

# U.S. EFFORTS TO REDUCE HEALTHCARE- ASSOCIATED INFECTIONS

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## HEARING OF THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE ONE HUNDRED THIRTEENTH CONGRESS FIRST SESSION ON EXAMINING UNITED STATES EFFORTS TO REDUCE HEALTHCARE- ASSOCIATED INFECTIONS

SEPTEMBER 24, 2013

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## **U.S. EFFORTS TO REDUCE HEALTHCARE- ASSOCIATED INFECTIONS**

**TUESDAY, SEPTEMBER 24, 2013**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The committee met, pursuant to notice, at 10:05 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Tom Harkin, chairman of the committee, presiding.

Present: Senators Harkin, Alexander, Casey, Whitehouse, Baldwin, Murphy, Burr, and Isakson.

### **OPENING STATEMENT OF SENATOR HARKIN**

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions will please come to order. At the outset, I just want to remind everyone that we have a vote scheduled at 11:45, so we're going to try to get through this, if we can, as soon as possible, because I doubt that we can get back after the lunch hour.

In the late 1970s, a group of researchers began to examine reports of patient deaths and injuries caused by anesthesia. They found wide variation in quality and a disturbing incidence of medical errors, leading to 6,000 deaths or serious injuries annually. ABC network's 20/20 news program covered the study, and the modern patient safety movement was born.

We are meeting today because more than 30 years later, safety and quality in healthcare facilities remains a pressing concern. Specifically, we're here to discuss a problem that has bedeviled healthcare for decades—infections acquired while a patient is being treated.

Every year, about 1.7 million people in the United States get these healthcare-acquired infections. They impose tremendous costs in dollars but, most tragically, in human suffering. The CDC estimates that these infections cause 270 deaths every day, and a recent study shows that the five most common hospital-acquired infections cost the system \$10 billion each year.

If you include all infections acquired in all settings, the cost is between \$30 billion and \$45 billion annually. That's money that could be spent on improving quality, reducing the cost of care, or any number of other investments.

Just as dangerous as an infection picked up in the hospital is the failure to properly detect and treat an infection. One of our witnesses, Ciaran Staunton, will tell a tragic story about his son that illustrates how the failure to detect can be a fatal problem. I'll let Mr. Staunton tell his story, but let me just say that his son died of an infection that was detectable and survivable.

An Iowan wrote me last week with a similar story. Last year, Vanessa's father, Wes Shubert, from Clear Lake, got a cut on his right wrist. Here's what she wrote me:

"His doctor failed to prescribe any antibiotics. Needless to say, it was downhill from that point. They did an emergency surgery to remove the infection from his knee, and then sent him home, even though I pled with the medical staff to please observe Dad overnight because something was not right."

Less than 24 hours later, Vanessa's father was back in the emergency room, and, tragically, he died shortly afterward of sepsis.

This is one of the thorniest healthcare quality challenges of our time. Federal and State governments are making significant investments in quality improvement, investments that both Dr. Bell and Dr. Conway will talk about in detail. For the first time, public officials, providers, payers, and other stakeholders have the tools to reward high-quality, not high-volume, care. And, perhaps most importantly, we're stopping payment for bad care that was included in the Affordable Care Act.

Our witnesses will discuss these initiatives in depth, but let me just touch on one of them. The Partnership for Patients, started in spring 2011, is a public-private partnership with over 3,700 participating hospitals. The work is starting to pay off, as Dr. Conway will describe, and I read his testimony. The hospital readmission rate is declining over the last 2 years, translating to thousands of seniors staying home and healthy.

In the private sector, conscientious providers, researchers, and academics have made great strides in improving quality of care. Our second panel will discuss some of these innovative approaches.

In Connecticut, the Public Health Department was recognized last year with a Future of Public Health Award for its work in reducing healthcare-associated infections in nursing homes. And in another State, Rhode Island Hospital has reduced the incidence of a particularly deadly infection by 70 percent. Officials said that hospital-wide participation and cooperation was essential to this success.

We need bold action, with everyone pulling in the same direction. A study in the journal *Health Affairs* found that, on average, a third of patients admitted to a hospital suffer a medical error or other adverse event, 10 times greater than what was previously thought. The most important lesson of today's hearing is that these mistakes and tragedies are avoidable. With hard work, innovation, transparency, communication, and investment, we can win this fight.

I will turn to Senator Alexander for his opening statement.

#### OPENING STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER. Thanks, Mr. Chairman. I thank you for putting the spotlight on this disturbing and vitally important part of our American healthcare system.

I've noticed—and I suppose anyone who's gone to the eye doctor or gone to the hospital or taken a family member to the hospital—that over the last several years, it seems like, suddenly, on the walls have appeared all these little sanitizing items, and the

nurses and the doctors and other healthcare workers are washing their hands every 5 minutes. It seems that way, and I don't remember that happening at that rate 5, 10, 15, or 20 years ago.

There's a growing awareness of the number of times that Americans go to hospitals to get well, but in the process become sick as the result of an infection. According to the Centers for Disease Control and Prevention, that happens to about 1 out of 20 people who are hospitalized, which is a very high number. And that's not what one expects when you go to a hospital. You expect some help in getting well, not some help in getting ill.

We're going to hear more about sepsis today. We welcome the families who have suffered tragedies as a part of that. But the other disturbing element of this is the fact that in a number of cases, the infections are caused by bacteria for which there is not a cure or not an easy cure, and that number is increasing. We'll hear more about that today as well.

One out of 20 patients, according to CDC, goes to the hospital, gets an infection, and in a growing number of cases, the infection is not the kind of an infection that can be cured. This takes a real human toll. Senator Harkin has talked about the financial toll as well.

It happens even at the Clinical Center of the National Institutes of Health, where they suffered an outbreak of an antibiotic-resistant bacteria last year. Through quick work, they did the detective work that the Chairman talked about, but not before seven patients died.

I'm proud that Tennessee's own Hospital Corporation of America has collaborated with several partners, including CDC, and published a study on effective prevention practices. I look forward to hearing from their chief medical officer in the second panel.

Prevention and elimination of healthcare-associated infections is crucially important. We have taken some steps with the Generating Antibiotic Incentives Now Act to try to make it easier for new products to be introduced into the developmental pipeline to deal with these bacteria that are resistant to cure. But we have a ways to go.

I look forward to the hearing. This is one of those issues that Congress is involved in that is relevant to every single American family, because any of us might one day find ourselves or a loved one in the hospital, and we don't like the statistic that 1 out of 20 might get an infection while there, and some of those infections are resistant to medicine that would cure them.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Alexander. And not to put too fine a point on it, but I think this is one of the most important hearings this committee has had or will have in this entire year. I say that because the more I've looked at it and the more I've been briefed on this, the more it is clear that with changes in approaches and structuring—some of the things I mentioned—this is not intractable.

This can be solved. But it's going to take some concerted effort, as I said, and some innovations that come from people who are here that are witnesses today and others. But this is something that we can do. And I'm sure I speak for my friend, Senator Alex-

ander—we mean to get to the bottom of this and figure out what we can do to set up the systems to really attack this issue.

We have two panels. Our first panel will be Dr. Patrick Conway. We welcome him back. He has a lot of responsibility these days as Acting Director of the Center for Medicare and Medicaid Innovation and also as the Chief Medical Officer for CMS. At the Innovation Center, Dr. Conway oversees development and implementation of innovative programs that aim to increase healthcare quality, decrease cost, and improve community health.

As the Chief Medical Officer, he is responsible for quality measures in Federal health programs, quality improvement, clinical standards, certification of all providers, and coverage decisions for treatments and services. Previously, he was director of Hospital Medicine and an associate professor at Cincinnati Children's Hospital.

We welcome you back.

We also welcome back Dr. Beth Bell, the Director of the National Center for Emerging and Zoonotic Infectious Diseases at the Centers for Disease Control and Prevention. Dr. Bell is responsible for CDC's efforts in responding to a broad range of emerging and established threats, including healthcare-associated infections. Previously, Dr. Bell served in multiple leadership roles at CDC, including the agency's response to the 2001 anthrax attacks and the 2009 H1N1 influenza pandemics.

We thank you for being here with us today, Dr. Bell.

Both of your statements will be made a part of the record in their entirety. I'll ask you, if you could, to just take 5 to 7 minutes and summarize those so we can get to questions.

Dr. Conway, please proceed.

**STATEMENT OF PATRICK CONWAY, M.D., MSc, CHIEF MEDICAL OFFICER AND DIRECTOR, CENTER FOR CLINICAL STANDARDS AND QUALITY, AND ACTING DIRECTOR, CENTER FOR MEDICARE AND MEDICAID INNOVATION, BALTIMORE, MD**

Dr. CONWAY. Chairman Harkin, Ranking Member Alexander, and members of the committee, thank you for the opportunity to discuss our work at the Centers for Medicare and Medicaid Services to improve the quality of care and patient safety in our health system.

Healthcare-acquired infections, or HAIs, are a serious national concern. About 1 of every 20 patients gets an infection while hospitalized. HAIs are one of the most common types of complications for patients who are hospitalized and, as was noted, result in billions of dollars of excess healthcare costs.

I distinctly remember in training as an intern an infant who died in our neonatal ICU from a central line bloodstream infection. The family was devastated. My attending, consistent with what was known at the time, said these infections just happen and are not preventable. Fortunately, we now know that most HAIs are preventable, and we are making significant national progress in preventing them.

I currently practice as a physician attending, taking care of hospitalized patients and their families on weekends, and our goal is to prevent all infections. The good news is that we are making



progress nationally. Over the last 4 years, central line bloodstream infections have declined 44 percent, and surgical site infections have declined 20 percent nationally.

From 2007 to 2011, the average monthly 30-day all-cause readmission rate was typically 19 percent or above. Toward the end of 2012, the rate declined to approximately 18 percent. It's now consistently below 18 percent nationally in 2013 and continues to decline. This decrease represents nearly 100,000 Medicare beneficiaries staying home and healthy instead of returning to the hospital.

The Hospital Engagement Networks and the Partnership for Patients, a public-private collaboration, are delivering promising early results. These networks are making improvements across 10 areas of focus. These include central line infections, readmissions, and early elective deliveries, among others. All 26 networks had at least a 30 percent improvement in at least six or more areas of harm reduction—dramatic results.

For example, more than 1,000 birthing hospitals in the partnership have generated a 44 percent reduction in early elective deliveries, helping to prevent costly neonatal ICU stays and the poor health outcomes of preterm birth. Some of the networks have reduced central line associated infections to close to zero.

We are making progress in preventing HAIs through three main mechanisms: financial incentives to improve quality; performance measures; and public reporting to improve transparency and the spreading and scaling of effective interventions, especially through coordination with our partners, including CDC.

First, CMS is transforming from a passive payer to an active purchaser of higher value healthcare services. Since 2008, Medicare payment policy refused to pay for care related to certain identified healthcare-acquired conditions, or HACs, that are not present on admission. This year, we finalized measures for the Healthcare-Acquired Condition Program, including measures of HAIs, which will negatively adjust payments for hospitals in the bottom quartile of performance.

Additionally, in 2014, Hospital Value-Based Purchasing will redistribute an estimated \$1.1 billion to hospitals based on their performance, including measures of infection and care coordination. The Affordable Care Act also established the Hospital Readmissions Reduction Program, which reduced Medicare payments to hospitals that have excess readmissions, beginning in 2012.

Our second major focus to improve care is coordinated aligned performance measurements that help providers and consumers better understand the quality of care and make more informed decisions. Consumer-focused Web sites, including Hospital Compare, are using quality measures to improve healthcare transparency, and transparency drives improvement.

Finally, we are working to ensure that the healthcare delivery system continues to improve and transform through the testing and spreading of effective interventions. For example, Quality Improvement Organizations work cooperatively with physicians, hospitals, and others to disseminate research evidence, share best practices, and provide technical assistance to decrease infections and coordinate care. This helps make a very real difference.

For example, a Florida QIO alerted us that a hospital in their area had central line infection rates at two to three times the national rate and high rates of mortality. We immediately intervened with a corrective action plan and leveraged the expertise from CDC and AHRQ. There have been no central line infections since we put in place this new system of quality controls. We also help spread learning from high performing systems to hospitals across the Nation.

By aligning payment incentives and checking our progress through quality measures, we, in collaboration with our partners in HHS and the private sector, have made significant improvements in reducing HAIs and improving care and patient safety. We partner with nonprofit organizations, such as the Patient Safety Movement Foundation, who you will hear from; hospitals; physician groups; consumers; States; and so many others to decrease HAIs and improve patient safety.

In my last role, leading delivery system improvement at Cincinnati Children's, our goal was to eliminate patient harm across our system. In my current role at CMS, our goal is to reduce and eventually eliminate patient harm and keep patients safe across our Nation.

We want all health systems focused on safety first. We recognize more work is needed to innovate and find the solutions to ensure that no patient suffers from an infection or condition that could have been prevented. Our work has saved thousands of lives, but we must stay focused on keeping all patients safe.

Your interest today contributes to that progress, and I'll be happy to hear your concerns or answer your questions about this important lifesaving subject. Thank you for your time.

[The prepared statement of Dr. Conway follows:]

PREPARED STATEMENT OF PATRICK CONWAY, M.D., MSC

Chairman Harkin, Ranking Member Alexander, and members of the committee, thank you for the opportunity to discuss our work at the Centers for Medicare & Medicaid Services (CMS) to improve the quality of care and patient safety at our Nation's hospitals. Through Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and, in 2014, the private health insurance Marketplaces, CMS helps provide health care coverage to over 100 million Americans. We are committed to ensuring that all our beneficiaries receive the highest possible quality of care, and we continually strive to achieve better health outcomes at a lower cost.

Improving patient safety at our Nation's hospitals is an important goal for the U.S. Department of Health and Human Services (HHS) and CMS. According to the Centers for Disease Control and Prevention (CDC), about 1 of every 20 patients gets an infection while hospitalized.<sup>1</sup> Healthcare-associated infections (HAIs) are likely the most common type of complication for patients who are hospitalized.<sup>2</sup> HAIs result in billions of dollars of excess healthcare costs.

HHS is committed to improving patient safety by reducing HAIs across the health care system, with hospitals as a prime arena for priority attention, as outlined in the HHS National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination.<sup>3</sup> One of the Agency Priority Goals is to reduce, by September 30, 2013, the national rate of HAIs by demonstrating significant, measurable reductions in hospital-acquired central line-associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI). Despite the significant burden of HAIs in the United States and the growing threat of antibiotic resistant pathogens, most HAIs are preventable; and the coordinated efforts of CDC, CMS, the Agency for Healthcare Research and Quality (AHRQ), and other HHS agencies

<sup>1</sup><http://www.cdc.gov/hai/burden.html>.

<sup>2</sup><http://www.psnet.ahrq.gov/primer.aspx?primerID=7>.

<sup>3</sup><http://www.hhs.gov/ash/initiatives/hai/actionplan/>.

have resulted in significant reductions in some HAIs. Notably, CDC data indicate that over the last 4 years CLABSI have declined 44 percent and surgical-site infections (SSI) have declined 20 percent. Last week, CDC also published new data showing dramatic declines in invasive (life-threatening) Methicillin-resistant *Staphylococcus aureus* (MRSA) infections. This study estimated that over 30,000 fewer invasive MRSA infections occurred in all settings in 2011 compared with 2005, and over 9,000 fewer deaths occurred among individuals hospitalized with MRSA. The study also showed a 54 percent decline in serious MRSA infections occurring among patients during hospitalization between 2005 and 2011.

There has also been success in the long-term national declines in CLABSI. In a recently released paper, CDC authors estimated that between 1990 and 2010, between 104,000 and 198,000 CLABSI were prevented among critical care patients in the United States. In an analysis currently undergoing peer review, CDC estimated the net economic benefits of preventing CLABSI in Medicare and Medicaid patients in critical care from 1990 to 2008 ranged from \$756 million to \$1.9 billion with the corresponding net benefits per case averted ranging from \$16,550 to \$24,060.

Additionally, CMS has made progress in preventing unnecessary readmissions. From 2007 to 2011, the average monthly 30-day all-cause readmission rate was typically 19 percent or above. Toward the end of 2012, the rate had declined to approximately 18 percent and is now below 18 percent nationally in 2013. If you compare the last 12 months to the baseline in 2010 through 2011, the decrease represents nearly 100,000 Medicare beneficiaries staying home instead of returning to the hospital. This decrease is an early sign that our focus on improving quality and care coordination is beginning to have an impact.

CMS is focused on improving patient safety and care in hospitals through payment incentives, transparency in quality measurement and public reporting, and the testing, scaling, and spreading of effective interventions through quality improvement collaboratives and clinician training. The Affordable Care Act and other laws are now enabling CMS to support better health and promote quality improvement and greater value while creating an environment that fosters innovation. Our objective is to ensure quality health care for generations to come—not just for Medicare and Medicaid beneficiaries, but for all people who depend on our Nation's health care system.

#### FINANCIAL INCENTIVES TO IMPROVE QUALITY

In the past, hospitals had little financial incentive to improve the quality of their care because Medicare and other purchasers paid hospitals for treating infections or errors even when they could have been prevented. Now, Medicare, State Medicaid programs, and many private sector health plans and purchasers, are moving rapidly to change payment systems to reward better outcomes instead of volume of services. In Medicare, the combined effect of the Hospital-acquired Conditions (HAC) Program, Hospital Value-Based Purchasing, Hospital Inpatient Quality Reporting Program, and the Hospital Readmissions Reduction Program already are creating strong incentives for hospitals to preempt infections and errors. CMS is working to transform from a passive payer to an active purchaser of higher-value health care services using the following tools.

##### *Hospital Acquired Conditions and Healthcare-Acquired Infections*

Since 2008, Medicare payment policy has further encouraged hospitals to identify ways to prevent certain HACs or conditions that are not present on admission. For these designated conditions, while Medicare pays hospitals the standard rates for the original admission, we no longer pay hospitals for the additional costs associated with the care and treatment of these HACs. In 2012, CMS added additional HACs to the list of conditions that would warrant CMS eliminating additional payments.<sup>4</sup> CMS clinical quality experts have worked closely with public health and infectious disease experts from CDC to identify and select additional preventable HACs, including HAIs to add to this list.

CMS has issued similar guidelines for Medicaid to incentivize provider-level quality improvement and cost-savings for States by requiring States to reduce Medicaid payments for hospital errors. Medicaid also funded the Transformation Grants, which aim to improve Medicaid's effectiveness and efficiency. For example, the

<sup>4</sup>A complete list of HAC categories and their corresponding complication or comorbidity (CC) or major complication or comorbidity (MCC) codes finalized for fiscal year 2013 can be found at: <http://www.cms.gov/Medicare/Medicare-fee-for-service-Payment/HospitalAcqCond/Downloads/HACFactsheet.pdf>.

Transformation Grants funded efforts to reduce central-line infections for premature infants in neonatal intensive care units.

In addition, section 3008 of the Affordable Care Act established the HAC Reduction Program to further reduce HACs and improve patient quality. CMS will begin implementing this program starting in fiscal year 2015 with the performance period starting this year. Under the HAC Reduction Program, hospitals in the lowest performing quartile with respect to the overall rate of certain HACs will see their payments reduced by 1 percent, providing an incentive for those hospitals to reduce the burden of HACs in their facilities.

#### *Hospital Value-Based Purchasing Program*

CMS has implemented programs to strengthen payment incentives to improve the quality of hospital care furnished to traditional fee-for-service Medicare beneficiaries. As required by the Affordable Care Act, beginning with October 2012 discharges, CMS began adjusting Medicare payments to most hospitals for inpatient acute care services based on how well they performed on a series of quality measures. This program, called the Hospital Value-Based Purchasing Program, is a carefully crafted program that was developed in a manner that incorporated significant stakeholder feedback.

