national promoting. We can do information among hospitals. But staff need the feedback that—here's our infection rate, here's what we're doing, here's where we're improving. So all of those go into something as simple as hand washing.

Senator WARREN. Dr. Pronovost, you wanted to add to this?

Dr. PRONOVOST. Senator, you should have been on our research team with your question. We were curious to see what allowed a hospital to get to zero like Boston Children's versus not. So we borrowed a technique from the nuclear industry called peer-to-peer review. They developed it after Three Mile Island—no regulatory role, where one nuclear facility visits another.

So we went into hospitals that were zero to try to understand. What we found was there was no magic bullet. But there was a clear chain of accountability and practices that led them to get to zero. So they were zero, and if the CEO said, "Our goal is zero," and they look at their rates, they knew it.

They were zero if they provided enabling support structures, so they had good infection prevention to educate staff. They were zero if the ICU director and nurse manager owned the problem. So we walked in there and said, "What's your rates?" And they knew it. They were zero if they had a culture where nurses could openly question doctors for not using the checklist, and that was well received.

They were zero if the frontline staff got feedback about their infection rates, and they investigated every infection as a defect. We know this chain of command. We just haven't implemented it. But if you did one of them, you may go down a little bit. You wouldn't get to zero. But if you put them all together, you have a great program.

Senator WARREN. So I'm going to ask for the chair's indulgence, if we can just follow with this line.

What would you change in Federal and State requirements, policies, to drive us in that direction? As I say, this is not the part about the cutting edge new magical things we've got to figure out, but the things like washing your hands that are going to drive down the rate of deaths, the rate of infections.

Why don't I start with you, Ms. McGiffert, and we'll come back down the line.

Ms. MCGIFFERT. I think there's a lot of things that can be done to make the payment incentives more meaningful. For example, in the hospital-acquired conditions payment program, the disincentive is simply to not pay for the hospitalization during which the event occurred. But that person on Medicare has to get wound care, doctor visits, back in the hospital, medications, all kinds of expenses that Medicare is paying for. And that hospital should be held responsible for the whole range of things that that patient needs.

Senator WARREN. So we've got a payment response.

Ms. MCGIFFERT. A payment response.

Senator WARREN. Very powerful. And I'll ask you to do these quickly, because I am over my time.

Dr. Disch.

Ms. DISCH. The one thing that I think about is what Minnesota is doing, and what they have, which many States have, are hospital engagement networks. They bring together the CEOs and senior leaders to take a look at what they are doing and have conversation across institutions, which creates the incentive of: "How come yours is doing so much better than ours?" And they talk among themselves.

Speaking with some of the officials from the Hospital Association, I said to them, "How many of the CEOs in our State do you think are really changing and becoming not only concerned about finance, but also the preventable event bottom line?" And she said, "It's really changing the dial when they sit down and talk and they share stories." But it's not just the CEOs. It's the senior team, just like was mentioned before. It's got to be medical leadership, nursing leadership, and that comparison and sharing of information is happening at the State level.

Senator WARREN. Dr. Pronovost.

Dr. PRONOVOST. Senator Warren, right now, we have reduced these infections dramatically. But there are several hundred hospitals who have rates 10 times the national average, and there is no accountability outside of Lisa's or the public reporting. They're fully accredited, and we know if they did these things, they can get to zero.

I would love to see us start with bloodstream infections, because you can't pull a hammer unless you have a good measure. But we have a good measure for this, and we have evidence that it's leadership. If you're not down low, it's a leadership failure. No excuses. So I think we could say we need a mechanism to say, "If your hospital is high, you shouldn't be accredited." There should be some greater sanction, because we know.

Senator SANDERS. Let me just jump in and pick up on a point. You're saying you know that there are some hospitals that have infection rates 10 times higher than other hospitals. Do the American people know who those hospitals are?

Dr. PRONOVOST. Senator, I know about those because of the work of Consumers Union, and several States require public reporting. And their newspapers—Chicago did it, Baltimore did it—would write newspaper articles listing the hospitals that are high. But outside of that public sanction, literally, there's no followup.

I mean, you'd say, "OK. Well, you're accredited, and you meet—to the Joint Commission," which is great. You do that. But people are dying. Who is responsible for saying 10 times too high isn't appropriate? And we know you can fix it.

Senator WARREN. So what would you do, Dr. Pronovost? What would be the next step? We've got Consumers Union out there hitting on this. But what would you do next?

Dr. PRONOVOST. I think we need, either at a Federal level or with the Joint Commission—but CMS should say, "If your rates"—and I would start with this one measure, because we know the measure is good, and the evidence that you can get low is good.

Senator WARREN. If your rates—

Dr. PRONOVOST. Are above the national average, you get told you have a quarter—because we know the infection rates plummet when you do these things, literally, immediately, within months.

Senator SANDERS. You're talking about accreditation.

Dr. PRONOVOST. Correct. You'll be sanctioned or you'll lose your accreditation.

Senator SANDERS. I want to get to Senator Whitehouse.

Senator WARREN. Go ahead. I apologize. I do want to be sure that Dr. James gets a chance to participate in this, too.

Senator SANDERS. Yes.

Senator WARREN. OK. Thank you, Mr. Chairman.

Senator SANDERS. Senator Whitehouse.

Senator WHITEHOUSE. Thank you very much, Chairman. The clear accountability that everybody, I think, agrees is a very important signal is hard to develop without clear data. I am concerned that there is kind of a tower of Babel problem, that a provider has to report through multiple means of reporting to the Federal Government; I think in every State through multiple means of reporting to the State government; through whatever reporting mechanisms the individual insurers that they do business with have built into their systems; through whatever local systems might have been set up if there's a regional or municipal quality initiative; and potentially through their ACO process and some of the quality improvement processes.

By the time you've loaded up all that reporting, two things have happened. No. 1, the reporting begins to eat up the actual repair, and, No. 2, the noise overtakes the signal. So if a hospital gets a bad report, the first thing that I hear them say is, "Oh, that data is not good. If you look at this, we're actually doing better over here."

So while, obviously, we want robust reporting, and while some of this is a moving target you need to keep up with, to what extent do you think we should be focusing on simplifying and directing attention to a few clear, agreed measures that can then become kind of barometers for the system behind them? Back to Dr. Disch's point that, fundamentally, this is a problem that is a system problem. You're not going to solve it with discipline on doctors for mistakes. You're going to solve it by recalibrating the culture in the system that supports these decisions.

Ms. DISCH. Can I just comment that I think that's an excellent point to start with, because I can indicate that there's one institution on which I sit on their quality committee, and they track 1,800 indicators. Now, there is no sense—

Senator WHITEHOUSE. So how do you possibly get a signal out of that?

Ms. DISCH. And the staff get very cynical, because they will say, "Oh, flavor of the month, scud missiles coming over the transom"—are the words that the staff use. So getting some kind of alignment and order would be immensely helpful—reconciliation.

Senator WHITEHOUSE. Ms. McGiffert.