The quality measures used in the program are consistent with evidence-based clinical practices for the provision of high-quality care. Hospitals are scored on improvement as well as achievement on a variety of quality measures. The higher a hospital's total performance score during a performance period, the higher the hospital's value-based incentive payment will be for a subsequent fiscal year. For fiscal year 2014, the Hospital Value-Based Purchasing Program will redistribute an estimated \$1.1 billion to hospitals based on their quality performance. We recently added the CLABSI measure beginning with the fiscal year 2015 program, and we finalized the addition of the CAUTI and SSI measures to the program for the fiscal year 2016 program. In the future, CMS expects to add new measures to the program that focus on patient health outcomes, cost reduction, and HAIs that significantly impact Medicare beneficiaries and reflect substantial quality of care variation among hospitals.

#### *Hospital Inpatient Quality Reporting Program*

The Hospital Inpatient Quality Reporting Program gives hospitals a financial incentive to report the quality of their inpatient services by tying the reporting of designated quality measure data to their ability to be paid the full amount of the annual update to the Medicare inpatient payment rate. CMS has adopted a number of HAI measures for the program, and some of this data is collected on CMS' behalf by the CDC through that agency's National Healthcare Safety Network (NHSN). The CDC has developed the HAI measures that are used in the Hospital IQR Program, and provides hospitals with additional analytic tools that enable them to assess their rates of performance and identify where additional efforts are needed. The HAI measures that hospitals currently report to the NHSN as part of the Hospital IQR Program are CLABSI, CAUTI, SSI, *Clostridium difficile*, and MRSA data.

#### *Hospital Readmissions Reduction Program*

The Affordable Care Act also established the Hospital Readmissions Reduction Program, which reduces Medicare payments to hospitals that have excess readmissions beginning in October 2012. Currently, we measure the readmissions rates for three very common and expensive conditions for Medicare beneficiaries—heart attack, heart failure, and pneumonia. We recently finalized expanding the readmissions program with measures for two more common conditions—chronic obstructive pulmonary disease and knee and hip replacements. These measures will be added to the program in fiscal year 2015.

The readmissions program—together with other Affordable Care Act payment and delivery reforms—is already having a positive impact. As discussed above, we are observing a significant decrease in the rate of patients returning to the hospital after being discharged. This decrease is an early sign that our payment and delivery reforms are having an impact.

### QUALITY MEASUREMENT AND PUBLIC REPORTING

In order to achieve meaningful quality improvements, performance on care delivery and outcomes should be measured using reliable, nationally endorsed measures. These measures must provide information that is timely, actionable, and meaningful to both providers and patients. CMS is aligning the existing reporting requirements for the financial incentive programs described above, and encouraging the adoption of broad scale electronic reporting of quality data. These quality measures are gen-

erally endorsed by the National Quality Forum, meet clinical validity and reliability requirements, and align with the National Quality Strategy. We are increasing our focus on patient-centered outcome measures that matter most for improving health. Our vision for the future of quality reporting is to implement a unified set of electronic quality measures and e-reporting requirements to synchronize and align CMS quality programs, reduce provider burden, and maximize efficiency and improvement.

#### *Electronic Health Records Incentive Programs and Meaningful Use*

The American Recovery and Reinvestment Act of 2009 provided support to physicians and other providers who adopt electronic health records by establishing the Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs. EHRs can make it easier for physicians, hospitals, and others serving Medicare and Medicaid beneficiaries to evaluate patients' medical status, eliminate redundant and costly procedures, and provide high-quality care. Through diagnostic and therapeutic decision support, clinical alerts and reminders, medication reconciliation, and built-in safeguards, EHRs can help providers make safe, effective decisions and provide high-quality care for their patients.

Participation in the Medicare and Medicaid EHR Incentive Programs has been robust. Approximately 80 percent of all eligible hospitals and critical access hospitals in the United States have received an incentive payment in the Medicare and Medicaid EHR Incentive Programs for adopting, implementing, upgrading, or meaningfully using certified EHR technology. As of July 2013, over 315,000 hospitals, doctors and other healthcare professionals have become meaningful users.<sup>5</sup> Additionally, more than 50 percent of eligible professionals have adopted EHRs and received incentive payments from Medicare and Medicaid. Forty-nine States and four territories have launched their Medicaid EHR Incentive Programs. Those States have paid almost \$2.25 billion in incentive payments to over 99,000 Medicaid-eligible professionals.

#### *Coordinating Quality Reporting Programs*

Though the quality-reporting and performance-based payment programs described above originate through separate statutory authorities, CMS strives to streamline reporting mechanisms across programs in order to reduce the burden on providers. For example, quality measures in the Inpatient Quality Reporting Program supply data underlying payment adjustments in the Readmissions Reduction Program as well as the Value-Based Purchasing Program. Similarly, CMS has coordinated with agencies throughout HHS to consolidate similar quality measures and to support adoption of high-priority measures based on stakeholder input and input from the National Quality Forum's Measures Application Partnership. In fiscal year 2014, we are also aligning the submission of hospital clinical quality measures under the Medicare EHR Incentive program with the hospital Inpatient Quality Reporting (IQR) program. Hospitals will now have the option of submitting 16 of the IQR measures electronically, which would satisfy the CQM component of the Medicare EHR Incentive program as well as the reporting requirement for these measures under the IQR program.

#### *Transparency for Consumers Through Hospital Compare and HealthCare.gov*

Clear, understandable information that is easy to access helps consumers make informed decisions about their health care, and gives them an important role in reducing and preventing HAIs. CMS created the Hospital Compare Web site<sup>6</sup> to better inform health care consumers about a hospital's quality of care. This tool, which includes CDC's NHSN HAI measure results and data, shows a hospital's performance on a wide variety of quality measures, including certain measures of healthcare infections. In the coming years, additional measures will be added to the Hospital Compare Web site, making this an even richer source of information for consumers.

Based on priorities identified in the National Quality Strategy, and authority in the Affordable Care Act, CMS is interested in promoting effective quality measurement through the Marketplace. To that end, HHS's strategy for establishing quality-reporting requirements to ensure that high quality health care is delivered through the Marketplace includes the consideration of existing relevant quality measure sets and quality improvement initiatives in conjunction with other factors, such as char-

<sup>5</sup>Summary of the EHR Incentive Program. July 2013. [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/July2013\\_PaymentandRegistrationSummaryOverview.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/July2013_PaymentandRegistrationSummaryOverview.pdf).

<sup>6</sup>For more information on the Hospital Compare Web site please visit: <http://www.medicare.gov/hospitalcompare>.

acteristics of the Marketplace population. HHS is engaging States, employers, consumer advocates, health insurance issuers, and other stakeholders as we continue to develop these quality-related requirements, and we issued a Request for Information on November 27, 2012. CMS intends to propose a phased approach to quality reporting and display standards for all Marketplaces. CMS intends that no new quality reporting standards for qualified health plans and Marketplaces will be in place until 2016 (other than those related to accreditation, if applicable), which allows time to develop standards appropriately matched to the Marketplace enrollee population and plan offerings. Until final regulations are issued, state-based Marketplaces would have the choice of adopting a similar approach or implementing their own quality reporting standards immediately and over time. This information will eventually be available for consumer-use on the HealthCare.gov Web site.

CMS recently released new datasets to promote transparency. This includes a dataset on hospital charges, including information comparing the charges for services that may be provided during the 100 most common Medicare inpatient stays.<sup>7</sup> Moreover, CMS also recently released selected hospital outpatient data, including estimates for average charges, for 30 types of hospital outpatient procedures.<sup>8</sup> It also released county-level data on Medicare spending and utilization in an easy-to-use dashboard format.<sup>9</sup> This data enables comparisons between the amounts charged by individual hospitals within local markets, and nationwide, for services that may be provided during similar inpatient stays. CMS has also made approximately \$87 million available to help States to establish and enhance effective Rate Review programs as well as to enhance or establish data centers that increase health pricing transparency. The data centers' work helps consumers better understand the comparative price of procedures in a given region or for a specific health insurer or service setting. Businesses and consumers alike can use these data to drive decisionmaking and reward cost-effective provision of care.

Consumer-focused Web sites, including Hospital Compare and Healthcare.Gov, are using quality measures to improve healthcare transparency. These sites allow consumers to view and compare information about the insurance plans and hospitals in their area, and pick the one that is best for them and their families. Through publicly reported quality measures, consumers and payers are better able to compare costs, review treatment outcomes, assess patient satisfaction, and hold providers accountable. This is done while ensuring the protection of personal health information and adjusting for factors beyond providers' control. Reporting also provides important resources and motivation for clinicians and other providers to improve performance.

#### SCALING AND SPREADING EFFECTIVE INTERVENTIONS FOR QUALITY IMPROVEMENT

As mentioned earlier, significant progress has been made to reduce HAIs. With this success, CMS has expanded its focus to ensure that quality continues to improve and the healthcare delivery system continues to transform through the testing and spreading of effective interventions.

##### *Quality Improvement Organizations*

Public and private efforts to support providers' desire to deliver higher quality care are critically important. These include programs sponsored by provider organizations and clinical specialty groups and quality improvement organizations (QIOs) that work cooperatively with physicians, hospitals, nursing homes, home health agencies, and others to disseminate research evidence to the point of care, share best practices and provide technical assistance.

Through large-scale learning networks, QIOs accelerate the pace of change and rapidly spread best practices. Improvement initiatives encourage innovation, respond to community needs, and lead the way to patient-centered care by including an active role for Medicare beneficiaries.

Some of the QIOs' current initiatives include contributing to the goal of achieving significant reductions in HACs, including HAIs; working with nursing homes to reduce pressure ulcers; reducing CLABSI; reducing re-hospitalizations by engaging

<sup>7</sup>For additional information on the Medicare Provider Charge Data, please see: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html>.

<sup>8</sup>For additional information on the Outpatient Medicare Provider Charge Data, please see: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Outpatient.html>.

<sup>9</sup>For additional information on the Geographic Variation Dashboard, please see: [http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV\\_Dashboard.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_Dashboard.html).

communities to improve the quality of care for beneficiaries as they transition between settings; and boosting population health by improving use of electronic health records for care management.<sup>10</sup> Additionally, CMS and CDC collaborate using HAI data to target prevention with the QIO networks.

#### *Survey & Certification*

The survey and certification program of CMS is designed to ensure that providers and institutional suppliers comply with the applicable health and safety standards. Many types of facilities that participate in Medicare or Medicaid are subject to unannounced, onsite inspections by State or Federal surveyors to be certified under those programs. Currently, the CMS Survey & Certification Group oversees compliance with health and safety standards developed in coordination with the CDC for more than 271,000 health care facilities of different types, including hospitals, laboratories, nursing homes, home health agencies, hospices, and end-stage renal disease facilities. For example, CMS is collaborating with CDC to expand survey and oversight capacity of non-acute healthcare settings and develop a new tool that State inspectors are using to ensure the quality of care in ambulatory surgical centers.

#### *Partnership for Patients*

The nationwide Partnership for Patients initiative aims to avert millions of preventable HACs and reduce hospital readmissions over 3 years, while providing savings to Medicare and Medicaid by reducing complications and readmissions during the transition from one care setting to another. Over 3,700 hospitals, as well as physicians and nurses' organizations, consumer groups, employers, and other major stakeholders, have pledged to help achieve the Partnership's goals.

Twenty-six Hospital Engagement Networks (HENs), which work at the national, regional, State, or hospital system levels, are identifying best practices and solutions in reducing HACs and readmissions and disseminating information to health care providers and institutions, nationwide. The HENs are focused specifically on 10 high-priority areas.<sup>11</sup> Associations and hospital systems like the American Hospital Association, Ascension Health, and the Michigan Hospital Association are serving as hospital engagement networks.

Work by hospital engagement networks that are funded by CMS's Center for Medicare and Medicaid Innovation (Innovation Center) is buttressed by collaboration and alignment of other Federal and private partners. Hundreds of private partners team with HENs and Federal programs to spread best practices. As one example, the American Congress of Obstetricians and Gynecologists works in partnership with CMS, HRSA, and others to support their members in taking actions to reduce early elective deliveries performed without medical indications, which are known to cause harm to babies.

Initial emerging results are encouraging. For example, more than 1,000 birthing hospitals in the Partnership have already generated a 48 percent reduction in early elective deliveries. Improvements are being seen across nearly all other hospital-acquired conditions targeted by the Partnership. The Partnership for Patients is achieving early promising results, demonstrating the potential to accomplish national patient safety goals through collaborative improvement.

#### *CMS's Innovation Center*

The Affordable Care Act provided CMS with valuable tools to test methods to improve the health care delivery system by creating the Innovation Center. The Innovation Center is focused on testing new payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished. The Innovation Center enables CMS to quickly and efficiently develop innovative payment and service delivery models along with a broad range of stakeholders. Some of the models being tested by the Innovation Center include efforts to reduce unnecessary hospital admissions among residents of nursing homes; improve care coordination for beneficiaries in Accountable Care Organizations; and incentivize primary care providers to offer high-quality, coordinated care. While the work of the Innovation Center tests many payment and service delivery models, these initiatives are only a part of our efforts to build a health care delivery system that will better serve all Americans.

<sup>10</sup>Details about each of these projects is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/Current.html>.

<sup>11</sup>The Partnership for Patients 10 safety areas of focus are: adverse drug events, CAUTI, CLABSI, injuries from falls and immobility, obstetrical adverse events including early elective deliveries, pressure ulcers, SSI, venous thromboembolism, ventilator-associated pneumonia, and hospital readmissions.

The Community-Based Care Transition Program supports 101 community-based organizations working in partnership with 432 acute-care hospitals to help high-risk Medicare beneficiaries residing in 40 States make successful transitions from hospital to home or to another post-hospital setting. Hospitals are a logical focal point for efforts to reduce readmissions, since the quality of care during a hospitalization and the discharge planning process can have an impact on whether a patient will continue to heal or return. However, it is clear that there are multiple factors along the care continuum that affect readmissions. The program links acute-care hospitals with home- and community-based service providers through formal partnerships. These partnerships between traditional medical providers and local social service providers are believed to be critical in reducing avoidable hospital readmissions among high-risk Medicare beneficiaries.

The Innovation Center is also testing new ways to efficiently deliver care and lower costs through its Health Care Innovation Awards. Round One of these 3-year awards focused on engaging a broad set of innovation partners to test new care delivery and payment models; identify new models of workforce development and deployment; and support innovators who can rapidly deploy care improvement models through new ventures or expansion of existing efforts to new patient populations. Collectively, these awardees are testing models designed to address a broad range of health care challenges. These range from a sepsis early recognition and response initiative to a multi-provider collaboration to create community-wide health intervention teams that help people get fast and appropriate care, reduce unnecessary hospitalizations, and lower costs. Each model will be evaluated on its ability to improve the quality of care and lower the cost for the target population it is designed to serve.

The first round of Health Care Innovation Awards, ranging from approximately \$1 million to \$26 million, were announced in May and June 2012 to 107 total participants. For example, the Methodist Hospital, in partnership with the Texas Gulf Coast Sepsis Network, is receiving an award to identify and treat sepsis before it progresses. Sepsis is the sixth most common reason for hospitalization and typically requires double the average length of stay. It complicates 4 out of 100 general surgery cases, has a 30-day mortality rate of 1 in 20, and leads to complications such as renal failure and cognitive decline. Through improved training, evidence-based and systematic screening for sepsis, and more timely treatment, Methodist Hospital and its partners aim to prevent progression of the disease, resulting in reduced organ failure rates, reduced mortality, reduced length of stay, improved patient outcomes, and lower costs.

#### *Coordination With Stakeholders*

Collaboration among multiple stakeholders in the healthcare community is necessary to spread and sustain reductions in HAIs on a broad scale. Collaboration leverages the combined programmatic efforts of stakeholders both across HHS and with external partners such as the Departments of Defense and Veterans Affairs, State governments, academic institutions, and provider and patient groups. For example, CMS, CDC, AHRQ, and State health departments continue to collaborate on HAI data-validation strategies to optimize the accuracy of data reported. Another example is AHRQ's Comprehensive Unit-Based Safety Program for CLABSI project, which, over the period 2008 through 2012, reduced the rate of CLABSI by 41 percent in over 1,000 Intensive Care Units across the country.

Additionally, various agencies across HHS collaborate to find system integration solutions in order to obtain reliable national estimates of HAIs for a more accurate view of the overall issue. To ensure that all Departmental HAI prevention assets are fully leveraged and coordinated, the Office of the Assistant Secretary for Health oversees a Senior-Level Steering Committee for Prevention of HAIs. With senior-level participation from across HHS, in 2009, this committee released a National Action Plan for the Prevention of Healthcare Associated Infections. This plan outlined opportunities and strategies to decrease HAIs in acute-care hospitals. In June 2013, HHS released a revised and updated version of the National Action Plan that expanded HHS' coordinated efforts in HAI reduction to non-acute care settings including ambulatory surgical centers, long-term care facilities, and end-stage renal disease facilities.

HHS is strengthening and building new partnerships to amplify prevention messages, promote the implementation of recommended practices in hospitals, ambulatory surgical centers, end-stage renal disease facilities, and long-term care facilities, and monitor progress at the national, regional, and local levels. Through continued emphasis on coordinating programs and strengthening our network of resources, CMS and its partners are able to provide technical assistance, testing, and financial



support for the development and implementation of strategies to prevent HAIs, particularly those focused at the level where patient care occurs.

#### LOOKING FORWARD

By aligning payment incentives and checking our progress through quality measures, we, in collaboration with our partners in HHS and the private sector, have made significant improvements in reducing HAIs and improving care and patient safety in hospitals. Through the work of the QIOs, Partnership for Patients, and the Innovation Center, we are beginning to test and develop new strategies that could lead to broader, national improvement. We recognize, however, more work is needed to innovate and find the solutions and technology to ensure that no patient suffers from an infection or condition that could have been prevented. Your interest today contributes to that progress, and I would be happy to hear your concerns or answer your questions about this important, lifesaving subject. Thank you for the opportunity to testify.

The CHAIRMAN. Thank you, Dr. Conway.  
Dr. Bell, welcome again and please proceed.

#### **STATEMENT OF BETH BELL, M.D., MPH, DIRECTOR, NATIONAL CENTER FOR EMERGING AND ZOO NOTIC INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA**

Dr. BELL. Chairman Harkin, Ranking Member Alexander, members of the committee, thank you for the opportunity to speak about CDC's activities to prevent healthcare-associated infections, HAIs. CDC works 24/7 to save lives and protect people from harm. Preventing HAIs is a very high priority for CDC.

Before I begin, I want to extend my sympathies to the millions of patients and families affected by HAIs each year. They are people like Peggy Lillis, the 56-year-old mother of two, a New York kindergarten teacher, who lost her battle with *Clostridium difficile*, a deadly diarrheal infection. No patient should be harmed by healthcare, and our ultimate goal is the elimination of HAIs.

HAIs are infections that patients acquire while receiving care. They are associated with increased mortality, with greater costs, and can occur in any healthcare setting. As previously noted, CDC data indicate that approximately 1 in 20 hospitalized patients develop HAIs, and over 1 million infections occur each year across healthcare settings.

In hospitals alone, HAIs result in billions of dollars of excess healthcare costs and contribute to the deaths of thousands of patients every year. In the worst cases, HAIs can lead to sepsis, a dangerous condition that can result in organ failure and death. Primary prevention of HAIs stops a root cause of sepsis.

Antibiotic resistance is one of our most serious health threats and one of CDC's most significant concerns related to HAIs. We estimate that one in five HAIs are antibiotic resistant. Patients with these resistant infections are more likely to die, and survivors have longer hospital stays.

Last week, we released a landmark report that presented a first ever U.S. snapshot of the burden and threats posed by antibiotic-resistant pathogens. Two of the three pathogens urgently prioritized in the report are primarily healthcare related—carbapenem-resistant *Enterobacteriaceae*, (CRE), and *C. difficile*.

Despite the significant burden of HAIs and the growing threat of antibiotic-resistant pathogens, most HAIs are preventable, and the

Nation has made significant progress in reducing the incidence of some HAIs. CDC has taken a lead role in addressing this important public health challenge. Data released by us this week indicate that over the last 4 years, central line associated bloodstream infections were reduced by 44 percent and surgical site infections by 20 percent.

We have also documented national declines in central line infections over the longer term. In a recently released paper, CDC authors estimated that between 1990 and 2010, between 104,000 and 198,000 central line infections were prevented among critical care patients in the United States. CDC experts have estimated that the prevention of these infections has saved Medicare and Medicaid hundreds of millions of dollars, and that for every \$1 spent on CDC HAI activities, Medicare and Medicaid saved, on average, \$10.

Last week, CDC also published new data on dramatic declines in MRSA infections. This study estimated that over 30,000 fewer invasive MRSA infections occurred in hospital and non-hospital settings in 2011 compared with 2005, and over 9,000 fewer deaths occurred among individuals hospitalized with MRSA.

CDC's portfolio of activities is critical to improving the national capacity to detect HAIs and protect patients and communities. CDC's world class experts target HAIs and the drug-resistant pathogens that can cause them by tracking HAIs and progress toward prevention goals, by responding to emerging threats through outbreak investigations, by developing guidelines for HAI prevention and filling gaps in knowledge, and by implementing prevention strategies with Federal and State partners.

While some progress has been made, CDC is working with CMS to ensure that the prevention gains we have seen thus far are sustained and carried over to other infection types and settings. We must address drug-resistant HAIs and *C. difficile* and improve antibiotic use in all healthcare settings.

We are launching a new component of the National Healthcare Safety Network, the Nation's largest HAI monitoring system, that will electronically measure and help facilities improve antibiotic use. For all of these infection types, CDC and CMS are looking to prevent not only infections within a facility, but also infections that move across facilities and cause unnecessary and costly readmissions.

In closing, CDC is focused on building on national progress and pursuing the elimination of HAIs wherever they are affecting patients. We know how to protect patients from most HAIs. These infections can and must be prevented.

Thank you.

[The prepared statement of Dr. Bell follows:]

PREPARED STATEMENT OF BETH BELL, M.D., M.P.H.

Chairman Harkin, Ranking Member Alexander, members of the committee, thank you for the opportunity to speak to you today about CDC's activities to prevent healthcare-associated infections (HAIs). CDC works 24-7 to save lives and protect people from harm. CDC has prioritized the prevention of healthcare-associated infections as one of the agency's Winnable Battles—public health priorities with large-scale impact on health and with known, effective strategies to address them.

Before I begin, I want to extend my sympathies to the millions of patients affected by healthcare-associated infections. No patient should be harmed by healthcare. We must always remember the patients who become debilitated and die from these in-

fections, as well as their families. CDC's ultimate goal is the elimination of healthcare-associated infections.

The Nation has made significant progress in reducing the incidence of some HAIs, as reported by CDC this week. Notably, CDC data indicate that over the last 4 years, central-line associated bloodstream infections were reduced by 44 percent and surgical-site infections by 20 percent.<sup>1</sup> Last week, CDC also published new data on dramatic declines in invasive (life-threatening) MRSA infections. This study estimated that over 30,000 fewer invasive MRSA infections occurred in hospital and non-hospital settings in 2011 compared with 2005, and over 9,000 fewer deaths occurred among individuals hospitalized with MRSA.<sup>2</sup> The study also showed a 54 percent decline in serious MRSA infections occurring among hospitalized patients between 2005 and 2011.<sup>3</sup>

CDC has also estimated long-term national declines in CLABSI. In a recently released paper, CDC authors estimated that between 1990 and 2010, between 104,000 and 198,000 CLABSI were prevented among critical care patients in the United States.<sup>4</sup> These findings suggest that technical innovations and dissemination of evidence-based CLABSI prevention practices recommended by CDC have been effective on a national scale.

CDC's portfolio of activities is critical to improving the capacity of healthcare facilities and States to detect HAIs and protect patients and communities. We know we must continue and expand on these efforts and are pleased to have the opportunity to discuss them with you today.

#### HEALTHCARE-ASSOCIATED INFECTIONS AND RELATED ANTIBIOTIC RESISTANCE

Healthcare-associated infections are infections that patients acquire while receiving care. They include a variety of infections ranging from those related to specialized intensive care procedures like mechanical ventilation, to infections caused by lapses in basic safe practices, like re-using disposable syringes or inappropriate cleaning of equipment. The most common types of healthcare-associated infections are central-line associated blood stream infections (CLABSI), catheter-associated urinary tract infections (CAUTIs), surgical-site infections (SSIs), gastrointestinal illnesses like *Clostridium difficile* (*C. difficile*), and pneumonias. HAIs are associated with increased mortality and greater cost of care, and can occur in any healthcare setting—hospitals, long-term acute care, dialysis clinics, ambulatory surgical centers, nursing homes/skilled nursing facilities, and even doctors' offices. In the worst cases, HAIs can lead to sepsis, a dangerous body-wide inflammation that can result in organ failure and death. Primary prevention of HAIs stops a root-cause of sepsis.

CDC data indicate that approximately 1 in 20 hospitalized patients develop HAIs and over 1 million infections occur each year across healthcare settings. In hospitals alone, HAIs result in billions of dollars of excess healthcare costs and contribute to the deaths of thousands of patients every year.<sup>5</sup> HAIs are caused by a wide range of pathogens. Infections from pathogens resistant to standard antibiotic treatment are now too common, and some pathogens have even become resistant to all types or classes of antibiotics. CDC estimates that 1 in 5 HAIs show some form of drug resistance making treatment more difficult for the patients and frequently more expensive.<sup>6</sup> Patients with these resistant infections are more likely to die, and survivors have significantly longer hospital stays, delayed recuperation, and more long-term disability. The loss of effective antibiotics can make even common infections dangerous and undermines our ability to fight infections and manage the infectious complications common in vulnerable patients with chronic conditions.

Antibiotic resistance is one of our most serious health threats and one of CDC's most significant concerns related to healthcare-associated infections. Resistance is not just a problem for the infected patient. When infections are not cured because they are resistant to the drugs we use, those infections persist and spread to others. Last week, CDC released a landmark report that presented a first-ever U.S. snapshot of the burden and threats posed by the antibiotic-resistant pathogens having

<sup>1</sup> CDC will be presenting these current numbers at the upcoming HHS Action Plan meeting on September 26, 2013.

<sup>2</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>3</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>4</sup> CLABSI Vital Signs MMWR: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm?s\\_cid=mm6008a4\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm?s_cid=mm6008a4_w).

<sup>5</sup> The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention: [http://www.cdc.gov/HAI/pdfs/hai/Scott\\_CostPaper.pdf](http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf).

<sup>6</sup> National Burden of Invasive Methicillin-Resistant *Staphylococcus aureus* Infections, United States, 2011.

the most impact on human health; these include healthcare-associated infections.<sup>7</sup> Two of the three infections prioritized as urgent in the report are primarily healthcare related—carbapenem-resistant *Enterobacteriaceae* (CRE) and *C. difficile*. CDC's report describes critical steps needed to address antibiotic resistance, including: improving antibiotic prescribing, preventing transmission of infections through infection control and environmental cleaning, and monitoring the spread of resistant pathogens. The following are just a few of the most urgent and serious HAI pathogens, affected by antibiotic resistance and inappropriate antibiotic use:

- ***C. difficile*** is a life-threatening diarrheal infection associated with antibiotic use that causes or extends nearly 250,000 hospitalizations and at least 14,000 deaths every year in the United States and over \$1 billion in excess medical costs annually.<sup>8,9</sup> *C. difficile* infections can be prevented. Early results from hospital prevention projects show 20 percent fewer *C. difficile* infections in less than 2 years when recommended infection-prevention and control measures are followed and more than 50 percent fewer infections when rigorous antibiotic stewardship programs are implemented.<sup>10</sup>

- **CRE** are hard-to-treat bacteria that are on the rise among patients in medical facilities, with over 9,000 estimated cases nationwide.<sup>11</sup> CRE have become resistant to all or nearly all the antibiotics we have today. Almost half of hospital patients who get bloodstream infections from CRE bacteria die from the infection.<sup>12</sup> By following CDC guidelines in the CRE toolkit,<sup>13</sup> we can halt CRE infections before they become widespread in hospitals and other medical facilities.

- **Extended-spectrum penicillin and cephalosporin-resistant Enterobacteriaceae** cause nearly 26,000 (or 19 percent) of healthcare-associated Enterobacteriaceae infections.<sup>14</sup> Patients with bloodstream infections caused by an ESBL-containing Enterobacteriaceae are about 57 percent more likely to die than those with bloodstream infections caused by a nonESBL-containing strain.<sup>15</sup> ESBL bacteria are the predecessors to CRE and can also be prevented by following the CDC guidelines in the CRE toolkit.

- ***Pseudomonas aeruginosa*** causes an estimated 51,000 healthcare-associated infections in the United States each year. More than 6,000 (or 13 percent) of these are multidrug-resistant, meaning that several classes of antibiotics no longer cure these infections.<sup>16</sup> Infection-control and appropriate use of contact precautions are important for the prevention of *Pseudomonas aeruginosa*.

- **Vancomycin-resistant Enterococci (VRE)** are resistant to vancomycin, an antibiotic of last resort, leaving few or no treatment options among very sick patients in hospitals and other healthcare settings. Approximately 20,000 (or 30 percent) of the healthcare-associated infections caused by *Enterococcus* each year are vancomycin-resistant.<sup>17</sup> Appropriate use of contact precautions and effective environmental cleaning reduces the transmission of VRE.

- **Methicillin-resistant *Staphylococcus aureus* (MRSA)** remains one of the most common causes of healthcare-associated infections despite significant progress in its prevention across healthcare settings.<sup>18</sup> Recent studies have shown that the use of a pathogen-killing soap and nasal ointment can potentially further prevent the spread of MRSA.

- ***Acinetobacter*** is a type of gram-negative bacteria that is a cause of pneumonia or bloodstream infections among critically ill patients. About 63 percent of *Acinetobacter* is considered multidrug-resistant, meaning at least three different

<sup>7</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>8</sup> CDI Vital Signs: <http://www.cdc.gov/VitalSigns/pdf/2012-03-vitalsigns.pdf>.

<sup>9</sup> CDC will be releasing new estimates on the burden of *Clostridium difficile* in the coming months.

<sup>10</sup> <http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/11797452823> and J Antimicrob Chemother 2012; 67 Suppl 1: i51–i63.

<sup>11</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>12</sup> CRE Vital Signs: <http://www.cdc.gov/VitalSigns/pdf/2013-03-vitalsigns.pdf>.

<sup>13</sup> CRE Toolkit: <http://www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html>.

<sup>14</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>15</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>16</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>17</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>18</sup> National Burden of Invasive Methicillin-Resistant *Staphylococcus aureus* Infections, United States, 2011.

classes of antibiotics no longer cure *Acinetobacter* infections.<sup>19</sup> Appropriate use of contact precautions and effective environmental cleaning reduces the transmission of VRE.

- ***Candida*** is a fungal pathogen that is the fourth most common cause of healthcare-associated bloodstream infections in the United States.<sup>20</sup> In some hospitals it is the most common cause. Some *Candida* strains are increasingly resistant to first-line and second-line antifungal treatment agents. Appropriate stewardship for antifungal medications reduces the development of *Candida* resistance.

#### RECENT SUCCESSES & CDC'S DETECT AND PROTECT PORTFOLIO

Despite the significant burden of HAIs in the United States and the growth of antibiotic resistant pathogens, most HAIs are preventable. Many of the recent HAI prevention successes reflect activities identified in the National Action Plan for the Prevention of Health Care Associated Infections which was developed under the coordination of the HHS Office of the Assistant Secretary. These include innovations in tracking HAIs and drug resistant pathogens and targeting problem areas with effective prevention strategies. CDC, working with CMS, AHRQ, and other agencies in the U.S. Department of Health and Human Services (HHS), has taken a lead role in addressing the important public health challenge by implementing strategies to detect HAIs and protect patients from them.

In an analysis currently undergoing peer review, CDC experts performed an historical economic model to measure the net economic benefits of preventing CLABSIs in Medicare and Medicaid patients in critical care units from 1990 to 2008 using the cost perspective of the Federal Government as a third party payer. The estimated net economic benefits ranged from \$756 million to \$1.9 billion with the corresponding net benefits per case averted ranging from \$16,550 to \$24,060.<sup>21</sup> The per-dollar rate of return on CDC investments ranged from \$4.54 to \$23.45.<sup>22</sup>

Using multiple detect-and-protect strategies, CDC's world-class experts target HAIs and the drug resistant pathogens that can cause them, including:

- monitoring HAIs and evaluating their risk factors, establishing benchmarks and targets, and tracking prevention progress toward those goals;
- detecting and responding to emerging and urgent threats through outbreak investigation and laboratory science;
- developing guidelines for HAI prevention and filling gaps in knowledge through applied research;
- implementing prevention strategies with Federal and State partners.

#### TRACKING HAIS AND HAI PREVENTION PROGRESS

CDC's National Healthcare Safety Network (NHSN) is the Nation's most widely used healthcare-associated infection tracking system. NHSN provides facilities,<sup>23</sup> States, regions, Federal partners such as the Centers for Medicare & Medicaid Services (CMS), and the Nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections. NHSN currently serves more than 12,000 medical facilities tracking HAIs.<sup>24</sup> Participation is expected to continue to grow.

CDC provides the standard national measures for HAIs as well as analytic tools that enable each facility to assess its progress and identify where additional efforts are needed. While ensuring data security, integrity, and confidentiality, NHSN gives healthcare facilities the ability to see their data in real-time and share that information with clinicians and facility leadership, as well as with other facilities (*e.g.*, a multihospital system) and partners such as State and local health departments or CMS quality improvement organizations. To limit burden on facilities and leverage efficiencies across government, NHSN serves as the conduit for facilities to comply with CMS infection reporting requirements (see figure 1). NHSN data are analyzed by CDC and others to direct actions for HAI prevention. Local, State, and national HAI trends are used to identify problems and areas of concern that need interven-

<sup>19</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>20</sup> Antibiotic Resistant Threats in the United States, 2013: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>21</sup> Pending publication, unpublished data currently under peer review.

<sup>22</sup> Pending publication, unpublished data currently under peer review.

<sup>23</sup> Current participants include acute care hospitals, long-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and nursing homes, with hospitals and dialysis facilities representing the majority of facilities reporting data.

<sup>24</sup> NHSN: <http://www.cdc.gov/nhsn/about.html>.

tion, and to measure progress in HAI reduction against national, State, and local prevention goals.

NHSN provides facilities with data collection and reporting capabilities needed to:

- identify infection prevention problems<sup>25</sup>;
- benchmark progress of infection prevention efforts;
- comply with State and Federal public-reporting mandates, and;
- ultimately drive national progress toward elimination of HAIs.

Patients can use NHSN data posted publicly on HHS's Hospital Compare Web site.<sup>26</sup> Patients are encouraged to visit the Web site to see how their local facilities are doing and discuss concerns with their healthcare providers.

To understand patterns of infections and how drug resistant-pathogens move through communities, and to build the evidence base of best practices to prevent spread, CDC relies upon its Emerging Infections Program (EIP).<sup>27</sup> The 10-State EIP network consists of partnerships between State health departments and university collaborators that provide critical evaluation of the epidemiology and public health impact of HAIs, the burden of emerging drug-resistant infections, and identification of new populations-at-risk for healthcare-associated infections. The EIP is currently working on new estimates of the overall burden of HAIs nationwide and providing updated information on the most commonly used antimicrobials and treatment indications. The network has begun plans to perform a large scale assessment of antibiotic use appropriateness and to test what interventions can be used to improve antibiotic prescribing and thereby reduce drug resistance and improve patient outcomes.

The National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (National Action Plan), developed under the leadership of the Office of the Assistant Secretary, sets specific targets based on NHSN, EIP, and other data systems for monitoring and preventing HAIs nationally and represents a national blueprint for promoting HAI prevention.<sup>28</sup> CDC has collaborated closely with HHS's Assistant Secretary for Health, the Agency for Healthcare Research and Quality (AHRQ), CMS, and other Federal agencies to implement the National Action Plan and expand its impact to additional healthcare settings.

#### OUTBREAK INVESTIGATION AND RESPONSE AND LABORATORY SCIENCE

CDC serves as a national and global leader in the investigation and control of HAI outbreaks. On a daily basis, CDC responds to inquiries from facilities and States about unexplained illness and/or death related to product, device, or environmental contamination and lapses in basic infection control or injection safety. CDC deploys experts including healthcare epidemiologists, infectious disease physicians, and laboratory scientists to assess healthcare settings, collect and analyze data, evaluate practices, and perform microbiologic testing in response to a newly recognized outbreak or problem. Through its investigations, CDC identifies and controls problems, develops new prevention strategies, and works with partner agencies such as CMS and the Food and Drug Administration (FDA) to implement policy changes. Some of our Nation's most significant healthcare problems are first identified through outbreak investigations conducted by CDC and its State partners, including last year's nationwide response to an outbreak of fungal meningitis and other infections related to a compounded medication associated with the New England Compounding Center (NECC). With 750 cases and 64 deaths reported to CDC to date, affected patients continue to suffer from these infections and the burden of treating them.

Outbreaks demonstrate the essential role that public health plays in keeping our country safe from infectious disease threats. Our national public health capacity is disseminated to State and local responders who work in partnership with CDC. Outbreak responses require skilled, trained public health personnel in State and local agencies capable of responding to outbreaks in a range of healthcare settings including hospitals, nursing homes, dialysis facilities, and doctor's offices. CDC support to State infectious disease programs is critical to local outbreak response capacity.

Outbreaks also highlight the importance of CDC's infectious disease laboratories to rapidly respond to and characterize unexplained death and illness. CDC has mul-

<sup>25</sup> In addition, NHSN allows healthcare facilities to track blood safety errors, antibiotic use, and important healthcare process measures such as healthcare personnel influenza vaccine status and infection control adherence rates.

<sup>26</sup> <http://www.medicare.gov/hospitalcompare>.

<sup>27</sup> EIP-HAI projects: <http://www.cdc.gov/hai/eip/>.

<sup>28</sup> *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination*: <http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html>.

multiple laboratories that provide outbreak response capacity for HAIs. CDC's drug-susceptibility laboratory serves as a World Health Organization (WHO) collaborating center for antibiotic resistance, providing worldwide reference capacity, conducting strain typing and additional molecular characterization of antibiotic resistant pathogens, and detecting novel and emerging antibiotic resistance in health care-associated bacteria. CDC's environmental microbiology laboratory maintains unique capacities to sample environments to identify contamination, determine routes of transmission, and isolate the cause of outbreaks of unknown etiology.