Ms. MCGIFFERT. I think the focus needs to be on outcome measures. When she talks about the 1,800 measures, a lot of those are process measures, like checklists, like these are the things we need to do, and hospitals do have to track that. But for public reporting,

we need outcome measures. Most of the reporting we have now are process measures that don't really tell us whether or not a patient actually got an infection or was harmed.

Senator WHITEHOUSE. Dr. Pronovost.

Dr. PRONOVOST. I think you're spot on, Senator Whitehouse. We report at Johns Hopkins well over 300 measures, and most of the outcomes are measured using billing data, and they are truly near worthless. I mean, we spend a ton of money, but what it does—we spend money improving coding, not improving care.

We know the top five causes of preventable death. She named some of them. We should, like we did for infections, develop measures for those and focus on those, prioritizing where people are dying. Outside of healthcare acquired infections, I do not believe we have a system for valid measures of any other harm.

Senator WHITEHOUSE. I'll change the topic a little for the remaining witnesses, because I'm getting a lot of head nodding. So I think we all agree with that so far.

Do you believe—starting with Dr. Gandhi and going over—that if you were to pick a couple of really core quality measures, try to steer some of the clutter away from them so that they became much more visible, much more clear, had much more signal coming off of them, that that would then affect the type of system operations and the type of culture that has been repeatedly talked about and would tend to propagate in other areas of the institution? Or do you think you really have to fight it infection by infection, issue by issue, against a wall of bad incentives?

Dr. GANDHI. I completely agree about the metric overload, and I think we do need to narrow it. The one concern I have about narrowing to four or five is that every focus goes there and there's a whole lot of other stuff that is important that doesn't get tackled, to your point. So I think part of those core metrics—

Senator WHITEHOUSE. Might there be some value in punching through to real success on those and then expanding it, rather than just banging against everything and not making progress?

Dr. GANDHI. Well, true, because I think then we basically don't make any significant progress on any of them. But what I was going to say is I think it's important to think about infrastructure and foundational things that will raise all the boats, basically. So we talked about incentives for CEOs. If you have a culture in your organization where people are afraid to speak up and talk about errors, you're not going to get very far on any of these issues. So we have measures of that, but there's not—

Senator WHITEHOUSE. If you go to the Ford plant, the biggest Ford plant that makes, I think, the vast majority of their trucks in Michigan, any person on the line can stop the line. And they're absolutely protected for doing that if they see any kind of a flaw. You're exactly right about that. It's a very good process.

Dr. GANDHI. And some organizations in healthcare have implemented those same strategies in healthcare.

Senator WHITEHOUSE. We did with the ICU initiative in Rhode Island. It worked really well.

Dr. GANDHI. Exactly. So how do we measure that and incentivize improvement on that? Just measuring it alone isn't enough.

And then the third piece in terms of infrastructure that I think about is training. We can't have our leaders telling people, "Well, just try harder next time." People have to understand safety science and safety principles and make sure that everybody in the organization understands how to actually improve things, because things are happening all over the place, and it has to come from the front lines to fix all of the things.

Senator WHITEHOUSE. Dr. Jha and Dr. James, real quick. I'm just over my time now.

Dr. JHA. The good news is we've done this. We've had noisy measurement programs, and the Federal Government has taken a leadership role through the Hospital Quality Alliance about a decade ago to align this stuff, identify a few key metrics, get everybody on board to start measuring and using it. I think because this is a public health problem, the CDC is in a natural role to lead it.

If we can identify the three to five big things and go after it, measure it systematically, and put in incentives—because we've all talked about culture. Culture comes from leadership, and leadership responds to incentives. If we have the right incentives, we've got the right leadership, and we've got the right culture.

Senator WHITEHOUSE. Dr. James.

Mr. JAMES. I'd like to ask you to think about a different dimension than this kind of reporting. We were doing this at NASA as I was leaving. It's called 360-degree reviews. If you talk to nurses and doctors in hospitals, they know who's doing it right and performing well, but they're afraid to say so if there's something wrong with their colleague or their boss.

That 360-degree review works really well. It's an anonymous review. You don't know who's reviewing you, but you get feedback. So for the first couple of years, you get feedback on what you need to fix. I got some interesting feedback at NASA on what I needed to fix. And doctors get that. But then after a couple of years, if the physician is not fixing, according to the feedback he's being given, then the administrators take some kind of action.

But within hospitals, it is known what's going on. You just have to find a way to pull that information up and get it available to the public.

Senator WHITEHOUSE. Chairman, back to you. Thank you very much.

Senator SANDERS. Thank you. Let me just continue with some questioning here. I think Ms. McGiffert was talking—or maybe it was Dr. Gandhi—about at the end of the day, what we're talking about is patients. I mean, maybe we're working—instead of going from patient on up, we're going from the top down to the patient.

In the course of this discussion, just several observations. Dr. Gandhi, I believe, mentioned that doctors prescribe medicine. That's the therapy, and one out of four patients can't afford to buy the drugs. What kind of insanity is it that we go through the whole effort of somebody diagnosing a disease, here's the therapy, and, oh, it's too bad you can't afford the drugs?

Dr. James talked about his own tragedy in his life, where after the treatment his son received, somebody knew that he shouldn't go out and run or do heavy athletics. But they forgot to tell him. So there was a lack of communication.

I know as part of the ACA hearings that we had, Medicare will spend a whole lot of money doing surgery on an older person. Then we send that person home, and, gee, we forget whether the person has enough food to eat in their house, whether their home is warm enough in the wintertime, or whether they have a clue about the 15 different medicines that they're taking.

We spend \$50,000 on surgery, but we don't spend \$500 a day on a social worker to make sure that those things are done. This speaks, I think, to a dysfunctional system, in general, which is to a large degree, if I may say so, profit-oriented rather than patient-centered.

Who wants to comment on that? Is that true or not true?

Dr. Gandhi.

Dr. GANDHI. I think it is true that we do not do enough to ensure patients are educated and partnering with us, that patients understand the plan, that patients have the resources when they go home to actually do what we ask them to do, and the incentives haven't been aligned to pay for that. So with some of the changes around accountable care organizations, for example, and population care as opposed to these distinct episodes, I think that will help to build that infrastructure.

Senator SANDERS. But in terms of cost, if we do a major surgery, and it's not infrequent that people end up coming back into the hospital in a week because they don't take the right medications or get the right food, that's not cost-effective.

Dr. GANDHI. But in the current system, that hospital gets paid again for that re-admission.

Senator SANDERS. Right.

Dr. GANDHI. The hospital, in the old system, didn't necessarily have the incentive to ensure that everything went great once the patient left. That's the real challenge, that the incentives have been completely—or, say, in a primary care practice, if you had a pharmacist in a primary care practice who could actually talk to patients on 15 drugs and explain things to them, it would help a ton. But how do you actually pay for that person? And the incentives haven't been there.

Senator SANDERS. And that is a serious problem, is it not?

Dr. GANDHI. Yes, it is.

Senator SANDERS. Especially for elderly patients.

Dr. GANDHI. Elderly patients on multiple medications. That's why you have adherence issues. It's not always cost. It can be side effects. It can be not understanding why they need to take it. And a primary care doctor in a 15-minute visit is going to have a really hard time spending an hour with someone to really explain what—

Senator SANDERS. And we pay for that lack of information and knowledge later on.

Dr. GANDHI. Exactly.

Senator SANDERS. Dr. Jha, let me ask you, with your experience in the VA, which is a different type of system, what does it do better, what does it do worse?

Dr. JHA. The VA really took a leadership role in the late 1990s under the Clinton administration with Dr. Ken Kizer. They made patient safety a priority before the IOM report. They put together

a national center for patient safety. They have done, I think, leading work in this area in tracking down adverse events, really understanding what causes them. They have been phenomenal in a lot of this.

My concern is that over the last few years, there's been a little bit less focus on patient safety in the VA. There's been a distraction with a lot of other issues. The VA in some ways represents some of the same problems that we've heard about, hundreds and hundreds of metrics now, loss of focus on what really matters to veterans. And because of that, I think we have not seen the kinds of gains in the VA that we'd like to see, and that we can get back again, because the infrastructure and the commitment is there to making it a safe organization.

Senator SANDERS. Ms. McGiffert.

Ms. MCGIFFERT. Can I make a little comment about that? I do think the VA is a good example. For example, a number of years ago, they started screening incoming patients for MRSA, an antibiotic resistant bug that people might carry on their skin. So their MRSA infections have gone significantly down. And the VA put out a directive saying, "We're going to do this all over the country."

In the private sector, we cannot do that. We cannot—the only way to do it is through Medicare, and Medicare is the big dog here. They make things happen. I would say one of the most important things that can happen is that Medicare keep pushing on public reporting, keep pushing on these incentive payments so that—and I do think there probably are ways that they can standardize and coordinate them a little bit better.

But this needs to keep going, and I think you're going to hear from a lot of hospitals who say, "Whoa, whoa, stop this." But from the consumer perspective, we want to see accountability for these kinds of events, and payment incentives are one way to do it.

Senator SANDERS. Dr. Pronovost, getting back to the issue I think Senator Warren raised, if you know—maybe people in Detroit or a given city may know it, that some hospitals have rates of infection 10 times higher than another hospital. And I think what we've heard is you give them a warning, "Get your act together or else." Yes? What is the "or else?"

Dr. PRONOVOST. I think our regulators, whether it's through CMS or the Joint Commission, have well-established policies for how to do this. They have largely implemented those on single complaints. So if you get a complaint—a patient has a complaint, they come and investigate—a healthcare organization. They review—if your policies are out of line, they could withhold Medicare funding, for example. They have a great power of sanctions.

What they haven't applied those to are for rates of these infections. So they'll come in, oftentimes for individual events, but they haven't focused on this glaring—

Senator SANDERS. If you don't get your infection rate down, you're going to get a cut in the amount of money—

Dr. PRONOVOST. Correct. There'll be some—and, again, they have a policy for issuing sanctions. They haven't pulled that trigger for outcomes, and I think that—we need to make sure, Senator, that what they do it on, the measures are valid, which, again, outside of HAI, there's not many of them. But for these bloodstream infec-

tions, as all of your States have reduced them dramatically, the science is good, the signal is good, and we need accountability.

Senator SANDERS. Dr. Gandhi, and then we'll get to Senator Warren.

Dr. GANDHI. I just want to again reiterate that—because I've seen this happen—this one measure suddenly becomes the focus for the entire organization, and they fix it. Check. Done. Right? Instead of then—but really changing the culture of the organization and what the organization is working on is so critical, because that's one issue of many. So I think these incentives and accountability is critical, but we need to have that at a higher level than maybe a single measure.

Senator SANDERS. Senator Warren.

Senator WARREN. Thank you. I want to go back to a point that Dr. Gandhi raised earlier, and that is that the commitment to patient safety can't stop when someone leaves the hospital or the doctor's office. Many people come home with a prescription or, in some cases, with several prescriptions, and they have to manage them on their own. But unlike something as basic as aspirin, almost none of these prescriptions come with standardized regulated consumer friendly instructions.

This is a huge hole in our patient-safety system. It has real consequences. In 2010 alone, the Centers for Disease Control found that more than 15,000 people died from unintentional prescription drug overdoses. That's entirely preventable, in my view, and entirely unacceptable.

Dr. Gandhi, let me just start with you on this. Can we assume that at least some of these overdoses have been caused by people who don't understand how to properly take their medications?

Dr. GANDHI. I think that's a very valid assumption.

Senator WARREN. OK. Good. Then let's go to the second part. Would you conclude that in addition to the thousands of people who die from unintentional medical overdoses each year, there are probably many more people who are taking their medications improperly because they don't understand the instructions?

Dr. GANDHI. There's very good data to say that patients are often not taking medications as they were originally prescribed. Now, there can be a lot of reasons for that, one of which might be they don't understand, one of which might be it's really expensive and they decide, "Well, maybe if I take half a pill instead of one, I'll still be OK." I mean, there's lots of reasons for that.

But I think lack of understanding of how to take the medicine, what it's for, what the potential side effects are—all of those are significant issues in the ambulatory sector.

Senator WARREN. Does anybody else want to weigh in on this?

Ms. McGiffert.

Ms. MCGIFFERT. Well, Consumer Reports has spoken before Congress recently, within the last 6 months, I think, on the need to improve labeling and information to patients. It's a critical issue, and I think it's something that Congress can do something about.

Senator WARREN. Good.

Dr. James.

Mr. JAMES. I knew two parents who lost young adult children to overdose of medication. What happens is often these are opioids

and they're very addictive, and a lot of doctors don't understand the power of the addiction for these patients. So they get a prescription, or if they don't get what they want, they can go to another pain mill and get these. The system needs to be fixed so that that cannot happen so these young adults don't die.

Senator WARREN. Dr. Disch.

Ms. DISCH. This is another good example of an issue that really does require patients and family conversations about the drugs, not just prescribing and saying, "Here's what we're going to put you on." There may be information that the patient or family has that this isn't a good drug, or the patient has taken it before.

There is a story where a patient was ordered to change his diuretic and to weigh himself and come back in a couple of days if he gained more than 3 pounds—great education, but the patient was homeless and didn't have a scale. So the discussion about, is this going to work for you; what are the goals; and really personalizing even something that seems as straightforward as a medication prescription really requires talking with the person and not just prescribing for.

Senator WARREN. Dr. Jha.

Dr. JHA. We've seen this happening, I think, in lots of other areas where we now have—we've changed the way we're labeling food. I mean, you can put lots of data out there, but if it's confusing, it's worse than not having any information at all. So, obviously, we've seen progress in this.