Advances in laboratory technologies such as high-throughput genome sequencing, along with improved capabilities in the field of bioinformatics, stand to revolutionize our ability to control infectious diseases including HAIs, enabling faster, more accurate, and cost-effective ways of preventing, detecting, and responding to known, emerging, and resistant pathogens. To help CDC gain the capacity to keep pace with this rapidly changing field, the President's fiscal year 2014 Budget proposes an Advanced Molecular Detection initiative<sup>29</sup> that would equip CDC's scientists and laboratories with two powerful technologies—molecular sequencing and bioinformatics—to help solve complex disease mysteries. Modernizing CDC's infectious disease laboratories and building its bioinformatics capacities are essential to ensure that the expanding use of these new technologies brings strong benefits for public health. With these new tools, disease detectives can solve more health mysteries and solve them faster.

#### GUIDELINES FOR PREVENTION AND RESEARCHING GAPS IN KNOWLEDGE

Information CDC learns from outbreaks not only serves to control the immediate problem, but also has a direct impact on future HAI prevention nationwide. Experience from outbreak investigations contributes to refinement of infection control guidelines and improvements in HAI tracking. CDC, working with the Healthcare Infection Control Practices Advisory Committee (HICPAC), develops evidence-based guidelines for HAI prevention. CDC's infection control guidelines set the standard of care for HAI prevention in the United States and are the basis of HAI prevention checklists.

CDC's experts also work to improve upon HAI prevention guidelines by filling critical gaps in knowledge. Through a cooperative agreement, CDC works with a network of academic partners, called the Prevention Epicenters, to address gaps in the evidence base related to the prevention of HAIs, antibiotic resistance, and other adverse events associated with healthcare. This unique forum enables academic leaders in healthcare epidemiology to partner directly with each other and with CDC experts to conduct innovative research designed to fill knowledge gaps that are most important to public health. Because the Prevention Epicenters work together, there is an emphasis on multicenter collaborative research projects, many of which would not be possible for a single academic center.

For example, the recent REDUCE MRSA Trial,<sup>30</sup> a collaboration of CDC, its network of Prevention Epicenters, and AHRQ, tested three MRSA-prevention strategies. The study results found compelling evidence that one of the interventions—the use of a pathogen-killing soap and nasal ointment on all intensive-care unit (ICU) patients—reduced bloodstream infections by up to 44 percent and significantly reduced the presence of MRSA and other pathogens in ICUs. A total of 74 adult ICUs and 74,256 patients were part of the study, making it the largest study on this topic and we believe that the results are already impacting practice and improving care in hospitals across the country.

#### IMPLEMENTING PREVENTION STRATEGIES WITH FEDERAL AND STATE PARTNERS

NHSN and CDC HAI prevention guidelines are used by all Federal agencies working on HAI prevention and are the basis for most State HAI prevention initiatives. CDC's NHSN data is used to measure the progress of the HHS Partnership for Patients initiative, for AHRQ's Comprehensive Unit-Based Safety Program, and to support targeted prevention activities for CMS Quality Improvement Organizations. CDC also develops tools to translate what we know works to prevent HAIs (CDC and HICPAC guidelines) into practice.<sup>31</sup> For example, CDC is improving basic infection control practices through collaborations with CMS to expand survey and oversight capacity of non-acute healthcare settings. CDC and CMS worked together to develop a new tool that State inspectors are using to ensure the quality of care in

<sup>29</sup> <http://www.cdc.gov/amd/>.

<sup>30</sup> <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1207290>.

<sup>31</sup> CDC HICPAC Guidelines: <http://www.cdc.gov/hicpac/>.

ambulatory surgical centers (ASCs).<sup>32</sup> CDC is working with CMS to expand incorporation of basic infection control content into CMS interpretive guidance for their conditions of coverage for outpatient settings. CDC continues to work with CMS to develop similar tools for use in acute care and other healthcare settings. CDC also develops tools to help facilities prevent the spread of drug resistant infections. In 2012, CDC released the CRE Toolkit<sup>33</sup> to provide education for doctors and nurses, hospitals, long-term acute care hospitals, nursing homes, and health departments. It gives step-by-step instructions for facilities treating patients with CRE infections and for those not yet affected by it.

Through funding under the Prevention and Public Health Fund, CDC also supports HAI coordinators<sup>34</sup> at all 50 State health departments. These coordinators use data from CDC's National Healthcare Safety Network to help target HAI prevention efforts locally, leveraging ongoing HAI projects and collaborating with local partners to avoid duplication. For example, the HAI coordinator at the Tennessee State Health Department collaborated with the local quality improvement organization (QIO) supported by CMS to target *C. difficile* prevention. This collaboration leveraged the complementary expertise of the organizations: the QIO recruited a group of interested and motivated facilities and is providing them with support on performance improvement, while the Tennessee State Health Department has provided those facilities with specific training on how to prevent and monitor *C. difficile* infections. The Tennessee State Health Department is also analyzing data on *C. difficile* infections being submitted to the CDC's NHSN to help both the facilities and the QIO monitor their progress and drive quality improvement.

#### FUTURE DIRECTIONS

In moving HAI prevention forward, CDC is focused on making progress wherever HAIs are impacting patients. Drug-resistant HAIs and *C. difficile* continue to take a toll on patients nationwide and must be addressed. To accelerate improvement, CMS began requiring the reporting of *C. difficile* infections through CDC's NHSN last year. CDC is launching a new component of NHSN, developed with CMS and others, that will electronically measure, benchmark, and help facilities improve antibiotic use—a leading driver of both drug resistance and *C. difficile* infections. CDC is testing new interventions such as antibiotic timeouts and antibiotic stewardship protocols that we hope can make real contributions to prevention progress. With our State partners, CDC is also piloting regional “detect and protect” collaboratives that are focused on preventing drug-resistant HAIs across communities by ensuring that hospitals, long-term acute care facilities, and nursing homes/skilled nursing facilities work cooperatively to limit the spread of dangerous pathogens within and across those facilities.<sup>35</sup>

For the prevention of CLABSIs, CDC is working with CMS to ensure that the prevention gains we have seen thus far in hospital intensive care units are carried over to general hospital wards, long-term acute care, and dialysis settings. CDC and CMS are also working to make improvements in the surveillance and prevention of catheter-associated urinary tract infections (CAUTI), which have increased over the past 2 years. CDC is refining the measurement and prevention science for HAI-related pneumonias and surgical-site infections, which represent a significant HAI burden. For all of these infection types, CDC and CMS are looking to prevent not only infections within a facility but also infections that move across facilities and cause unnecessary, costly readmissions.

#### CONCLUSION

Ensuring that appropriate infection control and antibiotic use practices are adhered to in all healthcare settings is a priority for CDC. Public health plays a pivotal role in ensuring a unified and integrated approach through systematic implementation of prevention practices, monitoring to detect problems, outbreak investigation and control, oversight, education, and research. Our work in HAI prevention illustrates the power of public health in action both to detect serious health problems and to lead State and Federal partners to implement targeted responses

<sup>32</sup>In a 2008 Federal survey of ASCs, 68 percent of 68 surveyed centers had noncompliance with the infection-control requirements in the Medicare ASC health and safety standards. CMS has found infection-control problems in ASCs to be both common and egregious, ranging from failure to clean equipment between patients and re-use of single-dose vials of medication for multiple patients.

<sup>33</sup>CRE Toolkit: <http://www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html>.

<sup>34</sup>HAI coordinators were recently named White House Champions for Change: Marion Kainer (TN) and Erica Washington (LA): <http://www.whitehouse.gov/champions>.

<sup>35</sup>Detect and Protect: [http://www.cdc.gov/hai/pdfs/cre/CDC\\_DetectProtect.pdf](http://www.cdc.gov/hai/pdfs/cre/CDC_DetectProtect.pdf).



that will protect our Nation and its citizens from infectious disease threats. As we continue to work toward elimination of HAIs, new healthcare settings and changing technology will create new challenges and will require fast detection and innovative responses to prevent harm to the public. CDC continues to address challenges as they arise and ensure that patients are safe in every healthcare setting. We know how to protect patients from most HAIs; these infections can and must be prevented.

Figure 1: Participation in CDC's National Healthcare Safety Network (NHSN) for CMS Value-Based Purchasing

| Location  | HAI Event   | Reporting Start Date      | CMS Reporting Program                              |
|---|---|---------------------------|--|
| Acute Care Hospitals .....                              | CLABSI—ICU .....  | 11-Jan .....              | Hospital Inpatient Quality Reporting Program.      |
|   | CAUTI—ICU .....   | 12-Jan .....              |  |
|   | SSI (COLO and HYST) .....   | 12-Jan .....              |  |
|   | MRSA Bacteremia .....   | <b>13-Jan</b> ...         |  |
|   | <b>C. difficile</b> LabID Event .....   | <b>13-Jan</b> ...         |  |
| Dialysis Facilities .....                               | I.V. antimicrobial start, Positive blood culture, Signs of vascular access infection. | 12-Jan .....              | ESRD Quality Incentive Program.                    |
| Long-Term Acute Care Facilities (LTAC).                 | CLABSI, CAUTI .....   | 12-Oct .....              | Long Term Care Hospital Quality Reporting Program. |
| Inpatient Rehabilitation Facilities (IRF).              | CAUTI .....   | 12-Oct .....              | IRF Quality Reporting Program.                     |
| Ambulatory Surgical Centers (ASC).                      | <b>None at this time</b> .....  | <b>13-Oct</b> ...         | ASC Quality Reporting Program.                     |
| Nursing Homes/Skilled Nursing Facilities <sup>1</sup> . | <b>None at this time</b> .....  | <b>n/a</b> .....          | <b>None at this time.</b>                          |
| All Facilities .....                                    | HCW Influenza Vaccination .....   | <b>14-Oct<sup>2</sup></b> | <b>All Reporting Programs<sup>2</sup></b>          |

<sup>1</sup> No information on proposed reporting in long-term care/skilled nursing, but CDC's LTC component made available for use in August 2012.

<sup>2</sup> Acute Care Hospitals began reporting HCW Influenza Vaccination January 2013 as part of Hospital Inpatient Quality Reporting Program; all other facility types to begin in October 2014.

The CHAIRMAN. Thank you very much, Dr. Bell.

Thank you both. We'll start a round of 5-minute questions, and due to the time element, I will try to adhere as strictly as I can to that 5 minutes.

Dr. Conway, one of the most common features of successful initiatives to reduce infection rates is cooperation and coordination across providers. How can the Federal Government create incentives, financial or otherwise, for healthcare providers who are often competitors to work together to advance patients' interests?

Again, a lot of this is in software programs. One hospital has one set of software, and another hospital has another software program. People go from one hospital to the other, and nobody talks to one another because these are proprietary, don't you know, and these two are competitors. How do we break that down? How do we provide for that kind of transparency that you mentioned and coordination, given that kind of a set up?

Dr. CONWAY. Thank you for the question, Senator Harkin. I'll answer it directly for HAIs and then the broader coordination, if that's OK.

Speaking directly to infections and safety issues, we have measures of the system of care, really focusing on that shared accountability with strong measurement systems working with our colleagues at CDC—for things like bloodstream infections, urinary tract infections, surgical site infections, really focusing not on the individual provider but the system of care and how we can coordi-

nate, use team-based care and improvement methods to successfully decrease those infections.

On the broader issue of sharing information and coordination of care, one, we're trying to measure transparency for things like the readmissions program and also include both payment incentives, so a potential for negative payment adjustments, as well as quality improvement in the field to coordinate care. So we're investing, through Partnership for Patients, our QIO program, and community-based care transitions program, millions of dollars in communities to link providers together to coordinate care so beneficiaries receive coordinated care and stay home and healthy.

Last, in the meaningful use in technology arena, we'll continue to push forward on interoperability and sharing of information, really empowering patients and consumers with information and incentivizing sharing of information to best coordinate care.

The CHAIRMAN. And you can do that across competitors' lines?

Dr. CONWAY. There's a couple of ways we try to address that issue. One is with our incentive programs and also new models that we're testing, such as accountable care organizations, really incentivizing better coordinated care, higher quality at lower cost, and really incentivizing providers to work together to coordinate care. We have our Medicare Shared Savings Program and then our pioneer ACOs and advanced care payment ACOs out of the Innovation Center. Those are examples of payment models.

We're launching a bundle payment initiative, which will incentivize care coordination both within the hospital to post acute care settings and into the community. So we have a number of interventions and models that we're testing to better coordinate care for populations of patients.

The CHAIRMAN. Thank you.

Dr. Bell, could you specifically address the issue of sepsis and CDC's work on infections and whether it has any affect on the rates of sepsis? We hear about other things. But how about sepsis—we're going to hear more about that in the second panel—or MRSA, the two that perhaps frighten people the most? Could you address both of those, in particular?

Dr. BELL. Thank you, Senator. Sepsis is a terrible condition that causes a lot of tragedy and suffering. Healthcare-associated infections are one of the root causes of sepsis. So the way someone dies, let's say, of a central line infection is by sepsis. So by preventing healthcare-associated infections, we are making a contribution to preventing sepsis.

There clearly is a lot more that needs to be done in terms of improving communication, linkage to care, and these are all areas that we're continuing to work on with our colleagues at CMS to make additional progress. But, as I say, the more we drive toward reducing healthcare-associated infections, the more we reduce one of the root causes of sepsis.

In terms of MRSA, we do have a little bit of good news about MRSA. As I mentioned, last week, we reported on trends in MRSA and actually found a 54 percent decline in MRSA infections in hospitalized patients and also declines in community-acquired MRSA and MRSA probably acquired in the hospital but manifested in the community.

This is an area where we are making some progress. We have a lot further to go. But it is an example of where, by using CDC guidelines, by tracking effectively so that we provide feedback to providers and to hospitals and to patients about progress and the incidence of these infections, we really can actually have a measurable impact.

The CHAIRMAN. Thank you both very much.

Senator Alexander.

Senator ALEXANDER. Dr. Bell, is it CDC's, Centers for Disease Control's, statistic that about 1 out of 20 people who go into a hospital gets an infection while there?

Dr. BELL. Yes, sir.

Senator ALEXANDER. What was it 10 or 20 or 30 years ago? Was it better or worse?

Dr. BELL. There were more infections 10 or 20 years ago than there are now. And, in fact, we're in the process of updating our estimates at the moment, and we're hoping, actually, that that 1 in 20, we'll be able to say, is less, maybe 1 in 25. I don't know.

We've definitely made progress in many areas, central line infections, for example. In the early 2000s, we were seeing 40,000 infections a year, and this last year, we saw 12,000 central line infections. So there's no doubt that there's been progress in some areas.

But in other areas, we're not seeing the progress we'd like to see. For example, as you noted, we're very concerned about resistant infections and about *C. difficile*. These are areas where we haven't made progress, and, in fact, in some situations, it seems like we're going backward.

Senator ALEXANDER. Well, I was going to ask that. You've made some progress in the number of infections, and I guess progress has been made in detecting infections. Is that correct, too? Are people more aware of it now?

Dr. BELL. Yes, certainly for some infections. But, again, that's an area, I think, where we really have a lot of room for improvements. Certainly, a number of outbreaks that we've investigated recently—one of the lessons from those outbreaks is the difficulty that hospitals and laboratories have in detecting, especially, some of these resistant pathogens. And that's an area where there really is room for improvement.

Senator ALEXANDER. Now, the resistant pathogens—this sounds like the work in HIV 10 or 15 years ago, where the medicines that were developed for it were—after a while, they didn't work because the immune system got used to them, I guess. Is the ability to develop medicines that deal with these bacteria getting more difficult? Why are we going backward in that, if we are?

Dr. BELL. Well, unfortunately, bacteria will always develop resistance. They're very clever organisms. They pass these—

Senator ALEXANDER. But hasn't that always been the case?

Dr. BELL. Yes, it has. But a number of factors have selected for some of these organisms that have developed resistance to more and more antibiotics. One of the reasons for that, we think, is over-use of antibiotics, and there are many estimates out there that half of the antibiotics that are used in the United States are unnecessary. So for that reason and for many other reasons, we are seeing

this class of bacteria that are becoming resistant to more and more antibiotics.

In our report that we published last week, we identified four areas, four things that need to be done to fight antimicrobial resistance. One of them is to prevent resistant infections. A second is to track them, as you mentioned, Senator, in terms of detection. A third is to improve antimicrobial use. And the fourth is to promote development of new drugs and new diagnostics.

Senator ALEXANDER. By improving the use, you mean don't use antibiotics more than necessary because it makes them less useful in combating these bacteria.

Dr. BELL. That's correct.

Senator ALEXANDER. What about the success, or lack of it, of Generating Antibiotic Incentives Now? Congress tried to respond to this last year. Has that been helpful?

Dr. BELL. Yes, sir. I think we've certainly been working with FDA on certain components of the GAIN Act. One of the first things that FDA did was to generate a list of the bacteria and other organisms that would be covered under the GAIN Act. We collaborated with them, and I think the list that the FDA has generated will provide a focus for industry to work on developing new drugs.

Senator ALEXANDER. In the first year of its use, have you found any changes that need to be made in it?

Dr. BELL. I think this issue of developing new antibiotics is a very long-term proposition, and that's one of the reasons why some of the other things that we're calling for to prevent resistance are so important in terms of improving use and prevention and tracking.

Senator ALEXANDER. Sometimes we have in our country great health crusades to try to eradicate a problem, for example, with polio. Is this a case where we should have as an objective eradicating infections acquired when you go into a healthcare facility? And if that is a goal, is it a realistic goal?

Dr. BELL. Well, Senator, we've said that that's our goal. And I think we can all agree, as patients, potentially, ourselves, as children or parents of patients, that it's not right, as you said, Senator, to go to the hospital to get cured and instead get an infection that could kill you.

So we have said that our goal is to eliminate HAIs, and I think that this is something that we all can unite on. I mean, no doctor wants to give their patient a healthcare-associated infection, either. Whether we can get down to zero HAIs, I don't know. But we certainly have a long way to go. There's much, much improvement that we can make as we drive toward that as a goal.

Senator ALEXANDER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Alexander.

In order, I have Senator Whitehouse, Senator Isakson, Senator Murphy, Senator Burr, Senator Casey, Senator Baldwin. Again, the clock is wrong. It's 10:36 right now. That clock is 15 minutes fast. But I remind everyone that we are still facing a vote at 11:45, and we have a very good panel that I'd like to followup with on this. So if you'd keep it short, I'd sure appreciate it.

Senator Whitehouse.

## STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you, Chairman. Thank you for holding this hearing. This is such an important subject. In Rhode Island, we have a group called the Rhode Island Quality Institute that has been working—you know it. I see the heads nodding.

Years ago, we took the Pronovost principles, the Keystone Project, and we went statewide in every ICU in Rhode Island. Every hospital participated. We're down more than 60 percent on central line-related infections. We're down nearly half on ventilator-associated infections, and we're running about one infection per 1,000 patient days, which I think is a lot better than the one in 20 that our Ranking Member referred to. We started in a good place with very good hospitals in Rhode Island, very good ICU care, and improved by applying those principles.

However, over the years of doing that, it was not CMS supported. It was a purely local initiative. Some of the things that you've referred to help create an environment where, for hospitals and for insurance companies, it makes sense to get engaged in this kind of activity.

But I would urge you to be more energetic about looking for ways to support these local initiatives, because it really is pulling the different hospitals, the different hospital systems, the different information systems together that makes it happen. And making that happen isn't easy for States that are strapped, and I think the return on that investment is huge. So I would urge you to do that.

I can't resist saying this when people who are in this Administration come. But, first of all, thank you for not saying "bending the healthcare cost curve." That is my least favorite expression, because it is a metric that has no accountability to it.

It's very frustrating when the hope for delivery system reform, the prospects for healthcare delivery system reform, the ability to take—burning 18 percent of GDP on healthcare and reduce it to more like 12 percent, where every other industrialized nation is—the Institutes of Medicine, the Rand Corporation, the President's Council of Economic Advisors, everybody is saying there's \$700 billion or \$800 billion a year to be saved by delivering better healthcare.

I would really, really like to see this Administration put out a savings target, not something vague, like we're going to bend the healthcare cost curve, but by this date, we're going to save this much money by improving the quality of care. I think that drives a message through all of the Federal bureaucracy to gear up.

I think that if President Kennedy had said we're going to bend the curve of space exploration, we never would have put a man on the moon. It's because a hard target was set, and all of the forces of this very capable country were focused on meeting that target. And until we have such a target, I think we're going to continue to be operating at less than our full capability. When you consider the lives that are at stake here and the savings that are at stake here, I think operating at anything less than full capacity is a real tragedy.

Those are my two thoughts—if you could find ways to help these local initiatives more, and thank you for not saying "bending the

healthcare cost curve.” But at least that’s a first step. But now the real step is to push this Administration to produce a hard target with a date and a number.

Go ahead and respond, Dr. Conway. That was not really framed as a question, but I do want your response.

Dr. CONWAY. I’ll be very brief. One, I can’t agree with you more about the importance of local quality improvement. Quality improvement happens locally. It happens on the ground with clinicians and patients in States and communities. So I can’t agree more.

On the concept of setting a target, thank you for your leadership in this area and for your comments. And on the HAI point, as an example, we’ve set the target of 40 percent reduction, and specific targets by every infection—and Dr. Bell may speak more to that—but certainly built on the concept of setting a target and aligning levers to go for that target.

Dr. BELL. Thank you, Senator. You kind of embodied a lot of our mantras about the important components of preventing healthcare-associated infections. And just to amplify a little bit on what Dr. Conway said, I think your point, first of all, about measurement is very important. This is what the National Healthcare Safety Network is for.

There are over 12,000 hospitals that participate in the National Healthcare Safety Network, 12,000 institutions including 5,500 hospitals. And in each of those hospitals, they have real-time access to their own data so that they can actually see where there are problems and drive quality improvements.

At the same time, because infections don’t happen just in one institution and are spread around in the community, the State health departments can look at these data, QIOs can look at these data, hospital engagement networks can look at these data, and we at CDC look at the data. And we provide benchmarks so that hospitals and States can determine where they are and figure out where the areas are where there needs to be improvement.

There are many examples, including examples in Rhode Island, in Tennessee, and a number of other States, where State health departments and QIOs have worked together. When they see a problem, they go into that institution and figure out how to fix it.

Senator WHITEHOUSE. Thank you, Chairman.

The CHAIRMAN. Thank you very much, Senator Whitehouse. Senator Isakson.

#### STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you, Mr. Chairman. I want to personally thank you, because 3½ years ago, I was hospitalized for a week with MRSA. And that’s one of the primary reasons I worked so hard on the GAIN Act, and I appreciate very much the attention to this. It is a huge issue and a devastating problem for many families.

Dr. Conway, to that end, when I worked on the GAIN Act, I wanted to do anything I could do to promote breakthrough antibiotics to deal with these infections that are so resistant. I have a concern that under the hospital inpatient patient system, bundled payments are often determined by the cost of existing antibiotics

that are used and don't take into consideration the cost of the development of the breakthrough antibiotics, which will be used rarely, but when used will actually save an otherwise life threatening infection.

Is there any way CMS can work with the system of reimbursement to recognize the tremendous cost of a breakthrough drug when it's introduced and accommodate for that?

Dr. CONWAY. Thank you for the question. We work closely with our payment colleagues on the payment systems in terms of payments and making sure we pay appropriately, including pay for new innovations. And Dr. Bell may speak more about the act.

Specifically, on the bundles, we are currently in the process of setting up that test. It's gone live in phase one. Phase two, which actually includes the bundles and the bundled payment care initiative and potential payment adjustments, will go live in October. We have had a back-and-forth with hospitals to make sure if there's, for example, truly cases that are unique or different or technologies that need to be used, how we can account for that.

So I will take this back to the team as well as an issue to make sure we're thinking about it and accounting for it as best as possible.

Senator ISAKSON. I appreciate your doing so, because the last thing we'd want to do would be to have a disincentive for the development of the very drugs we're trying to promote being developed.

Dr. Bell, I know the focus on this is hospitalization. First of all, as a Georgian, thank you for you and Dr. Frieden and the thousands of professionals out on Clifton Road that are the world's health center. We appreciate all the good work that you do.

I know we're focusing on in-hospital infections. But I want to direct a question to you about non-in-hospital infections. I've introduced legislation for reimbursement for diabetic patients for needle destruction devices for their home, because they use hypodermic needles to administer insulin and their drugs all the time.

I know there are unintended consequences of infections that are contracted at home or in settings not in the hospital from needle sticks. Do you think that non-institutional needle stick infections are a big problem in this country?

Dr. BELL. Thank you, Senator, and thank you for the kind words. We certainly agree that while we've made progress in hospital settings and especially in intensive care units, out-of-hospital settings, including, for example, ambulatory surgical centers, long-term acute care facilities, are really places where we need to make a lot more progress. And we certainly have many examples of where infections are transferred around from one institution to another, and the problem is amplified.

Needle sticks are obviously one way that pathogens can be transmitted. And, as you say, it's in these sort of not as well controlled settings, like nursing homes, which is another example where we see outbreaks associated with needle sticks or unsafe injection practices.

So I agree with you that this is a major problem, what's happening outside of the hospitals. This is sort of our area of focus, and we've been working with CMS to try to kind of extend some of the successes that we've found in a hospital to other settings.

Senator ISAKSON. We received an estimate from a major healthcare carrier in the country that \$175 million in costs every year, annually, are for non-institutional needle stick infections that are contracted because of reuse of needles or pricks by needles or things like that. Maybe we can talk to Director Tavenner and Dr. Conway and take a look at the reimbursement formula you currently have, because I think the agency can make the determination itself as to whether the cost benefit makes sense to reimburse for diabetics in terms of needle destruction devices.

And I would appreciate hearing from you, if you'd take a look at that, Dr. Conway.

Dr. CONWAY. Yes, sir. We'd be happy to take a look at that and get back with you on the record.

Senator ISAKSON. Thanks for what both of you do for healthcare. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Murphy.

#### STATEMENT OF SENATOR MURPHY

Senator MURPHY. Thank you very much, Mr. Chairman. Thank you for convening this hearing.

Thank you to both of our witnesses for the great work that you do.

I just want to first associate myself with the remarks of Senator Whitehouse. I think it's time to put some real meat on the bones with respect to setting some cost targets here, frankly, as we try to pursue a pretty painful conversation about entitlement reform. One of the few places within that discussion that we're going to be able to find bipartisan agreement is in our mutual interest in trying to put some real numbers around what delivery system reform can deliver in terms of dollar savings. So I think that's a very useful exercise with respect to setting a target.

My first question is probably directed to you, Dr. Conway. These are some pretty impressive numbers in terms of the reductions that we've seen, whether we're talking about surgical site infections or central line associated infections. And I don't think it's a coincidence that it comes on the heels of a pretty dramatic payment reform instituted in 2008, in which CMS basically said to hospitals,

"We're going to stop paying you for these infections. We'll obviously take care of you up until that point, but that's going to be on your dime."

I remember when that change was made. There were a lot of hospitals in Connecticut, even though we were a little bit ahead of the curve on this, that were worried about the fairness of that change, because their contention was that,

"We certainly know we can control a lot of this, but some of it we feel is outside of our control. So how can you hold us accountable for everything?"

That being said, real results have been delivered by hospital after hospital. So my question is: How much do you think this tough love approach caused this acceleration of change in terms of



practices, and then what does that tell us for other areas in which we can dedicate that kind of approach to payment reform?

It seems to me that if it has worked here, it could certainly work in other areas, even with respect to hospital systems where there are real outliers in terms of excessive practice, to just say, "Listen, we're going to pay up to this line, and we're not going to pay after that." If it's worked here—and you'll have to tell me if you think it's worked here—why wouldn't it work for other areas as well?

Dr. CONWAY. Thank you, Senator, for the question. I think you make excellent points, and to reflect back, essentially, we have had success for healthcare-acquired infections and healthcare-acquired conditions. There's more work to do, but there's been a significant improvement.

I think there's two major factors. There's an array of minor factors, but I think the two major factors are payment incentives that align with better care, and directly we're targeted with specific measures and goals to decreasing healthcare-acquired infections.

I think we've also made significant investments in improvement in the field. So through our quality improvement organizations, through CDC and public health departments, through research, through our research agencies, through Partnership for Patients—really helping hospitals and clinicians with the hard work of improvement. And I think you do need that technical assistance to drive that system improvement to be successful.

I think we're starting to see success in other areas. Hospital Value-Based Purchasing—we put this on our Web site not so long ago. Over 80 percent of the measures have improved significantly, so much so we're having to remove process measures that are topped out and add in more outcome measures.

End-stage Renal Disease—there's a bundle and a quality incentive program—costs controlled with the bundle and the quality measures for dialysis care going up substantially in this country. So I think the key is to align payment incentives with better care and lower costs for populations of patients and then invest in the technical assistance infrastructure and technology to allow health systems to achieve those results.

Senator MURPHY. Well, I would just encourage you to be bold about this tough love approach with respect to reimbursement. We are wasting billions of dollars on a small handful of hospitals and healthcare systems around the country that have just tremendous outlier rates in terms of utilization. And at some point, we just have to decide to not pay for that.

Here's my question on bundles. Most of the payment reforms have been directed toward how you pay hospitals. But, of course, a lot of physicians that interact with those hospitals are not necessarily part of that payment reform, because they're getting paid separately.

What's our experience in terms of the cooperative relationship between hospitals and physicians who may be outside of those hospitals from an organizational standpoint? And won't more bundled payments further encourage hospitals and outside physicians who are using the hospital for procedures to collaborate on a lot of the best practices that we've seen lead to a dramatic decrease in infections?

I'd love to move faster when it comes to bundles payments. I'd love for CMS to be looking more aggressively at new bundles, whether it be in pilot programs or blowing them out systemwide. And it seems to me that we would move faster on controlling hospital-based infections if we had more bundled payments, especially for surgical events in the hospitals.

Dr. CONWAY. I'll be brief, given the time. Your comments are well taken. I think there are three points, briefly. On accountable care organizations, a number of those are physician-led, and we did advance payment models, and many of those ACOs are collaborations which are successful.

On bundles, we also believe there is potential for physicians to collaborate with hospitals and control cost and improve quality substantially. And in our core payment programs, where we have statutory authority to do bundling and other innovative payment mechanisms, we are looking to do that, and we look forward to working with you on these issues.

The CHAIRMAN. Thank you very much.

Thank you, Senator Murphy.

Senator Burr.

#### STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman.

Dr. Conway, I've heard you use payment incentives, quality incentives, and I'm curious—and I'm not up to snuff enough on how bundled payments work today or how these different incentives work that you've mentioned. Is this really a financial benefit to people who adopt it, or is it foregoing a penalty that was in place?

Dr. CONWAY. In terms of the payment programs, let me briefly go through them, because they vary in their setup.

Senator BURR. Well, without getting into the specifics, is this actually more money through the reimbursement, or is it less of a cut?

Dr. CONWAY. The majority of the programs—the Healthcare-Acquired Conditions Program from 2008 was no additional funding if these events occurred. The Healthcare-Acquired Conditions Program that we just finalized was a set of measures, including HAIs and HACs, that if you're in the bottom quartile of performance, you get a negative payment adjustment.

The Hospital Value-Based Purchasing Program is budget neutral. So about half of hospitals get more money because they perform well, and half get less.

Senator BURR. Incentives always—when you use the word, one expects that there's a financial benefit to individuals. So the reason that there's not overall buy-in may be the fact that there's not real incentives there. It's just the lack of maybe what they feared.

Dr. Bell, what's the rate of HAIs from hospitals versus HAIs from ambulatory outpatient surgery centers? Is there a significant difference?

Dr. BELL. Our estimate of 1 in 20 infections is from hospitals. We don't have very good estimates about ambulatory surgery centers. It's one area, as I was mentioning to Senator Isakson, where we really feel like we need better information.

Senator BURR. But isn't that a crucial comparison that we need to make? I mean, as a layman, I would think that hospitals were more susceptible because of the intervention needs of that patient, where outpatient surgery centers—is it part of the actual surgery where the infection is incurred, or is it in the days after as they're in the facility?

Dr. BELL. These days, there are a lot more complicated surgeries that are taking place in ambulatory surgery centers. So this sort of clean break between the hospital and the ambulatory surgery center is perhaps not as clean as it once was.

Also, we've had many years now of work in hospitals to reduce healthcare-associated infections, and we've shown progress, for example, in reducing surgical site infections in hospitals. We don't have the same history in ambulatory surgery centers. And some of the principles that we've applied about communication, about measurement, about team work, and about infection control are really principles that we think need to be strengthened in ambulatory surgery centers.

Senator BURR. Is there any dispute that the VA within their hospital system decreased their infection rate with a simple mandate that every person who enters a room uses a hand sanitizer when they enter and uses a hand sanitizer when they leave?

Dr. BELL. I'm not familiar with that specific instance with the VA, Senator. But I can certainly agree that hand washing is probably the single most important thing that anyone can do to prevent transmission of infections.

Senator BURR. Has every hospital in the country adopted a philosophy similar to that, where you sanitize before you go in and you sanitize when you leave?

Dr. BELL. Yes, sir. I think that's probably fair to say.

Senator BURR. You think every hospital has adopted that?

Dr. BELL. I think every hospital certainly has a policy about hand washing.

Senator BURR. Dr. Conway, I want to reiterate something that I think Senator Isakson hit on, and I'm going to state it in a slightly different way. If the reimbursement system that we have in place suggests that you may or you may not be reimbursed for innovation, let me suggest to you that innovation will get to a point and not exceed that.

Now, if from a standpoint the studies that CDC is going through, which I think have been supported, that in part it's the changes in practices, in part it's fueling innovation for new treatments so that we can cure the infection as quickly and as cost effectively as we can, we can get to a point that we can't get past if, in fact, there's not confidence that CMS will properly reward the innovation from the bench. So we've got legislation in place that promotes it.

I would say to my colleagues that's not necessarily going to solve this problem if, in fact, people who venture down this road aren't convinced that the reimbursement of their intellectual property, their cost of development, in some cases, half a billion dollars—and I think Dr. Bell was correct—we're finding out the development of the next class of antibiotics is going to be a very long time coming. If the certainty is not there, this innovation won't happen.

I thank the Chair.

The CHAIRMAN. Thank you very much, Senator Burr.  
Senator Casey.

#### STATEMENT OF SENATOR CASEY

Senator CASEY. Dr. Conway and Dr. Bell, thanks for your testimony and for your good work. I wanted to focus on children and, in particular, what a lot of the experts that we talk to—and I know that you're both in that category—and, certainly, child advocates always remind us that children aren't small adults, so we always have to have treatment regimens and approaches to them that might differ from how we deal with adults.

Dr. Conway, I wanted to start with you. With regard to both the question of hospital-acquired infections as well as the efforts to reduce readmission rates, is there a particular strategy or focus that you've brought to bear as it relates to children? I notice in your testimony there's a section entitled, Hospital Readmissions, but I didn't see anything in there about children. Is there anything you can tell us about how you approach children with regard to both those issues?

Dr. CONWAY. Senator Casey, thank you for the question. Especially as a pediatrician, I always appreciate talking about children. Two things—on the healthcare-acquired infections, children are a focus. Actually, one of our hospital engagement networks is a children's hospital association network led by Steve Muething at Cincinnati Children's involving CHOP and many leading children's institutions. They've generated dramatic results in decreasing healthcare-acquired infections for children—so I'd want you to hear that—really powerful, good results.

On the readmissions, this is an area where I think it is important to note that children have some differences from adults, and there's some research in this area. So you have more of your healthy children, who have one set of issues, on sort of care coordination services—back to the community.

One of the major issues in pediatric healthcare for readmission—and this is the population I mainly take care of in the hospital—is children with multiple chronic conditions. I think there, we really need to think about a medical home that serves that family, from a social service as well as a direct healthcare delivery standpoint.

A number of children's hospitals are doing very innovative work on medical homes in neighborhoods and accountable care organizations for children with complex healthcare needs. And we'd love to help share some of that work and think through how we could accelerate that work with you.

Senator CASEY. With regard to the Affordable Care Act, both as it relates to children and readmissions, but also more broadly for the entire population, can you speak to the impact, or can you measure the impact of the ACA to date on readmissions?

Dr. CONWAY. On readmissions, when we started the readmission program and our investment in QIOs and Partnership for Patients—I have a run chart on my wall—a quality improvement tool—that shows rock solid readmissions 19 percent to 20 percent

for decades in the Medicare population. And we can come back to children.

One of my colleagues said it has dropped like a rock. It has significantly declined in the last 18 months, and people did not know if that was possible. And I think it's a combo of negative payment adjustments for poor performance and investing in quality improvement.

I was with colleagues, chief medical officers—and you'll hear from one in a little bit—who said,

“You know, we used to have these care coordination programs for people with congestive heart failure. We stopped them because our hospital was losing money. Now we've realigned those incentives.”

That same person told me just recently, “We've reinvested in these clinics that help coordinate care for people with multiple chronic conditions.”

That's what we want out of our health system. We want a coordinated health system where people are investing in better health. In readmissions, we've made dramatic progress in improvement across the Nation.

Senator CASEY. In about a minute that I have left, Dr. Bell, I wanted to ask you about—and you certainly spoke to this in your testimony and by way of questions. But could you just itemize for me the way that CDC is working with hospitals on both—well, let me just limit it to hospital-acquired infections. What's kind of the list of things that you engage with them on?

Dr. BELL. Very quickly, first of all, we help hospitals collect data about healthcare-associated infections and use that data to benchmark and track progress and find problems. That's the National Healthcare Safety Network. And this is an infrastructure that's provided to hospitals and that they use in real time.

Second, we provide them with tools to help them figure out how to solve problems when they get them. These come out of our guidelines and out of a lot of the sort of applied research that we do to figure out what is the right thing to do.

And the third thing that we do with hospitals is oftentimes connect them with other resources in the community, health departments, CMS, QIOs, so that they can take advantage of all the expertise that's available to them.

And, of course, fourth, we hate to see outbreaks, but at the same time, we want people to be looking at what's going on in their hospitals, and we support them and help in outbreak investigations, in laboratory testing when things get very complicated, and, generally speaking, in providing any other kind of technical assistance of that sort.

Senator CASEY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey.

Senator Baldwin.

#### STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you, Mr. Chairman and Ranking Member. I'm pleased that you've held this hearing today. It's one of the

key issues that we need to grapple with if we are going to transform to a high-quality and lower-cost healthcare system. I want to associate myself also with Senator Whitehouse's remarks about urging the Administration to set a numerical goal, a dollar goal, as opposed to the terminology we've become so familiar with of bending the healthcare cost curve, which is too nebulous, I have to say.

I wanted to make a couple of points and recognize, Mr. Chairman, that you'd like to hear from our second panel, as would I, before our votes are called on the floor at 11:45—but just a couple of points and observations and maybe some comment back. I'm very proud of the figures emerging out of Wisconsin. It was almost a decade ago that a voluntary quality reporting data base was created through a partnership, with very promising reports. I think Wisconsin hospitals have a 56 percent lower level of healthcare-acquired infections than the national average.

So we're proud of that, but obviously want to do better and understand what public policy drives us in that direction as well as what sort of private-public partnerships can advance those goals. Over the August recess, I had a marvelous opportunity to visit and have discussions on this very topic with a couple of different folks.