There's been a lot of very good work to start pointing to what kind of information you need to show patients, and how you can present it in a way that people can understand. This is not rocket science. People have done the work on this, and this is a place where I would think the FDA—and, again, this is a little beyond my area of expertise of who does the regulating around this. But it seems to me that this is something that we have a clear role on to make the information much more consumer friendly so normal people can understand it.

Senator WARREN. Good.

Dr. Gandhi.

Dr. GANDHI. I want to reiterate what Dr. Disch said. I agree that a label alone will not solve this problem. It's a part of the problem, but it's really having those good conversations with patients about medications. But the other piece, too, is giving providers the tools to have those good conversations.

So these patient friendly tools—electronic medical records, for example—could really help to provide a nice calendar to a patient—here's what you take and why and what days and so on. So I think there's tools that we need to give to providers to help these conversations really go well.

Senator WARREN. Good. I very much appreciate the point on this. But I want to summarize it this way, by saying it's clear that there are dangers associated with improper medications. It's also clear that we have consumer friendly labels for over-the-counter drugs—Tylenol, cough syrup—and that we do not yet have those on prescription drugs.

What I'm hearing the panel say is that we won't solve everything by getting better labels. But if we had more consumer friendly la-

bels on prescription drugs—this is one of those things kind of like washing hands. It's at least a low-cost, simple, direct way to make an improvement in patient safety that could save lives and certainly save people who have suffered.

I just want to say on this one that the Food and Drug Administration has been working on getting consumer friendly labels for more than 30 years, and we still don't have them. So this is an area where I think we should continue to push and particularly continue to push the Food and Drug Administration. They have the authority to do this. We need to have patient friendly labels on prescription drugs.

Thank you, Mr. Chairman.

Senator SANDERS. Thank you, Senator Warren.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman. While Senator Warren is here, and Senator Murphy was here also, I want to thank both of them. We are working together, along with a few other Senators, on a piece of legislation to address the problem of hospital acquired infections. We are looking at trying to improve the meaningfulness—if that's a word—of the data collection and the distribution of that data, its transparency. We're looking at trying to reinforce the State-based hospital acquired infection reduction efforts, because so much of this has come out of local initiatives. We are looking at improving antibiotic stewardship.

We are also looking at trying to improve the data across hand-offs. That's the question that I want to ask all of you now. We have, I think, a fairly good sense, as Dr. Pronovost pointed out, of the four or five elements that combine together, to solve a lot of the hospital acquired infection problems. They fight uphill against incentives that often cost the hospital money, cost them money to implement the program, and they lose the revenues that they actually got for treating the hospital-acquired infection they caused. So it's kind of a double hit to them.

In that environment, where there is actual control, and you've got a CEO of the hospital and the hospital system, even then we see these problems. So when you're dealing with the handoff for a patient who, say, is going from a hospital setting to a nursing home, and very likely back to the hospital and back to the nursing home more than once, should we be optimistic about our ability to tackle that problem while we're still having so much trouble with the first problem? And what kind of reporting do you think would be most helpful?

Let me ask first Dr. Gandhi, because this is your expertise. What should we be doing about expanding this beyond an intra-corporate setting within one organization to try to reach to the handoffs between organizations?

Dr. GANDHI. First, I think there need to be standards about how these handoffs should happen, because, honestly, if you've seen one hospital do a handoff, you've seen one hospital do a handoff. So what are the key critical pieces of information that need to get communicated? What timeframe do they need to be communicated in?

There are still hospitals out there that say a discharge summary can be done within 30 days of discharge. Patients go in to see their

primary care doctor tomorrow, and we're saying it's OK that there can be 30 days for a hospital discharge to get done. So timeliness and content of those communications is really key. Electronic medical records can help with this, and there's work going on there.

But then there's also a really critical human component, and the term we've been using lately is warm handoff. So if a patient is sick enough to go from a hospital to a rehab—they're not going home. They're going to another facility—often, I would say, the norm is that nobody from the hospital is actually talking to someone in that receiving facility.

The patient gets on a stretcher with the chart and goes off with no communication verbally, and we've seen that when you do that verbal communication, some really important information gets conveyed. So standardizing that entire process, content, timeliness, and when you need that person-to-person dialog is really fundamental.

We're just starting on this. But I don't think we can wait to say, "Hospitals, fix yourselves," before we worry about this, because this care across the continuum can't just be put aside until a later point.

Senator WHITEHOUSE. And assuming, as you've said, that there are process measures that could be checklisted for that handoff, where do you think in the oversight universe the responsibility for overseeing that checklist should reside? Is that an AHRQ issue? Is that a CDC issue? Is that a CMS issue?

Dr. GANDHI. We could create measures. I don't know if it's Medicare or who it would be. But just as an example, I was at Partners Healthcare as a chief quality and safety officer. We created a measure. We said these 10 things need to be in a discharge summary, and if you get 9 out of 10, you get a 0. We could measure it, and we could improve it, because we could measure it.

I think your point that there needs to be a measure that can be tracked—I think Medicare could certainly be part of this. These are sometimes not easy to abstract from records, but we could figure out how to do it. So I think that somebody like Medicare would make sense.

Senator WHITEHOUSE. Dr. Jha and then Dr. Disch.

Dr. JHA. One important problem here is if you look at the HITECH Act, which you know well, Senator—and we are providing incentives for doctors and hospitals to put in electronic health records and by all means it's going pretty well.

Senator WHITEHOUSE. Don't get me started on this one.

Dr. JHA. I know this is a topic near and dear to your heart, Senator. But just for everybody else, let me—

Senator WHITEHOUSE. We left out nursing homes and behavioral health providers when we did that, so they're not part of the meaningful use program, which is really brilliant for people who are—

Senator SANDERS. See, he told you not to get started on that.

Dr. JHA. My apologies, Senator, for egging him on on this, because I know this is an issue near and dear to your heart. But it is exactly the problem we're talking about, because the sickest, the most complicated, the most expensive patients leave the hospital and go to nursing homes, go to rehab facilities. Those places do not have electronic health records. We've tracked their data, and

they're lagging way behind. So you can have a great electronic health record with an electronic summary, and you have to print it out and fax it, and that is no way to do business in 2014.

Senator WHITEHOUSE. Understood.

Dr. Disch.

Ms. DISCH. I think we have to do a little both/and thinking here, because it's actually seductive to think—and we've talked about a couple of specific issues, labeling, infections, handoff, and really do a deep dive on those. But we also have to step back and say if we are trying to change preventable death, maybe like the aviation industry did, we have to start thinking about things like high reliability organizations, where the whole organization is aligned. We have people who do not tolerate deception, or they're preoccupied in a good sense with failure. We've got leaders that really are committed.

We've got to do a both/and. We've got to work on some of these initial issues. But I worry that we will focus on let's fix this problem of the moment, let's fix that problem, and the aviation industry had to really restructure how they did business. So that has to still be on our radar screen.

Senator WHITEHOUSE. Thank you.

Dr. James.