I had a chance to visit a neonatal ICU. Senator Casey was talking about children and adults. But especially with neonatal centers, you have a patient who can't talk about their symptoms, can't explain, and so we're relying on exceptional diagnostics.

In that respect, I also want to share observations from a visit I had with a small business called Isomark, a spin-off from research at the University of Wisconsin, where they've developed a patented technology that can be used to monitor the breath and detect hospital-acquired infections perhaps as early as a couple of hours after onset, serving to make treatment more effective if the need for it can be identified early.

With those two themes in mind, I would ask what you are seeing as the most effective private-public partnerships driving down HAIs, and also the importance you see in early detection of the onset of these infections in patients of all ages.

Dr. CONWAY. I guess I'll start. Dr. Bell can continue. The Wisconsin Quality Collaborative—I've been to Wisconsin and seen that work and talked to Chris Queram, who leads a lot of that work with just tremendous results. That actually will lead to what I think is one of the most effective public-private partnerships.

We are with quality collaboratives in States and regions across this country, partnering with them, thinking about how we can work together, how to drive quality improvement. Even in our recent proposed rule, we put out a proposal where we could potentially essentially deem some of these local measures of quality as meeting Federal programs' needs if they met certain requirements. We've gotten very positive feedback on that.

I applaud Wisconsin and really think those public-private partnerships with collaboratives in the field working with providers is one of our most effective public-private partnerships. And we're doing that a lot through QIOs and Partnership for Patients. Sorry. I'll try to talk faster.

On early diagnostics and innovation, I actually came from a private sector background. We should reward and pay for innovation.

I think it's critical to do so. I don't know the details of that diagnostic, but I'll say early detection—with the residents and medical students I teach in the hospital, I always tell them sepsis is a clinical diagnosis with your clinical acumen and the diagnostic tools we have at our disposal. You'll hear more about that in the next panel, but I think it's critically important.

Dr. BELL. Thank you. Just to add a little bit, one of the things that we at CDC have been doing is funding a prevention collaborative—State health departments to set up prevention collaboratives, including, I think, the State of Wisconsin. The point there is for the State health department to be able to look across the continuum of care in all the different groups in a particular community that are working in this area and bring them all together to take advantage of each of their areas of expertise and identify problems and move forward.

I think that sort of underlying everything about healthcare-associated infections is a public-private partnership. And it's one of the roles that we'd like to see State health departments play as they put together these prevention collaboratives in States.

I think your point about early detection—CDC is all about early detection. And I can't emphasize too much how critical it is that hospitals learn how to identify infections early. As I mentioned, it's just very unfortunate the number of outbreaks that we end up investigating. And when we look back, we find that there were any number of infections that had occurred, and that somehow the dots were not connected, and there just wasn't the kind of awareness that we'd better think about this, that maybe something's going on.

That's something that we try to emphasize in every situation. And, certainly, it's a message from many of our outbreak investigations.

The CHAIRMAN. Thank you, Dr. Bell.

Thank you, Senator Baldwin.

Thank you both very much for your great testimony. Before you leave, I'll just ask unanimous consent that the record stay open for 10 days for additional statements and questions by Senators. That would apply both to this panel and the next panel.

Thank you both very much.

We'll call our second panel up and introduce them. Ciaran Staunton is the co-founder of the Rory Staunton Foundation. Its mission is to educate and conduct outreach efforts aimed at the rapid diagnosis and treatment of sepsis, particularly in children. I'll let Mr. Staunton tell his story, but it's a very tragic story about his 12-year-old son, Rory.

We thank you for being here today, Mr. Staunton.

Dr. Jonathan Perlin is president of Clinical and Physician Services and chief medical officer of HCA, the Hospital Corporation of America. Dr. Perlin is responsible for leading HCA's patient safety programs to eliminate preventable drug resistant healthcare-associated infections.

Prior to that, Dr. Perlin served as Undersecretary for Health in the U.S. Department of Veterans Affairs. As the senior most physician in the Federal Government and Chief Executive Officer of the Veterans Health Administration, Dr. Perlin led the Nation's largest integrated health system.

And we thank you for joining us today.

Mr. Joe Kiani founded the Patient Safety Movement Foundation, with a mission to reduce the 200,000 preventable patient deaths that occur in U.S. hospitals every year. Under Mr. Kiani's leadership, the Patient Safety Movement Foundation held the first Patient Safety Science and Technology Summit in January of this year with former President Clinton as the keynote speaker.

Mr. Kiani is also the chairman of the board of the Masimo Foundation for Ethics, Innovation, and Competition in Healthcare to encourage and promote activities, programs, and research opportunities that improve patient safety. He is also the founder, chairman, and CEO of Masimo Corporation.

I'm sorry. I made an oversight. I want to yield to Senator Alexander for purposes of an introduction.

Senator ALEXANDER. I think you did a good job of introducing Dr. Perlin.

The CHAIRMAN. I'm sorry. I didn't read my notes.

Senator ALEXANDER. No, no. I join you in welcoming him. He has appeared here before. He's the chief medical officer of the Hospital Corporation of America, and he's been a leader in this area. I look forward, especially, to his report about how HCA has tackled this problem both in terms of prevention, detection, and his comments about antibiotics and what we can do there.

So thank you, Mr. Chairman, and thank you, Dr. Perlin, for being here again.

The CHAIRMAN. Thank you, Senator Alexander.

Again, your statements will be made a part of the record in their entirety. I'd ask that you sum up in 5 minutes.

Mr. Staunton, we'll start with you. Please proceed.

**STATEMENT OF CIARAN STAUNTON, THE RORY STAUNTON  
FOUNDATION, NEW YORK, NY**

Mr. STAUNTON. Thank you, Mr. Chairman.

Thank you, Ranking Member Alexander, and members of the Senate committee. And I thank your wonderful staff who have organized us here today.

My name is Ciaran Staunton. I am Rory Staunton's dad. I'm here today with my wife, Orlaith, and Rory's sister, Kathleen, is also here with us today. Rory's Uncle Fergus is right behind me. He is a Minister in the Irish government. They have recently had some movement on sepsis themselves, some initiatives.

Our son died from sepsis. However, before I give you our personal testimony, I'd like to acknowledge all of the families and the loved ones who are here today, including Carl Flatley to my left, whose daughter, Erin, died from sepsis in 2002 at the age of 23.

This is a long awaited day for many sepsis advocates, those who have lost loved ones and sepsis survivors such as Renita Kilby here, who came here in a wheelchair from Fredericksburg, VA, and those in the medical profession globally who have worked tirelessly to raise the awareness of sepsis. I thank you all.

Mr. Chairman, I'm not going to go through a lot of statistics, but I will give you a few facts that I hope everyone watching and hearing remembers. Sepsis kills more Americans than AIDS. Sepsis kills more American children than pediatric cancer. Sepsis is the



most expensive condition billed to Medicare. Sepsis costs the American economy \$17 billion a year. It is the most expensive reason for hospitalization.

Our son, Rory, died tragically on April 1, 2012. Mr. Chairman and Senator Casey, that was 2 weeks exactly after both of you shook hands with our son in the White House on Saint Patrick's Day. He was dead from sepsis. This was a day that no parent ever wants to go through. It was the day a beautiful young man died from sepsis, something we had never heard of until our son was dead. It was the day our daughter, Kathleen, lost her adoring big brother.

Following Rory's death, we read the statistics that 70 percent of Americans had never heard of sepsis. We also discovered that it is one of the largest killers, not just in the United States but in the world, yet sepsis has not received the attention it deserves from governments throughout the world or, indeed, our own government up until today. This is why the Staunton family, through the Rory Staunton Foundation, is determined to change this.

Our beloved son's tragic death from sepsis began on Wednesday when he fell and scraped his elbow while playing in his school gym. The gym teacher proceeded to cover the wound without washing it and did not send him to the school nurse who was in her office. This was the first of many institutional failures.

When Rory came from school, he hung out, did his homework, had some pizza, and went to bed. Later, my wife heard him in the bathroom, and he was saying, "It's my leg. It's my leg." The next morning, we called his pediatrician, Dr. Susan Levitzky, immediately. Rory's temperature was 104. He never had a temperature that high. We had tried some over-the-counter medications. None of it was working.

She agreed to see him at 6 p.m. that evening. He was unable to make it to the car, and his mom had to assist him. When we got to the pediatrician's office, she noted that he was shivering. He had 102 auxiliary. She noticed his pulse was 140, his blood pressure was 100 over 60, and his respirations were 36 per minute. We pointed out his skin, which the pediatrician noted as being mottled and blanched.

She noted that he had upper abdominal pain and had a cut on his left elbow. We told her it was the pain in his leg that he was screaming about. He vomited a large amount of yellowish fluid, and Rory said, "It's the pain in my leg that's bothering me." The pediatrician said it was from the fall.

Nonetheless, she referred him to the emergency room for rehydration with a diagnosis of gastric flu. This represents the second incidence of an institutional failure. At the emergency room, they concurred with the diagnosis of gastric flu, ignoring any other symptoms. They gave him IV fluids. We didn't know then, but, in fact, blood tests were ordered stat. As far as we know, they were never read.

What we do know is that he was discharged, and these blood results, when returned to the ER, showed that among other alarming signs, Rory's blood was producing white blood cells at rates that were very abnormal and would suggest a serious bacterial infection. Twelve minutes before Rory left NYU Langone Hospital in

New York, his vital signs were taken, and his condition had deteriorated.

No one took the time to review all available information. They discharged him, noting “patient improved,” despite the fact that his vital signs were totally irregular and had deteriorated since his arrival there. The hospital staff concluded that he had a sick stomach and was suffering from dehydration. This flu, they said, might take up to a week to clear and that he would have diarrhea, but would feel better in a few days. This was the third and final failure of an institution, causing Rory’s death.

On the following morning, Friday, Rory’s temperature was still very high. He was very tired. His leg hurt a lot, and he was very dizzy. We were not convinced that this was a stomach virus, and we began calling his pediatrician. She told us not to worry about the temperature. She told us to focus on getting food into him.

Despite our attempts to convince her that that was impossible, we nonetheless tried to get Gatorade, Sprite, ginger ale, Coke—anything we thought he would drink. We even tried some chicken soup. He took one sip and returned to sleep. He had diarrhea, and we were happy because we thought this was what the pediatrician had told us was a sign of intestinal flu.

His mom stripped him down and checked to see if they had missed a bug bite. She also checked him for signs of meningitis. Finally, that evening, Mr. Chairman and members, seeing our son’s skin turn black and blue and his face begin to turn yellow, we took him to the ER where all hell broke loose.

Despite the best efforts of the wonderful staff in the ICU, our son, Rory, died at 6:29 p.m. on April the 1st. He was in severe septic shock with multiple organ failure. Our beloved son was the light of our lives. Some of you met him, as I said earlier.

He was a child no one would ever forget. He was only 12 years old, and he was already five-foot-nine and over 160 pounds. He was very interested in life and had many questions on international politics, science, technology, and the ways of the world. And unlike many young children, CNN was his favorite station.

He was captain of his school debate team, and he had won many awards for speaking. He was on the Lego Robotics team. He was elected by his peers to serve on the school’s Student Council.

An advocate for children with special needs and working in conjunction with the Special Olympics, Rory had already set up a campaign to curtail the use of the “R” word at his school. The “R” word, meaning retard, is a word that is used as a put-down term by some children. Rory was deeply upset by the use of this word and had the children at his school sign a pledge that they’d no longer use it.

He was a natural leader, eyeing a career in politics or aviation. He dreamed of being the next Sully Sullenberger. He read and reread Sully’s memoir. Rory had already flown an airplane for his 12th birthday. And although he was only six when Rosa Parks died, he had already read everything about her. Her bravery deeply affected him.

We believe, as those around him do, that the world has lost an incredible human being who was also a fantastic big brother to his sister Kathleen. After Rory died, we found a letter that he had

written to the Swedish Ambassador to North Korea asking how a country like North Korea could afford such an enormous army and have such a famine at the same time.

Mr. Chairman, we have most of the others in the records. But let me just say that we, as a family, are compelled that no other family should go through what we are going through. No parent should have to buy a coffin for their child. No little girl should have to say goodbye to her brother.

We see the statistics that are still going on, and we know for a fact since we actually started our campaign, we have received emails from people saying, "Because of your campaign, you have saved our child." And that is why we got New York State to pass the Rory Regulations. Those regulations will save between 6,000 and 8,000 New Yorkers every year.

What happened to Rory, unfortunately, could happen to any of your children. It still happens, and we want to make sure that everyone looking at this looks as a parent or a grandparent. In Britain, they've already acknowledged they have to re-look at us. It's our call to many.

And, finally, Mr. Chairman and members, sepsis is treatable. Treatment reduces costs and saves lives. Our Rory shouldn't have died. No one else's child should. And with the help of these hearings today, many American lives will be saved.

Thank you very much.

[The prepared statement of Mr. Staunton follows:]

#### PREPARED STATEMENT OF CIARAN STAUNTON

Chairman Harkin, Ranking Member Alexander and members of the Senate Health, Education, Labor, and Pensions Committee, and your wonderful staff—thank you for inviting me here to testify at this important hearing, "U.S. Efforts to Reduce Healthcare-Associated Infections." My name is Ciaran Staunton. I am Rory's Staunton's dad. I am here today with my wife, Orlaith and Rory's sister, Kathleen.

My son Rory died from sepsis. However, before I give you our personal testimony, I would like to acknowledge all of the families and loved ones who are here today including Carl Flatley, Erin Flatley's dad. Erin died from sepsis at age 23 in 2002. This is a long awaited day for sepsis advocates, those who have lost loved ones, sepsis survivors, and for those in the medical profession globally, who have worked tirelessly to raise awareness of sepsis. I thank you.

- Sepsis kills more Americans than AIDS.
- Sepsis kills more American children than pediatric cancer.
- Sepsis is the most expensive condition billed to Medicare. (Weir, HCUP Statistical Brief #107, 2011)
- Sepsis costs the American economy over \$17 billion a year. It is the most expensive reason for hospitalization. (Hall, NCHS Data Brief, No.62, 2011)

Our son Rory died tragically on April 1, 2012 and that was the day our lives changed forever. It was the day that no parent ever wants to go through. It was the day our beautiful young man died from sepsis, something we had never heard of before. Following his death we read the statistic that 70 percent of Americans had never heard of sepsis and we also discovered that sepsis is one of the largest killers not only in the United States but in the world. Yet, sepsis has not received the attention it deserves from governments throughout the world or indeed up until today in these United States. The Staunton family, through The Rory Staunton Foundation, is determined to change this situation.

The story of our beloved Rory's tragic death from sepsis begins on Wednesday when he fell and scraped his elbow playing in his school gym. The gym teacher proceeded to cover the wound without washing it and did not send him to the school nurse who was in her office. This was the first of many institutional failures.

When Rory came from school he hung out, did his homework, ate some pizza and went to bed. A little after midnight, in the early hours of Thursday morning, we

awoke to hear Rory throwing up in the bathroom, not a lot of sickness but he was screaming “my leg, my leg.” My wife, Orlaith brought him back to bed and he fell asleep as she rubbed his leg. The following morning he had a fever and continued to complain of the pain in his leg.

We began calling his pediatrician immediately as his temperature was over 104 (he had never had a temperature that high) but more worrying was that the over-the-counter medication commonly used, wasn’t bringing the temperature down. After many calls to the pediatrician’s office, she called us back and we insisted that she see him. She agreed to see him at 6 p.m. that evening. On Thursday evening, supported by his mom as he was unable to make the journey on his own, Rory made his way to her office where she, the pediatrician noted that he was shivering, had a fever of 102 auxiliary and had an extremely red throat.

- his pulse she noted as 140,
- his blood pressure 100/60,
- his respirations were 36 per minute.

We pointed out his skin, which the pediatrician noted as being mottled and blanched.

She noted that he had upper abdominal pain and had a cut on his left elbow.

We told her it was the pain in his leg that he was screaming about. He vomited large amounts of yellowish fluid while in her office. Rory said, “It’s the pain in my leg that’s bothering me.” The pediatrician said it was from the fall, he said no.

Nonetheless she referred him to the Emergency Room for re-hydration with a diagnosis of gastric flu. This represents the second incidence of an institutional failure.

At the emergency room they concurred with the diagnosis of gastric flu, ignoring any other symptoms present. They gave him IV fluids. We didn’t know then, but in fact blood tests were ordered stat., however as far as we know they were never read.

What we do know is that he was discharged and these blood results, when returned to the ER, showed among other alarming signs that his blood was producing white blood cells at rates that were very abnormal and would suggest a serious bacterial infection.

Twelve minutes before Rory left the hospital his vital signs were taken, his condition had deteriorated. It appears that no one took the time to review all available information. They discharged him noting “patient improved,” despite the fact that his vital signs were totally irregular and had deteriorated since his arrival there. The Hospital staff concluded he had a sick stomach was suffering from dehydration.

This flu they said, might take up to a week to clear. They said he will have diarrhea but will feel better in a few days. This was the third and final failure of an institution causing Rory’s death.

On the following morning, Friday, Rory’s temperature continued to be high, he was very tired, his leg hurt a lot and he had complained of dizziness. We were not convinced of the stomach virus diagnosis, and we began calling his pediatrician.

The pediatrician told us not to worry about the temperature. We were told to focus on getting food into him. Despite our attempts to convince her that that was impossible, we nonetheless bought him Gatorade, sprite, ginger ale, coke—anything we thought he would drink. Late that afternoon we made a trip to get chicken soup. He took one sip and returned to sleep. He had diarrhea and we were elated as the pediatrician told us to expect this—a common sign of intestinal flu. We thought for sure this was definitely the stomach virus they told us about.

His mom stripped him down and checked to see if they had missed a bug bite. She also checked him for signs of meningitis.

Finally that evening, seeing his skin turn blue/black and his face begin to turn yellow, we returned with him to the ER where all hell broke loose. Despite the best efforts of the wonderful staff in the ICU our son Rory died at 6:29 p.m. on that Sunday evening, April 1, 2012. He was in severe septic shock with multiple organ failure.

Our beloved son Rory was the light of our lives. He should never have died.

Rory was a child no one ever forgot. Although, only 12 years old, he was already 5’9” tall and weighed over 160 pounds!

Rory was deeply interested in life and had many questions on international politics, science, technology and the ways of the world. In fact, CNN was his favorite station!

He was captain of his school debate team where he had won many awards for speaking, he was on the Lego Robotics team, and he was elected by his peers to serve on the school’s Student Council.

An advocate for special needs children and working in conjunction with the Special Olympics, Rory had already set up a campaign to curtail the use of the “R” word at his school. The “R” word being the word “retard”, a put-down term used by some children. Rory was deeply upset by the use of this word and had the children at his school sign a pledge to stop using it.

He was a natural leader, eyeing a career in politics or aviation. He dreamed of being the next Sully Sullenberger. He read and reread Sully’s memoir. He had already flown his first airplane, a 12th birthday gift from us. Although he was only 6 when Rosa Parks died, he had already read everything about her. Her bravery deeply affected him. We believe, as those around him do, that the world has lost an incredible human being who was also a fantastic big brother to his sister Kathleen.

After Rory died we found a letter that he had written to the Swedish Ambassador to North Korea asking how a country like North Korea could afford such an enormous army and experience such famine at the same time. Rory had such an incredible moral compass.

Rory was named President of “Kidadelphia”, a country formed by his neighborhood friends whose motto was, “In God and Fun We Trust.”