Mr. JAMES. Very quickly, this goes back to what Dr. Jha said a little bit. There needs to be a national standard for medical records that everybody dances to. Right now, there's a number of different systems, and they don't communicate well. I've heard that from doctors. I'm not a doctor, obviously. But that needs to be fixed at the Federal level, in my opinion.

Senator WHITEHOUSE. Thank you, Chairman. This is far and away the most important hearing happening today in Washington, DC, because of the importance of this issue and your attention to it, and this incredible panel that you brought together has really been terrific.

Senator SANDERS. Thank you, Senator Whitehouse.

I want to concur with what Senator Whitehouse just said. We don't know the exact number, but we are talking probably about hundreds of thousands of people a year dying from preventable problems in hospitals and God knows how many outside of hospitals. What we do know is that this issue has not gotten the attention that it deserves, and I hope that today is the beginning of an effort to focus more light on it.

I want to thank all of you and echo again what Senator Whitehouse said. This has been a terrific hearing. I have learned a lot. I hope people who have viewed it on CSPAN have learned a lot. You've given us ideas, not only in terms of what the problems are, but where we have got to go and the role the Federal Government has to play in terms of the CDC, the FDA, Medicare, Medicaid. So we have a lot to work with.

I again want to thank you for all the work that you have done and for your powerful presentations today. Thank you very much, and this hearing is adjourned.

I did want to add that Senator Boxer wanted to put in some work on patient safety issues into the record, and with unanimous consent, we'll do that.

[The information referred to can be found in additional material.]
Senator SANDERS. Thank you all very much.
[Additional material follows.]

ADDITIONAL MATERIAL

MEDICAL ERRORS—A REPORT BY THE STAFF OF U.S. SENATOR BARBARA BOXER

I. EXECUTIVE SUMMARY

Medical errors are a quiet and largely unseen tragedy. Every year between 210,000 and 440,000 Americans die as a result of medical errors and other preventable harm at hospitals, according to researchers. These numbers are equivalent to a jumbo jet crashing every day with no survivors. Based on these figures, medical errors could be considered the third-leading cause of death in America, behind heart disease (more than 590,000 a year) and cancer (more than 570,000 a year).¹

After meeting with a family who lost a child to medical errors, Senator Boxer asked her staff last year to compile a list of the most common and devastating medical errors. What the staff found out was that there was not a single list—there were many lists.

So last spring, Senator Boxer wrote to Federal officials urging them to put together a single, unified list. In July 2013, the Partnership for Patients—a new public-private partnership funded through the Affordable Care Act—responded by releasing a list of the 9 most common medical errors²:

1. Adverse Drug Events;
2. Catheter-Associated Urinary Tract Infections;
3. Central Line-Associated Blood Stream Infections;
4. Injuries from Falls and Immobility;
5. Obstetrical Adverse Events;
6. Pressure Ulcers (Bedsore);
7. Surgical Site Infections;
8. Venous Thromboembolism (Blood Clots); and
9. Ventilator-Associated Pneumonia.

On February 4, 2014, Senator Boxer wrote to 283 California acute care hospitals asking them to respond with the actions they are taking to reduce these nine most common medical errors. She was pleased that nearly 53 percent of those surveyed—149 hospitals—responded to the inquiry, and she will continue to seek answers from those that failed to reply.³

Here are some of the major findings:

- All of the hospitals that responded reported taking at least some steps to address the most common medical errors.
- Many hospitals agree on common approaches to reducing these errors, which are outlined in this report.
- Some hospitals are stepping out and pursuing unique approaches to preventing these errors.
 - For example, Kaiser Permanente requires nurses to wear colored sashes or vests when dispensing medication to patients to prevent interruptions and distractions that could lead to errors.
 - UCLA Medical Center disinfects hospital rooms using ultraviolet technology, prohibits the use of home-laundered scrubs, and bans doctors and other staff with open wounds, bandages or casts from scrubbing into surgeries to help prevent infection.
 - And Desert Valley Hospital in Victorville reported that it reduced the number of surgical site infections from 16 in 2009 to 2 in 2013 after starting an innovative program that rewards medical staff who are observed practicing good hand hygiene by entering them into a drawing for a chance to win a prize.

Many more examples of how hospitals are responding to this epidemic are contained in this report. Senator Boxer believes that publicizing these best practices will save lives and encourage other hospitals to take these and other common-sense steps to reduce medical errors.

Senator Boxer thanks all the hospitals that participated, as well as the Patient Safety Movement Foundation and the family of Leah Alexander, who helped to bring this issue to her attention. She has pledged to continue to focus attention on this issue to help prevent these needless tragedies.

II. TAKING ACTION TO PREVENT MEDICAL ERRORS

Based on the hospitals' responses to Senator Boxer's letter, the Senator's staff identified some common themes in how hospitals are addressing medical errors, as well as some of the challenges they face:

Checklists

Several of the nine preventable medical errors have well-known interventions and “checklists” that many hospitals follow. Many hospitals indicated that they use these uniform checklists and “bundle” systems for Ventilator-Associated Pneumonia, Catheter-Associated Urinary Tract Infection, and Central Line Blood Stream Infection. However, hospitals did not cite the use of similar interventions in the cases of Falls, Adverse Drug Events and Obstetrical Adverse Events.

Identifying safe practices

Implementing safe practices under one set of preventable medical errors often has beneficial effects in reducing another type of medical error. For example, venous thrombosis prevention was cited as an intervention to reduce ventilator-associated pneumonia.

Changing the culture

General responses by the hospitals include a cultural change to focus on system-wide fixes rather than assigning blame, peer review committees to review cases of medical errors, weekly “harm reports,” daily safety huddles, and creating new bonds of collaboration both inside and outside of an organization.

Alarm fatigue

Many hospitals cited “Alarm Fatigue” as a top patient safety concern, when health care workers become desensitized to a large volume of equipment alarms.

Stopping infections

For infection control, use of chlorhexidine antiseptic on the skin was the most common intervention cited.

III. DETAILED FINDINGS FROM HOSPITAL RESPONSES

To better understand how California hospitals are addressing these challenges, we broke down their responses to each of the most common medical errors identified by the Partnership for Patients:

Adverse Drug Events

A preventable adverse drug event is a harm experienced by a patient as a result of exposure to a medication through medical error. Adverse drug events affect nearly 5 percent of hospitalized patients, making them one of the most common types of medical error.⁴

Common Approaches	Unique Approaches
Use barcode technologies and electronic health records with computerized prescriber order entry, which helps to eliminate errors due to illegible handwriting and works to promote standardization of medications and dosage.	Require all inpatient nurses to wear a colored sash or vest to prevent interruptions and distractions during medication administration. Independently verify high-risk medications and doses by at least two clinicians prior to administration.
Actively involve pharmacists throughout a patient's hospitalization, from reviewing the medications a patient is on at admission to reviewing a patient's electronic health record for prescribing errors.	Employ smart IV infusion pumps that use drug libraries to warn the clinicians when they have programmed the infusion pump outside safe parameters.