Here is how others in the world saw Rory:

- “He was the most profound 12-year-old I have met,” Kevin Burgoyne/Debate Coach and Sixth Grade Humanities teacher.
- “It was possible to look at a child and, as an adult said, I could be more like him,” Roger Hitts, President Sunnyside Gardens Park.
- “Even after one meeting, I knew I would never forget him and I would say the same about his sister Kathleen. Two powerful young people,” said, Pulitzer Prize winner and *New York Times* writer, Jim Dwyer.

After he died, we discovered that Rory had died from sepsis. In our deep state of despair we were shocked to find out that sepsis kills more Americans than the combination of breast cancer, lung cancer and stroke combined. It kills more Americans than AIDS. It is the largest killer of children in the world—6 million.

We as a family felt compelled to ensure that no other child or adult died because of this killer. We contacted our New York State Governor Andrew Cuomo. He shared our anger and he immediately put us in touch with the New York Health Commissioner Nirav Shah. Commissioner Shah felt an urgent need to address sepsis and vowed to change New York State policy.

Working with us, Commissioner Shah and Governor Cuomo announced the introduction of “Rory’s Regulations.”<sup>1</sup> These regulations, named for Rory now require all hospitals in New York State to adopt protocols to identify and treat sepsis. The protocols will be evidence-based and will in addition; deal with fluid resuscitation timeframes for infants and children. It includes the demand for sepsis training of all staff including laboratory and pharmacy. The sepsis regulations were adopted on May 1, 2013 with the support of all New York hospitals. Rory’s Regulations will help New York set a “gold-standard” for patient care. Governor Cuomo believes that 5,000 to 8,000 lives a year in the State of New York will be saved as a result of Rory’s Regulations.

Sepsis is a medical emergency. It is the body’s often deadly response to infection. It requires early detection and treatment for survival. Every minute counts. Administration of antibiotics and fluids saves lives. For example, Intermountain Health Care in Utah reported savings of \$38 million per year as a result of a sepsis program. When the Intermountain team launched a protocol-based approach to improving sepsis care, the health system’s 25 percent sepsis mortality rate was already below the national average. Four years later Intermountain had a 9 percent mortality rate; as a result, Intermountain saves 85 more lives each year and saves \$38 million in annual costs. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012)

Experts agree that key to fighting sepsis is ensuring quick diagnosis and treatment within the “golden hour,” when it can be most effective.

The New England Journal of Medicine states,

“... During septic shock, there is an absolute decrease of 7.6 percentage points in the survival rate for each hour.” ((10.1056/NEJMe1203412) was published on May 22, 2012, at NEJM.org) Global Sepsis Alliance concurs, that we must ‘recognize sepsis as a medical emergency requiring administration of fluids, antibiotics and other appropriate treatments of infection within 1 hour of suspicion of sepsis.’”

<sup>1</sup> <http://w3.health.state.ny.us/dbspace/propregs.nsf/4ac9558781006774852569bd00512fda/4774b2c3cb19d1a385257b02005e2fdb>.

Pilot initiatives in some hospital systems have shown great strides in decreasing sepsis mortality through effective implementation of what is basically a “check list”—a standardized protocol to facilitate quick and accurate diagnosis and fast and effective treatment as soon as any sign of sepsis arises. A recent multi-hospital report showed that mortality rates dropped in half with these basic steps. (Miller, *Am J Resp Crit Care Med* 2013).

If this strategy was applied to all Americans, it could save more than 150,000 lives a year—more than 400 people a day,

But only one State has required these simple protocols be implemented in all hospitals. New York State’s adoption of Rory’s Regulations represents the first government in the United States mandating evidence-based protocols for the early diagnosis and treatment of sepsis.

Sepsis is a medical emergency. Sepsis needs to be suspected; once it is suspected and treated we can save lives and save the U.S. economy billions.

We are calling on Congress to institute a Federal nationwide program of education on early detection of sepsis with similar standards in all 50 States. We are also calling on Congress to create a comprehensive educational resource so that doctors, nurses and, yes, parents and patients can include sepsis as a possible diagnosis when a patient shows up in an emergency room with similar symptoms to Rory. Sepsis is not a deadly disease when caught in time. Antibiotics are remarkably effective and many die from ignorance of how to recognize the condition as Rory did.

Mr. Chairman we have heard from at least five sets of parents since Rory died who are certain that Rory and the publicity surrounding his case saved their children’s lives when their kids began to suffer from similar symptoms and they demanded that doctors test for it. We want to ensure that it becomes common practice in every State in the union that such tests and consideration of a sepsis diagnosis be the norm in medical practice. There can be no more Rorys. Our hearts are broken and we want to ensure that no other parent lives through this nightmare. Know that the care that Rory received is not unusual for sepsis patients in America, is this the care you would choose for your children?

In Britain, the government there recently outlined a complete overhaul of sepsis procedures after an examination that revealed 37,000 people had died, many of them needlessly.<sup>2</sup> We in America can hardly fail to match that.

Rory’s story of sepsis was a wakeup call to many. We believe that knowledge is power. If we had known about sepsis, Rory would be alive today. If Rory’s doctors had suspected sepsis he would be alive today. Unfortunately, there are many, many Rory’s in the United States.

There is hope. Sepsis is treatable in a manner that reduces costs.

The Rory Staunton Foundation seeks to reduce the number of sepsis-caused deaths through education and outreach. Our son Rory should not have died. The Rory Staunton Foundation will work tirelessly to advocate for changes and press ahead with awareness and education regarding sepsis.

Thank you for your attention today.

The CHAIRMAN. Mr. Staunton, thank you very much, and I’m sorry that in the interest of time we had to move on. But I again want to thank you for turning your anguish not into a withdrawal, but into a very positive movement—you and your wife and your family—to use this terrible tragedy as something to alert people and to, hopefully, engage people all around the world to focus on this issue.

So my thanks to you and congratulations for having the courage to do this in the face of this terrible tragedy in your own family.

Mr. STAUNTON. Thank you for highlighting the case, sir, and the whole issue, sir.

The CHAIRMAN. You bet.

Dr. Perlin.

<sup>2</sup> <http://www.theguardian.com/society/2013/sep/12/nhs-patients-dying-sepsis-care-failings>.

**STATEMENT OF JONATHAN B. PERLIN, M.D., Ph.D., MSHA, FACP, FACMI, PRESIDENT, CLINICAL AND PHYSICIAN SERVICES AND CHIEF MEDICAL OFFICER, HCA/HOSPITAL CORPORATION OF AMERICA, NASHVILLE, TN**

Dr. PERLIN. Good morning, Chairman Harkin, Ranking Member Alexander, and members of the committee. Thank you for the opportunity to present this testimony. It is a privilege to be here. I am Dr. Jonathan Perlin, president, Clinical and Physician Services and chief medical officer of Hospital Corporation of America.

First, I would like to take a moment to recognize the family of Rory Staunton, to whom I offer my deepest sympathy and whose commitment to elevating attention to sepsis and its prevention inspires the work we do.

I would also like to take a moment to thank Senator Burr and other members of the Senate Veterans Committee who are so supportive in terms of improving health, infection prevention, and outcomes for America's veterans in a way that could teach all American healthcare.

Today, I would like to speak to how a learning health system can help address some of our Nation's most pressing challenges in infection prevention and patient safety, like sepsis. Specifically, I would like to discuss how the REDUCE MRSA study provides a model for rapidly and efficiently accelerating the prevention of healthcare-associated infections and could be applied to improving the early recognition and treatment of sepsis.

Healthcare-associated infections, HAIs, or infections acquired through medical care, afflict almost 2 million patients annually. About 80,000 of those patients die. Most HAIs are preventable. Beyond the catastrophic human toll, avoidable infections also represent the unnecessary use of healthcare resources.

A major concern with healthcare-associated infections is antibiotic resistance. Used unnecessarily or inappropriately, antibiotics kill the most susceptible organisms and, in their void, create a favorable environment for the selection of more resistant bacteria, resulting in a scary alphabet soup of superbugs, including *C. diff.*, MRSA, CRE, multidrug-resistant TB, VRE, among others, that threaten even the healthiest patients.

I'd like to talk about our work to combat one of these superbugs, MRSA. HCA in partnership with CDC, AHRQ, Harvard Pilgrim Health Care, UC Irvine, Rush Medical College, and Washington University, recently concluded the REDUCE MRSA study. MRSA, along with *Staph aureus*, generally, account for approximately one-quarter of all deaths from hospital-acquired infections. With the goal of preventing all potentially avoidable harm, prevention of MRSA infections is a national priority.

The REDUCE MRSA trial, conducted across 74 intensive care units at 43 HCA-affiliated hospitals, involving 74,000 patients, answered the question of which of three alternative approaches to prevent MRSA infection is truly best. The answer sets a new standard for infection prevention.

This trial showed that universal decolonization, using antimicrobial soap and nasal ointment at the time of admission for all ICU patients, reduced all bloodstream infections, including those caused by MRSA, by 44 percent. This study demonstrates the

power and efficiency of a learning health system, defined by the Institute of Medicine as one committed to both the generation and use of scientific evidence in practice.

REDUCE MRSA is notable not only for its outcomes, but for its methods. It didn't take a single hospital 43 years. It took 18 months. It didn't take a single-purpose research team, but was implemented by healthcare professionals during the course of routine patient care.

The study didn't occur in a laboratory, but within community hospitals across the country. This type of pragmatic research answers real-world questions in real-world environments that generalize to real-world situations, and it provides a powerful model for accelerating science.

The principles can be applied to accelerating the understanding, prevention, and treatment of sepsis. Sepsis can result from community and, as noted earlier, hospital-acquired infections. Not everyone who has an infection develops sepsis, yet everyone with sepsis has an infection.

The learning health system platform can help us discover which clinical and biochemical indicators suggest risk for sepsis, become sharper in recognizing sepsis and intervening earlier, and build the evidence defining best treatment. The current state-of-the-science provides insight into markers of severe sepsis, and the state-of-the-art is to put the science into use through a campaign to recognize severe sepsis as early as possible.

But turning the clock back further is required. Metaphorically, we can identify the building that's on fire. We need to be able to recognize risk for sepsis, and that means we need to be able to see the earliest signs of smoke, and even prevent fires. Methods used in the REDUCE MRSA study can help us identify early signals, test competing care strategies, and determine the best practices in fighting sepsis and reducing its catastrophic toll.

In closing, I would like to commend CDC and this committee, Senator Harkin, Senator Alexander, and members, for your support of a learning health system. HCA joins in your support of CDC through its participation in the CDC Corporate Roundtable. And REDUCE MRSA study was not only one of the largest trials ever done. It was one of the most efficient. Its results save lives, save resources, and suggest scientifically informed policy.

Thus, I encourage your continuing support of the work of CDC, AHRQ, NIH, CMS, and other Federal agencies in fostering pragmatic research to combat the threat of antibiotic resistance, healthcare-associated infections, and sepsis. I would like to acknowledge our collaborators, in particular, Richard Platt, Susan Huang, and John Jernigan, the CDC Prevention Epicenters Program, and AHRQ.

On World Sepsis Day, and in the presence of the family of Rory Staunton, it seems a fitting time to commit to a learning health system.

Thank you, Chairman Harkin, Senator Alexander, and members of the committee, for your leadership.

[The prepared statement of Dr. Perlin follows:]



## PREPARED STATEMENT OF JONATHAN B. PERLIN, M.D., PH.D., MSHA, FACP, FACMI

Good morning Chairman Harkin, Ranking Member Alexander, and members of the committee. Thank you for the opportunity to present this testimony—it is a privilege to be here. I am Dr. Jonathan Perlin, president, Clinical and Physician Services and Chief Medical Officer of Hospital Corporation of America (HCA).

First, I would like to take a moment to recognize the family of Rory Staunton, to whom I offer my deepest sympathy and whose commitment to elevating attention to sepsis and its prevention inspires the work we do.

Today, I will speak to how a learning health system can help address some of our Nation's most pressing challenges in infection prevention and patient safety. Specifically, I would like to discuss how lessons from the REDUCE MRSA study provide a model for rapidly and efficiently accelerating the prevention of healthcare-associated infections and could be applied to improving the early recognition and treatment of sepsis.

## BACKGROUND

Healthcare-associated infections (HAIs), or infections acquired through medical care, afflict almost 2 million patients annually. About 80,000 of those patients die. Most HAIs are preventable. Beyond the catastrophic human toll, avoidable infections also represent the unnecessary use of healthcare resources.

A major concern with HAIs is antibiotic resistance. Used unnecessarily or inappropriately, antibiotics kill the most susceptible organisms and, in their void, create a favorable environment for the selection of more resistant bacteria. This has resulted in a scary alphabet soup of superbugs, including *Clostridium difficile* (*C. diff*), Carbapenem-resistant Enterobacteriaceae (CRE), Methicillin-resistant *Staphylococcus aureus* (MRSA), multidrug-resistant tuberculosis (MDR TB), and Vancomycin-resistant Enterococcus (VRE) that is threatening even the healthiest patients.

In a recent report *Antibiotic Resistance Threats in the United States, 2013*, The Centers for Disease Control and Prevention recommends a four-pronged strategy to address resistance:

- (1) prevention of infections;
- (2) tracking resistant bacteria;
- (3) improved use of antibiotics; and
- (4) development of new antibiotics and diagnostic tests for resistant bacteria.

This is complemented by increased attention to reducing the overuse of antibiotics, selecting the most appropriate and organism-specific antibiotic for each clinical situation, and prescribing and complying with courses of therapy for the recommended duration of time. Good stewardship, or the careful use of antibiotics in both humans and animals, improves patient outcomes and enhances the prevention and treatment of HAIs and sepsis.

## REDUCE MRSA AND THE LEARNING HEALTH SYSTEM

I would like to talk about our work to combat one of these superbugs, MRSA. HCA, in partnership with CDC, Harvard Pilgrim Health Care, University of California Irvine School of Medicine, Rush Medical College, and Washington University St Louis, recently concluded the REDUCE MRSA trial.

Methicillin-resistant *Staphylococcus aureus*, more commonly known by its abbreviation, MRSA, was identified in the recent CDC report as a serious threat to human health. MRSA, along with *Staphylococcus aureus* generally, account for approximately one-quarter of all deaths from hospital-acquired infections. With the goal of preventing all potentially avoidable harm, prevention of MRSA infections is a national priority.

The REDUCE MRSA trial, conducted across 74 intensive care units (ICUs) at 43 HCA-affiliated hospitals, involving 74,000 patients, answered the question of which of three alternative approaches to prevent MRSA infection in ICU patients is truly best. The answer sets a new standard for infection prevention. This trial showed that universal decolonization—using antimicrobial soap and nasal ointment at the time of admission for all ICU patients—reduced *all* bloodstream infections, including those caused by MRSA, by 44 percent.

This study demonstrates the power and efficiency of a learning health system, defined by the Institute of Medicine (IOM) as one committed to both the generation and use of scientific evidence. REDUCE MRSA is notable not only for its outcomes, but for its methods. It didn't take a single hospital 43 years to amass the power of this study—it took 18 months. It didn't take a single-purpose research team, but was implemented by nurses and infection prevention professionals during the course

of their routine patient care. The study also didn't occur in a laboratory, but within community hospitals across the country. This type of pragmatic research answers real-world questions in real-world environments that generalize to real-world situations, and it provides a powerful model for accelerating science. For more detail of this trial, please refer to the article published in the June 2013 edition of the *New England Journal of Medicine*, *Targeted versus Universal Decolonization to Prevent ICU Infection*. Additional information about the learning health system may be accessed through the commentary published by the IOM, *A win for the learning health system*. Both full-text articles are included as attachments.

#### SEPSIS AND AN OPPORTUNITY TO APPLY THE LEARNING HEALTH SYSTEM

The learning health system, as employed in the REDUCE MRSA trial, is critical to accelerating our understanding, prevention, and treatment of sepsis. Sepsis is a final common pathway for a number of diseases, including community and hospital-acquired infections. Not everyone who has an infection will develop sepsis, yet everyone with sepsis has an infection. The learning health system platform can help us discover which clinical and biochemical indicators suggest risk for sepsis, become sharper in recognizing sepsis and intervening earlier, and build the evidence defining best treatment.

The current state-of-science provides insight into markers of severe sepsis, and the state-of-the-art is to put this science into use through a campaign to recognize sepsis as early as possible. But turning the clock back further is required. Metaphorically, we can identify the building that's on fire. We need to be able to recognize risk for sepsis, and that means we need to see the earliest signs of smoke, and even prevent fires. Methods used in the REDUCE MRSA study can help us identify early signals, test competing care strategies, and determine the best practices in fighting sepsis and reducing its catastrophic toll.

#### CONCLUSION

In closing, I would like to commend CDC, and this committee, for support of a learning health system. The REDUCE MRSA study was not only one of the largest trials ever done; it was one of the most efficient. Its results save lives, save resources, and suggest scientifically informed policy. Thus, I encourage your continuing support of the work CDC, AHRQ, NIH and other Federal agencies do to foster pragmatic research to combat the threat of antibiotic resistance, HAIs, and sepsis. I would like to acknowledge all of our collaborators, in particular Richard Platt, Susan Huang, and John Jernigan, the CDC Prevention Epicenters Program, Harvard Pilgrim Health Care Institute, and the Agency for Healthcare Research & Quality.

On World Sepsis Day, and in the presence of the family of Rory Staunton, it seems a fitting time to commit to a learning health system. Thank you, Chairman Harkin, Senator Alexander, and members of the committee for your leadership.

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The CHAIRMAN. Thank you very much, Dr. Perlin.  
Mr. Kiani, please proceed.

#### STATEMENT OF JOE KIANI, FOUNDER, THE PATIENT SAFETY MOVEMENT, IRVINE, CA

Mr. KIANI. Good morning, Chairman Harkin, Ranking Member Alexander, and members of the committee. Thank you for holding this very important and timely hearing, and thank you for the op-

portunity to speak about the vital efforts underway to reduce the number of healthcare-associated infections and preventable hospital deaths each year.

First, I want to offer my condolences to Mr. and Mrs. Staunton and the families of others who lost loved ones to preventable hospital deaths, both those with us here today as well as the millions of families who are not here.

I am here today because I decided that I can't wait for another person to stop this tragedy. The number of preventable deaths, at 200,000, has doubled since the original IOM report of 100,000 in 1999. That's equivalent to two jumbo jets crashing and killing everyone on board every day. I believe that with your help, we can drop the number of preventable deaths, if not to zero, then very close to that within the next decade.

What I have discovered is that most, if not all, of the causes of preventable hospital deaths have solutions that don't require new research and development or FDA approval. I've also discovered that no one knows the total number of preventable deaths, let alone the number of deaths in each different category of challenges. These facts, while shocking, spell huge opportunity for dramatic improvement in patient safety.

Please allow me to tell you what we have done. We created the Patient Safety Movement Foundation to aggressively address this problem with a mission of zero preventable deaths by 2020.

We believe we can accomplish this by working together and doing the following: unite the healthcare ecosystem, identify the challenges that are killing patients to create actionable solutions for them—we call these patient safety solutions—ask hospitals to implement the patient safety solutions, promote transparency, ask medical technology companies to commit to share their data so that we can create the Patient Data Super Highway and one day use it to help identify patients at risk, correct misaligned incentives, and last but not least, promote love and patient dignity.

I'm happy to report that many hospitals and medical technology companies have already made their commitments and are taking action. We also have made great progress with CMS under Dr. Conway's leadership to do more to ensure patient safety.

At the inaugural Patient Safety, Science, and Technology Summit this year, we developed six patient safety solutions to address the most common causes of preventable patient deaths. At our next summit in January 2014, with the help from the Joint Commission, we will unveil three to four more patient safety solutions and steps we plan to take to achieve our goal of zero by 2020. We will do this one hospital and one med tech company at a time if we have to.