Example of Hospitals Using Unique Approaches

Sutter Health reports a 59 percent improvement overall in Adverse Drug Events with Harm since joining the Partnership for Patients in 2012. As part of that effort, Sutter Health has employed smart IV infusion pumps. According to Sutter Health, “In 2013, the smart pump technology led to 2,778 severe harms averted system-wide.”

Catheter-Associated Urinary Tract Infections

A urinary tract infection is “an infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney.”⁵ According to the Centers for Disease Control and Prevention (CDC), among urinary tract infections acquired in the hospital, approximately 75 percent are associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine. Between 15–25 percent of hospitalized patients receive urinary catheters during their hospital stay.

Common Approaches	Unique Approaches
Use sterile or "clean" technique during insertion and during catheter care.	Allow nurses to remove catheters using approved guidelines without a physician order to expedite the removal of unnecessary catheters.
Assess catheter necessity daily	Set a standing time to remove catheters post operatively (e.g., 2 days after surgery) unless a surgeon directs otherwise.
Maintain hand hygiene	

Example of Hospitals Using Unique Approaches

Hemet Valley Medical Center has reduced their catheter-associated urinary tract infection rate in the ICU from 2.28 per 1,000 catheter-days in 2011 to 1.72 per 1,000 catheter-days in 2013. They reported, "We have also drafted a standing order to allow nurses to remove foley catheters per approved guidelines in order to expedite the removal of foley catheters. This is in the process of being approved by our medical staff and the expectation is that this will further reduce our rate of infections."

Central Line-Associated Blood Stream Infections

A central line is a catheter placed into a large vein in the neck, chest, or groin. According to the CDC, "an estimated 41,000 central line-associated bloodstream infections occur in U.S. hospitals each year. These infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality."⁶

Common Approaches	Unique Approaches
Use disinfection caps or central line anti-microbial IV port covers.	Include a checklist in the patient's electronic health record.
Use maximal sterile barriers: Cap, mask, gown, gloves, drape.	Train staff how to insert a central line in a simulation center.
Maintain hand hygiene	Have an infection control specialist check a patient's line multiple times a week and/or watch during placement to ensure that the sterile technique is followed.
Use appropriate skin preparation agent and allow it to dry	
Use chlorhexidine baths and cloths	

Example of Hospitals Using Unique Approaches

Olympia Medical Center reports that it has achieved zero central line infections over the last 6 months. Olympia Medical Centers writes that part of its efforts include that an "Infection Control Practitioner checks each line three times a week, as well as watching during placement for sterile technique."

UC San Diego Health System formed a task force to address Central Line-Associated Blood Stream Infections. According to its response letter, UC San Diego Health System

"built a tool within the electronic medical record (EMR) for documenting Central Line Insertion Practice (CLIP) bundle performance at the time of central line insertions placed in inpatient care sites as well as the emergency departments. This tool prompts providers to comply with required bundle elements and facilitates accurate data abstraction."

Injuries from Falls and Immobility

Each year, between 700,000 and 1 million people in the United States fall in the hospital. A fall may result in fractures, lacerations, or internal bleeding, leading to increased hospital stays and healthcare costs. According to the AHRQ, research shows that close to one-third of falls can be prevented.⁷

Common Approaches	Unique Approaches
Educate patients and their families	Use bed, chair, and portable alarms for high-risk patients.

Common Approaches	Unique Approaches
Assign risk to patients based on a scoring system	Use "fall bands" on the arms of patients or colored socks to identify that these patients are high risk. Place high-risk patients in rooms closer to nursing stations. Establish an early mobility plan in the ICU to help mobilize patients earlier and prevent muscle weakness. Incorporate fall prevention education in new employee orientation.

Example of Hospitals Using Unique Approaches

Riverside County Regional Medical Center has taken numerous steps to reduce the number of injuries from falls. According to the Riverside County Regional Medical Center,

"Some of these were the assigning of a 'fall score' to patients, placing patients closer to the nursing stations and utilizing a 'sitter' if necessary. Also colored arm bands are used to identify those patients that are a high fall risk. There is also the 'Early Mobility' plan in the ICU to mobilize patients earlier to prevent muscle weakness and assist in the prevention of ventilator associated pneumonia."

Obstetrical Adverse Events

One of the most common obstetrical adverse events involves early elective delivery. According to the Leapfrog Group,

"A recent review of the evidence has shown that these elective deliveries can have serious negative consequences for the mother and baby."⁸

Ways that obstetrical medical errors can harm the mother include a higher risk of having a cesarean section as well as a higher risk of postpartum complications, such as anemia and endometriosis. Babies born at 37–38 weeks are at much higher risk of death. They are also at a far higher risk for harms like respiratory problems and admission to the neonatal intensive care unit (NICU).

Common Approaches	Unique Approaches
Establish a "hard-stop" policy (e.g., 39 weeks) to allow low-risk pregnant patients to go into spontaneous labor in order to reduce the rate of early elective deliveries.	Initiate drills and training using simulation equipment and specialty-trained teams. Conduct emergency drills for situations like postpartum hemorrhage. Debrief after emergency situations with multidisciplinary team. Reduce cesarean delivery among first-time moms.

Example of Hospitals Using Unique Approaches

Kaiser Permanente implemented a Perinatal Patient Safety Program in 2003. Kaiser writes that this program includes "implementation of the National Institute of Child Health and Human Development (NICHD) fetal monitoring nomenclature and standardized simulation-based education to address high-risk adverse events (e.g., shoulder dystocia, instrument-assisted deliveries, postpartum hemorrhage, etc.)."

Pressure Ulcers

A pressure ulcer, or bed sore, is an injury usually caused by unrelieved pressure that damages the skin and underlying tissue.⁹ They can range from mild (minor skin reddening) to severe (deep craters down to muscle and bone). According to the AHRQ, "The estimated cost to treat a pressure ulcer is between \$500 and \$40,000. Yet, pressure ulcers can be managed and prevented."¹⁰

Common Approaches	Unique Approaches
Assess all patients for pressure ulcers prior to and upon admission.	Use of low air loss surfaces (e.g., using air mattresses on emergency stretchers for high-risk patients).

Common Approaches	Unique Approaches
Nursing staff should discuss pressure ulcers during shift reports.	Use of turn logs and turn clocks as a reminder to reposition the patient. Employ a wound care team.

Example of Hospitals Using Unique Approaches

Cedars-Sinai reports a 74 percent reduction in pressure ulcers, to less than a dozen annually. Cedars-Sinai notes,

“The nursing department lead the effort to achieve this reduction in pressure ulcers by executing the following list of actions: (1) improved clinician education, (2) standardized pressure ulcer assessment, staging, and reporting, (3) implemented triggers for additional interventions such as nutrition consults, (4) and improved the procurement and distribution of appropriate support surfaces and skin care products throughout the facility.”

Surgical Site Infections

According to the CDC, a recent study found that surgical site infections were the most common healthcare-associated infection, accounting for 31 percent of all of these infections among hospitalized patients. In addition, one study found 16,147 surgical site infections following 849,659 operative procedures.¹¹

Common Approaches	Unique Approaches
Use chlorhexidine baths or showers in lieu of regular tub baths.	Prohibit staff with open wounds, bandages, or casts from scrubbing in to surgical cases.
Maintain normal blood sugar post-operatively	Conduct black light inspections on a random sample of operating rooms after cleaning.
Eliminate unnecessary foot traffic during the surgical period that ranges from anesthesia administration through recovery.	Minimize blood transfusions.
Use proper hair removal techniques and ensure minimal skin trauma related to hair removal.	Use rotating staff and “secret shoppers” for hand hygiene observations (i.e. the more times staff are observed washing their hands, the more likely they are to win a prize).

Example of Hospitals Using Unique Approaches

UCLA Health System has seen an 18 percent improvement in surgical site infections from 2010 to 2013. Part of the UCLA effort to reduce medical errors includes an enhanced operating room attire policy which prohibits the use of home-laundered scrubs. Additionally,

“MDs and staff with open wounds, bandages or casts on their hands may not scrub in to surgical cases as their hands are not able to be adequately decontaminated.”

Desert Valley Hospital reports that it reduced the number of surgical site infections from 16 in 2009 down to 2 in 2013. Desert Valley Hospital attributes part of this success to an effort that “created the CSI (control the spread of infection) Program house-wide.” The CSI program runs the “secret shopper” and staff prize model for rewarding hand hygiene.

Venous Thromboembolism

Venous thromboembolism is a condition that includes both deep vein thrombosis and pulmonary embolism. Deep vein thrombosis is the formation of a blood clot in a deep vein, usually in the leg or pelvis. The most serious potential complication of a deep vein thrombosis is the possibility that the clot could dislodge and travel to the lungs, becoming a pulmonary embolism.¹² According to AHRQ, venous thromboembolism is the most common preventable cause of hospital death.¹³

Common Approaches	Unique Approaches
Employ wound care specialists	Have pharmacy department follow all patients with venous thromboembolism.

Common Approaches	Unique Approaches
Assess patients for risk pre-operatively	Reduce unnecessary central venous catheter days and minimize the size of these catheters. Have the electronic health record prompt the clinician to order deep-vein thrombosis prevention (mechanical intervention or pharmaceutical intervention) or to document the reasons why it was not ordered.

Example of Hospitals Using Unique Approaches

UC San Diego Health System reports that central venous catheters (CVCs) are frequently associated with deep vein thrombosis of the upper limbs. So the hospital system reports that it is

“striving to reduce unnecessary central venous catheter (CVC) days, minimize the size of CVCs, and ensure proper CVC insertion technique.”

Ventilator-Associated Pneumonia

According to the CDC,

“Ventilator-associated pneumonia is a lung infection that develops in a person who is on a ventilator. A ventilator is a machine that is used to help a patient breathe by giving oxygen through a tube placed in a patient’s mouth or nose, or through a hole in the front of the neck. An infection may occur if germs enter through the tube and get into the patient’s lungs.”¹⁴

The CDC also notes that in 2002, 250,000 healthcare-associated pneumonias developed in hospitals and were connected to 36,000 deaths.¹⁵

Common Approaches	Unique Approaches
Elevate the patient’s head 30–45 degrees	Use percussion vest in the ICU to help wean patients off of the ventilator more quickly. Make effort to keep patients extubated if they have removed their own tube for any reason. Avoid gastric over-distention, when too much air is allowed into the stomach.
Institute a daily “sedation vacation”	
Assess the patient’s readiness to extubate daily	
Maintain oral hygiene regularly	
Prevent deep vein thrombosis	

Example of Hospitals Using Unique Approaches

University of California, Davis Medical Center reports that it has achieved a 76 percent reduction in Ventilator-Associated Pneumonia from 2009–13. According to the UC Davis Medical Center response letter, this effort includes “Quality and Safety Champions” who “attend multidisciplinary rounds, monitor bundle compliance at the bedside for healthcare practitioners at all levels and provide ‘just-in-time’ coaching.”

IV. CONGRESSIONAL AND ADMINISTRATIVE ACTIONS TO REDUCE MEDICAL ERRORS

The 2010 health reform law, the Affordable Care Act, is saving lives and reducing medical errors. The law led to the creation of the Partnership for Patients, which is dedicating \$1 billion to prevent hospital-acquired conditions. The Affordable Care Act has also created three new pay-for-performance programs, which will reward hospitals that deliver high-quality care and penalize those that fail to reduce medical errors.

Outlined below are recent congressional actions aimed at reducing medical errors, including those enacted by the health reform law.

- Since 2003, as a condition of participation in the Medicare program, Federal regulations require that hospitals maintain a Quality Assessment and Performance Improvement (QAPI) program to “track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.”¹⁶ A January 2012 report by the Department of Health and Human Services’ Office of the Inspector General found in a survey that staff did not report 86 percent of events to incident reporting systems, partly because of misperceptions about what constitutes patient harm.¹⁷ In 2011, CMS launched the Hospital Patient Safety initiative, in which they are piloting new surveyor tools for assessing compliance with Federal regulations.¹⁸

- The Hospital Inpatient Quality Reporting was originally added to Federal law by the Medicare Prescription Drug, Improvement and Modernization Act and was later amended by the Deficit Reduction Act of 2005.¹⁹ Under this program, CMS pays hospitals that successfully report designated quality measures a higher annual update, and failure to report the measures results in a payment reduction. Once the data is received from hospitals, CMS publicly reports the data on its “Hospital Compare” Web site.
- The Deficit Reduction Act of 2005 required CMS to select at least two hospital-acquired conditions for which hospitals would not be paid higher Medicare reimbursement.²⁰ Since 2008, CMS has maintained a list of hospital-acquired conditions that includes catheter-associated urinary tract infections, falls and trauma, late-stage pressure ulcers, surgical site infections, and deep vein thromboembolism.²¹ Under the Patient Protection and Affordable Care Act of 2009, starting in 2011, CMS has applied this payment policy to the Medicaid program to encourage hospitals to actively prevent these conditions.
- The Patient Safety and Quality Improvement Act of 2005 established Patient Safety Organizations under supervision of the AHRQ. Patient Safety Organizations receive reports of patient safety events from health care providers and provide analyses of these events.²² They also operate under Federal privacy protections to encourage providers to report medical errors and to work with health systems to resolve systemic issues.
- The Patient Safety and Quality Improvement Act of 2005 also authorized AHRQ to promulgate “Common Formats” so that hospitals can report adverse events in a uniform, unambiguous manner.²³ The goal of Common Formats is to allow for the “apples to apples” comparison of medical errors across multiple hospital systems.
- The Patient Protection and Affordable Care Act created the CMS Innovation Center for the purpose of testing “innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care” for those individuals who receive Medicare, Medicaid, or Children’s Health Insurance Program (CHIP) benefits.²⁴ The CMS Innovation Center, now known as the Center for Medicare & Medicaid Innovation, provided \$1 billion in funding for the Partnership for Patients, a public-private partnership to improve the quality of health care. The Partnership has published a list of the nine most common and harmful medical errors. The goals of the Partnership are to reduce medical errors by 40 percent and re-admissions by 20 percent.
- The Patient Protection and Affordable Care Act also authorized three pay-for-performance programs that will adjust Medicare payments to hospitals based on the quality of care delivered. The Hospital Readmission Reduction Program began in October 2012 and penalizes hospitals with higher-than-expected re-admissions for beneficiaries initially admitted for selected conditions. The Value Based Purchasing Program²⁵ began in October 2012 and provides penalties as well as incentive payments based on hospitals’ performance on quality measures, including reducing surgical site infections. The Hospital-Acquired Condition Reduction Program²⁶ will reduce payments to hospitals that are in the top quartile for hospital-acquired conditions starting on October 1, 2014. CMS has adopted AHRQ safety indicators encompassing pressure ulcer rate and deep vein thrombosis rate, among others, as well as measures from the CDC, such as central line-associated blood stream infection and catheter-associated urinary tract infections.²⁷

V. RECOMMENDATIONS

1. All Federal programs designed to reduce medical errors should work off a single list where appropriate, specifically the Partnership for Prevention’s list of the nine most common medical errors.
2. The Department of Health and Human Services should report to Congress the time it takes for quality measures to be developed, endorsed, and ultimately implemented in programs related to medical error reduction. A strategy for how to accelerate this process should also be included.
3. In the next round of regulations for electronic health records, the Office of the National Coordinator should include a standard way of reporting medical errors, specifically the Common Formats developed by AHRQ. This will allow hospitals and researchers to better collect data on errors, their frequency, and where they are occurring.
4. When assessing whether hospitals are meeting the requirement to track and report adverse events as a condition of participation in the Medicare program, surveyors and accreditors should evaluate the information collected by hospitals using AHRQ’s Common Formats.

5. Congress should review the adequacy of whistleblower protections to ensure that health care providers are able to report medical errors without retribution.

6. The Department of Health and Human Services' Office of the Inspector General should examine the Hospital Patient Safety Initiative's new surveyor tools and analyze their impact on increasing staff reporting of medical errors.

VI. CONCLUSION

Preventing medical errors will not only save lives, it will also improve the quality of health care for all Americans.

And it is not just a moral imperative to act—it is an economic necessity. One study estimated that the direct costs of medical errors totaled \$19.5 billion annually.²⁸ Another study found that all of the costs of medical errors, including lost productivity, could amount to \$1 trillion annually.²⁹ By stopping these errors before they occur, we can save taxpayers, businesses and our health care system billions of dollars each year.

In the Jewish tradition, there is a saying: “Whoever saves a life—it is as if that person has saved the whole world.” Today, we have the opportunity to save a life over and over again. We have the chance to save hundreds of thousands of lives and prevent heartbreak and pain for so many families.

If we work together, we can prevent these needless tragedies. If we ensure that doctors, nurses, hospital administrators, medical technology leaders, Federal officials and patient advocates are all focused on this common goal, we can make great progress in preventing these avoidable deaths and ending the epidemic of medical errors in this country.

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RESPONSE TO QUESTIONS OF SENATOR WARREN BY PETER PRONOVOST, M.D., PH.D.

Collecting accurate and timely data is essential for initiatives that seek to improve patient safety and the quality of patient care. Work to curb hospital-acquired infections relies heavily on meaningful, real-time data—because a hospital can’t address a problem if they don’t know it’s there.

The Food and Drug Administration (FDA) is also working to collect better data in order to improve patient safety. The FDA’s Sentinel Initiative currently uses information from insurance claims to proactively identify adverse events and to evaluate the safety of prescription drugs after they are on the market. Starting later this year, the FDA will begin to require that medical devices carry a Unique Device Identifier, or UDI. This special number on devices will help hospitals and providers identify and track individual devices as they are used in patients and holds great promise for improving patient safety.

Question 1. What steps can we take to ensure that new UDI data can be used efficiently and immediately to improve patient safety?

Answer 1. The UDI system will facilitate recall resolution, improve the accuracy of adverse event reports, enhance care coordination among multiple physicians caring for the same patient and enable more sophisticated postmarket surveillance. To achieve these benefits, though, UDI must be included in electronic health information—particularly patients’ electronic health records (EHRs) and claims; imposing minimal burden and realizing significant value.

Currently, patients’ health records lack a standardized way to list the devices implanted in patients. Creating a field in EHRs for UDI will provide hospitals, doctors and patients with accurate information on the devices implanted in patients. If needed, providers could use this information to contact patients with recalled products and deliver appropriate followup care. Similarly, these data will help clinicians know which devices are implanted in their patients, especially for patients that see multiple providers. UDI data from EHRs will also provide patients and physicians with more precise data to submit more accurate adverse event reports, which currently often lack critical data on the make, model and lot number of potentially malfunctioning devices. Last, hospitals can utilize data from EHRs to conduct their own analyses on product performance.

Similarly, claims data lack information on the precise devices used in care. For example, a claim may indicate that a patient received a hip replacement, but the claim lacks information on the specific device implanted. Including a field for UDI in claims will provide payers with data on the products implanted in their beneficiaries. When a recall occurs, the health plan—which often has up-to-date contact information—can ensure that the patient is notified and receives appropriate followup care. Additionally, health plans could conduct their own analyses on device performance, as they currently do with drugs.

Last, the Food and Drug Administration’s (FDA’s) Sentinel program could also be utilized to evaluate device safety, as directed by Congress in 2012. Sentinel relies predominantly on claims, which as previously stated, lack information on devices used. Should claims include UDI data, Sentinel would have the necessary information to analyze device information as is currently done with drugs and biologics.

Claims have limitations and should not be the sole method of conducting post-marketing surveillance. However, unlike other sources of data, claims contain standardized, longitudinal data on large numbers of patients that may see multiple providers. Analyses of claims are an important tool that—in concert with adverse event reports, EHR data, registries and other tools—can protect patients from unsafe or ineffective products.

Question 2. Can UDI information be incorporated into the Sentinel system to evaluate the safety of medical devices after they are on the market?

Answer 2. The FDA's Sentinel system has been successfully used to identify problems with drugs and biologics. For example, FDA added warnings to a blood pressure medicine (olmesartan medoxomil) for intestinal problems (sprue-like enteropathy) based on Sentinel findings. Sentinel cannot, though, currently efficiently evaluate the safety of medical devices.

This is because Sentinel's primary data source is claims. While claims usually include data on many of the drugs patients receive, claims lack information about medical devices patients receive. For Sentinel to efficiently evaluate device performance, as directed by Congress, claims must include a field for the UDI of implanted devices used in care and providers must use that field to send information to health plans. With that data, Sentinel would have the necessary information on devices to conduct analyses, to learn, and to improve.

[Whereupon, at 11:37 a.m., the hearing was adjourned.]