But you can move mountains. We want to thank you, Chairman Harkin and Ranking Member Alexander, for holding this hearing today to highlight this issue. Simply holding this hearing is a great step forward. But you can do much more. We are looking to you to lead and spur changes in government policies to achieve our shared goal of zero preventable deaths by 2020.

We have humbly listed our recommendations in my written testimony. But there are some highlights of things you can do to move us much more quickly to zero preventable deaths that I'd like to share with you here now.

No. 1, create transparency. Improve our understanding and improve consumer choice and knowledge by creating a standardized language and process to define, measure, and report preventable hospital patient deaths, much like SEC does for finance.

No. 2, provide hospitals with incentives and disincentives to reduce preventable deaths. We believe if you suspend payment for even the primary condition until it is determined whether the cause of death was preventable, and when hospitals have not implemented strategies to prevent these deaths, not pay it, they will. Also, if hospitals implement strategies to prevent patient death, not only should they be paid, but they should also be shielded from malpractice lawsuits to the fullest extent possible.

No. 3, create the Patient Data Super Highway. Grant ONC the authority to investigate and decertify products that pursue information blocking practices.

No. 4, promote patient dignity. Mandate that each hospital identify a patient advocate so that their families can get help in real time if they experience lack of empathy or problems with their care.

And last but not least, in every healthcare-related bill that you consider, be sure that innovation in healthcare is not only not impeded, but it is promoted.

In conclusion, the good news is that preventing avoidable patient deaths can largely be accomplished with solutions that are available today. But we all need to act now. Every week, we are losing 4,000 of our family members, neighbors, and friends to preventable healthcare-associated infections and other forms of preventable deaths.

If Congress creates laws that align the incentives of the healthcare industry properly, we can reduce, if not completely eliminate, preventable deaths. We are excited to work with you on this problem and together achieve zero preventable deaths by 2020.

I look forward to your questions. Thank you.

[The prepared statement of Mr. Kiani follows:]

#### PREPARED STATEMENT OF JOE KIANI

Good morning, Chairman Harkin, Ranking Member Alexander, and members of the Senate Health, Education, Labor, and Pensions Committee. Thank you for holding this very important and timely hearing and thank you for the opportunity to speak about the issues related to patient safety and the vital effort under way to reduce the number of healthcare-associated infections and preventable hospital deaths each year.

This is a major problem that is imminently addressable. Despite this fact, healthcare-associated infections and other patient safety hazards persist in causing needless deaths and suffering while increasing healthcare costs. Healthcare-associated infections are a subset of avoidable harms and the larger problem of preventable institutional deaths.

Patient Safety is an issue that has been close to my heart and my area of focus for more than 25 years. As a son of a dedicated nurse, who taught me at a very young age how important it was to help others in need, I grew up with a strong sense of commitment to use my abilities to increase patient safety. As an engineer out of college, I focused on innovation in healthcare and sought to create the best medical technologies possible to deliver hope to families and to our smallest patients—premature babies struggling for their lives. With the assistance of many dedicated people, I have been able to help improve patient care and reduce cost through development of breakthrough technologies.

I fundamentally believe technology and innovation play an important and critical role in the evolution of medicine and patient safety. We know so much less than we could about the human body and disease. When we actually understand the

amazing human body and the root causes of the diseases that plague it, I project our ability to treat, if not prevent or cure, those diseases and the costs associated with this, will be much improved. While we now understand this concept, we are nowhere close to reaching this goal. Therefore, to slow down our commitment to health care innovation would be as shortsighted as failing to invest in the personal computer revolution 35 years ago. One wonders where we would be had we followed the opinion of the Digital Equipment Corp. co-founder, who infamously said in 1977: “There is no reason for any individual to have a computer in his home.” That narrow vision did not work for DEC and it would not have worked for the rest of us, had we embraced it.

We are better off today than we were 100 years ago when the average life expectancy in the United States was 48 years. Today, it is 78, but we still can’t prevent or cure many cancers, nor stop and reverse heart disease. Yet, we can stop most, if not all of the 200,000-plus preventable deaths that occur each year in our hospitals.

This will require an “all-in” commitment, and is the reason I helped found the Patient Safety Movement, a “Network of Creative Cooperation,” as President Clinton put it; a collection of caring clinicians, patient advocates, hospitals, innovators and medical technology companies, who came together to eliminate preventable deaths by 2020. We believe there are seven major areas of work ahead of us:

- Break down the silos and unify the healthcare ecosystem.
- Promote transparency.
- Create Safety Solutions to the challenges that are causing preventable deaths.
- Use incentives and disincentives to reduce preventable deaths.
- Eliminate misaligned incentives.
- Create the “Patient Data Super Highway.”
- Promote Love and Patient Dignity.

At the Patient Safety Movement, we believe addressing the challenges and capitalizing on the opportunities will require all members of the health care ecosystem to actively engage in order to eliminate preventable deaths. Congress has a big role to play in this as you consider public policy options to improve patient safety.

Whether you are young or old, Republican or Democrat, black, or white, religious or not, this is an issue that we all can and must gather around to fix, and fix it now. I believe it is our moral imperative to do all that we can now, because the solutions to many, if not all, of the problems that lead to preventable deaths are available today and do not require new science or FDA approval. They just require us to act—individually and collectively. They require us to make a stand so that mediocrity, disconnections, lack of conviction, apathy, and an “us and them” mentality does not get in the way of what is best for patients.

You have many tools at your disposal, from public health programs that measure and track infections and deaths, to reimbursement systems that create incentives to do the right thing. We stand ready and willing to assist you if you step up and accept the safety challenge.

#### THE PATIENT SAFETY CHALLENGES

Challenges that are causing the preventable deaths, such as hospital-acquired infections, failure to rescue, and medication errors, already have solutions that we just need to implement. But, disconnected information and understanding of the patient care pathway and the inability to share information among providers is another problem that is costing us lives and dollars, and it’s currently without a solution. The case of 12-year-old Rory Staunton, who died of sepsis at a New York hospital in July 2012, is a sad reminder of how the lack of communication between providers, combined with the lack of interoperability among multiple machines in the hospital can contribute to tragedy.

Only a few days after suffering what appeared to be a minor cut from a fall in his school gym, Rory passed away from a septic infection. The data to save him was there—it just wasn’t following him as he visited his providers and wasn’t being communicated properly, and so no one connected the dots.

We need patient data in real time so that caregivers can be alerted by predictive algorithms on the status of their patients in real time, not after a preventable death has already occurred.

If we can bring the machines and IT all together with intelligent predictive algorithms, physicians, along with patients and their families can be informed of dangerous trends; lives can be saved; and process of care can be improved substantially, further reducing cost. Currently such algorithms can’t be realized however, because there is no easy means to integrate the data streams of the numerous medical devices. The “Patient Data Super Highway” that is required for this goal doesn’t exist.

This is because many companies do not allow other companies to have access to the patient data their products produce or capture.

While technology and processes may be arguably half of the solution, empathy and love for the vulnerable is the other necessary half. The dehumanization of people as soon as they become patients in hospitals contributes to preventable deaths. We walk into hospitals as the brave and free and turn into voiceless hostages of an unsympathetic system. I don't buy the argument that if clinicians became involved emotionally with their patients they may not do as good a job. Empathy has a place in health care—it offers patients and their families' dignity and can go a long way toward reducing stress and getting patients and their families to become participants in the care and safety of themselves or their loved ones. An unsympathetic system contributes to suboptimal care, and it is one of the reasons patients and their families often are eager to sue their caregivers if something goes wrong.

#### PATIENT SAFETY: A CHALLENGE THAT WE CAN, AND MUST MEET

Currently we are losing more than 200,000 of our loved ones each year to preventable hospital deaths. Amanda Abbiehl, Lewis Blackman, Leah Coufal, Emily Jerry, and Rory Staunton, are just 5 of the 200,000 precious lives we lose each year in our hospitals.

Each year in the United States, about 2.5 million people die.<sup>1</sup> Of those 2.5 million, 700,000 die in hospitals.<sup>2</sup> Of the 700,000, experts believe the number of preventable U.S. hospital deaths totaled more than 200,000 last year. That is 3,800 deaths per week or more than 500 every single day. It is like 2 full jumbo jets crashing every day with all aboard dying. These deaths far exceed motor vehicle accidents (43,000), breast cancer (42,000), and AIDS (17,000)-related deaths, combined.<sup>3</sup>

These statistics are even more startling when you consider the Institute of Medicine's report *To Err is Human*, which came out nearly 15 years ago, pegged the number at approximately 100,000 preventable hospital deaths annually, at a cost of \$29 billion.<sup>4</sup> Now it's 200,000.

If we continue at this rate, by 2020 it is conceivable we would lose more than 2 million of our loved ones to preventable hospital deaths. To me, this is unacceptable. When you meet a family that has lost a loved one, you realize how even one preventable death is unacceptable, let alone 2 million!

Importantly, the numbers of adverse events caused by infections and other issues is much higher. In 2010, an estimated 1.6 million Medicare patients experienced an adverse event. Medicare's own data showed that 44 percent of these incidents were considered preventable.<sup>5</sup>

#### COST IMPACT

I am sure everyone in this room shares our belief that there is no dollar value that can be put on a life lost, but the costs are enormous. Consider the following:

- Some studies report the economic cost of preventable errors at \$17 to \$50 billion annually.<sup>6,7</sup> Many of these errors result in death.
- The Centers for Disease Control and Prevention reports hospital-acquired infections lead to nearly 100,000 deaths and cost \$30 billion each year. CDC estimates about 1.7 million HAIs annually.<sup>8</sup>

<sup>1</sup>Murphy SL, et al. National vital statistics reports; vol 60 no 4. Hyattsville, MD: National Center for Health Statistics. 2012.

<sup>2</sup>Trends in Inpatient Hospital Deaths: National Hospital Discharge Survey. 2000–10. National Hospital Discharge Survey (NHDS) data from 2000 through 2010. 118: March 2013.

<sup>3</sup>HealthGrades Quality Study: Patient Safety in American Hospitals, HealthGrades, July 2004.

<sup>4</sup>Kohn LT, et al. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999.

<sup>5</sup>Levinson DR, et al. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries, Department of Health and Human Services Office of the Inspector General, November 2010.

<sup>6</sup>Shreve, J, et al., *The Economic Measurement of Medical Errors*, sponsored by Society of Actuaries Health Section, prepared by Milliman Inc., Schaumburg, IL (June 2010).

<sup>7</sup>Brennan, TA, et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results from the Harvard Medical Practice Study I," *New England Journal of Medicine*, 324:370–76 (1991).

<sup>8</sup>*Journal of Medicine*, 324:370–76 (1991). Scott, Douglas R., "The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention," Centers for Disease Control and Prevention, (March 2009) accessed at [http://www.cdc.gov/hai/pdfs/hai/scott\\_costpaper.pdf](http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf).

- Pressure ulcers and postoperative infection are the two highest volume preventable errors and cost more than \$6.5 billion annually, according to researchers.<sup>9</sup>

There are many more examples, where saving patients' lives will also save taxpayers, consumers and premium payers money. Clearly, the opportunity is large and Congress should take steps to save money and lives wherever prevention strategies are available.

#### PATIENT SAFETY MOVEMENT FOUNDATION

We created the *Patient Safety Movement Foundation* to aggressively address this problem with a mission of ZERO preventable deaths by 2020.

We believe we can accomplish this by working together and doing the following:

1. Unify the healthcare ecosystem and secure commitments to action from health care providers and others in the healthcare ecosystem;
2. Identify the challenges that are killing patients to create actionable solutions to the challenges; We call these Patient Safety Solutions;
3. Ask hospitals to implement the Patient Safety Solutions;
4. Promote transparency;
5. Align misaligned incentives;
6. Create and use the Patient Data Super Highway; and
7. Promote love and patient dignity.

The Patient Safety Movement is taking on this challenge and is galvanizing the entire healthcare ecosystem. Part of the reason, we experience 200,000+ preventable deaths after all of the work that has been done since the IOM report is that all parties that impact patient safety have not been at the table. While clinicians are responsible for care at hospitals managed by administrators and supported by payers, including the government, they utilize devices and drugs invented by clinicians and companies. All of these entities are committed to patient safety, but rarely have they all worked together to collectively create and implement solutions to reduce preventable deaths. We need to bring everyone together from doctors, nurses, hospital administrators, patients, patient advocates, engineers, government agencies, accreditation agencies, elected officials and medical technology innovators to find actionable solutions to commit and achieve ZERO preventable deaths as soon as possible.

We have many institutions that have already made their commitment and are taking action, including Intermountain Healthcare in Salt Lake City, Sinai Health System in Chicago, Mercy Hospital of Buffalo, Hoag Hospital of Orange County, Medstar in Columbia, MD as well as the American College of Obstetricians and Gynecologists, the Newborn Coalition, and LeahsLegacy. We also have many medical technology companies, including Cercacor, Cerner, Drager, GE Healthcare, Masimo, Sonosite Fuji Film, Smiths Medical, Surgicount and Zoll who have committed to share their data to benefit patients worldwide. Numerous doctors, nurses, executive leaders, and patient advocates have partnered with the Movement and are committing to do everything they can to push toward ZERO preventable deaths.

- At the *Patient Safety Movement's* first *Patient Safety, Science and Technology Summit*, this past January, we successfully secured the commitment of nine medical technology companies to share their data. We thank them for their commitment to patient safety. These are the first bridges we have built to help connect and construct the Patient Data Super Highway. Former President Clinton has been instrumental and been very supportive of this effort. He not only attended our Summit, but is highlighting our work at this year's Clinton Global Initiative meeting in New York. We developed six Patient Safety Solutions to address the pressing problems of failure to rescue, medication errors, transfusion overuse, intravascular catheter-related infections, sub-optimal neonatal oxygen targeting, and failure to detect critical congenital heart disease. Each of these solutions identifies the gap, and highlights the necessary leadership, clinical and technology steps to eliminate these problems.

- We are working with the Joint Commission and seeking their help to encourage implementation of Patient Safety Solutions.

- We are working with CMS to educate and incorporate the Patient Safety Solutions into Federal policy. We are very encouraged by the pace that CMS, under the leadership of Dr. Patrick Conway, is working with us on ideas for how we can make our hospitals and surgery centers much safer.

<sup>9</sup> Van den Bos, Jill; Rustagi, Karan; Gray, Travis; et al., "The \$17.1 Billion Problem: The Annual Cost Of Measurable Medical Errors," *Health Affairs*, Volume: 30, Issue: 4 APR 2011.

- We are working with elected officials to increase awareness on the magnitude of the preventable death problem in our hospitals and to develop and implement solutions.

All these steps have been taken in just 1 year. At our next summit in January 2014, we will unveil even more Patient Safety Solutions and steps we plan to take to achieve our zero by 2020 goal. We know our movement is nascent, but we believe it is potent and reflects the readiness and underlying desire *by* the healthcare ecosystem to *put an end to preventable hospital deaths*.

We want to thank you Chairman Harkin and Ranking Member Alexander for holding this hearing today to highlight this issue. We ask that this hearing be the start, not the end, of your efforts to address preventable deaths. We are looking to you to lead and spur changes in government policies to further incent best practices and to achieve our shared goal of zero preventable deaths by 2020.

#### THE NECESSARY LEGISLATIVE RESPONSE

We know Congress and the Administration have been actively focused on this issue of reducing preventable deaths and increasing patient safety with many programs, but we humbly suggest the following:

- **Create a System of Transparency.** Transparency is a critical component in measuring and understanding the total number of preventable hospital deaths and the root cause of each death. This information will allow clinicians, policymakers, and others to take proactive steps to reduce and eliminate needless mortality, going forward. The current reporting systems do not require consistent, accurate, measurable and electronic reporting on the total number and causes of deaths, especially related to whether the death was preventable. We cannot improve what we do not measure. You may be surprised as I am, that today no one knows the exact number of deaths due to preventable causes. That has to change immediately.

- **Recommendation:** Government should take the lead in this effort. To create transparency, and improve consumer choice and knowledge, we believe there should be standardized processes to define, measure and report Hospital Acquired Infections and Conditions by hospital and in total. Reporting should be electronically facilitated through the Meaningful Use program and via claim submissions. Congress should require HAI and HAC rates to be publicly reported to facilitate quality comparisons, much like SEC does for finance.

- **Use incentives and disincentives to reduce preventable deaths.**

- **Recommendation:** We believe Congress should expand the current HAC Medicare policy to include a list of causes of preventable death. We believe Congress should suspend payment for even the primary condition until it is determined whether the cause of death was preventable. If preventable, and the hospital has implemented evidence-based strategies for prevention, such as those indicated by the Patient Safety Solutions, the hospital would receive payment for the primary condition. If the hospital had not implemented the strategy, then payments for both the primary and secondary conditions would be denied.

Also, if hospitals implement evidence-based practices such as the Patient Safety Solutions, they should be shielded from malpractice lawsuits to the fullest extent possible, such as through an affirmative defense and limits on damages.

We believe Congress should also expand the current HAC Medicare policy by expanding the non-payment policy for secondary conditions that develop after a patient is admitted to a hospital. The current list of conditions has not been updated since 2012, partly due to limits on what conditions can be added. Currently, only preventable, high-cost, high-volume conditions for which there are evidence-based precautions are eligible. Congress should eliminate the “high-cost, high-volume” limitation so that any known preventable condition is eligible for the list if there is a clinical intervention strategy to prevent it.

- **Create the “Patient Data Super Highway.”** For more than a decade Congress and the Administration have devised and implemented policies to spur the use of information technology in healthcare. The reasoning behind this is clear: seamless information technology should enable us to identify problems in real time and resolve them before they become deadly. As a result, medical professionals have begun to increasingly rely on medical technology and information systems to treat their patients. Today, however, these technologies are not always able to communicate or interoperate. But this isn’t always an issue of design or standards: some technology vendors—as well as some providers—pursue business practices to create what are called “walled gardens,” which are strategies that block information sharing between different systems in order to capture market share and/or additional revenues in the future. This is an issue that has been identified by the Office of the National Coordinator as a barrier to progress in the Meaningful Use program. This practice



fundamentally diminishes the value of health IT, undermines congressional intent in enacting programs to incentivize the use of technology in healthcare. These practices are harming our progress to protect patients and must be stopped; technology solutions must be required to openly share information particularly when their purchase is subsidized with taxpayer dollars and patients' lives are dependent on it. Rory Staunton's case is an example of the problem and opportunity that lies ahead. In fact, according to an article in the *Los Angeles Times*, 80 percent of medical errors in hospitals involve communication problems between healthcare professionals.

**Recommendation:** We believe Congress should grant the Office of the National Coordinator for Health Information Technology (ONC) the authority to investigate and decertify products that pursue information blocking practices. We shouldn't provide incentives or reimbursement for products that do not openly share data freely with not just the hospitals, but under HIPPA, to the patient and all parties that can use it to improve patient safety.

- **Provide the Same incentive to Medical Technology Companies that is offered to Hospitals.** Today, there are no incentives, only penalties, for medical technology companies that are trying to do the right thing and identify why a patient was harmed by their product to do so publicly. Hospitals are afforded protections for reporting adverse events through Patient Safety Organizations.

**Recommendation:** Congress should extend the legal safe harbors afforded to providers through Patient Safety Organizations to technology vendors to promote transparency that will benefit the system overall.

- **Promote Patient Dignity.** Too often a patient's or a family's cry for help is ignored. Patients and their families must be partners with healthcare providers through education and engagement strategies that empower both providers and consumers.

**Recommendation:** We believe there should be a Patient Advocate at every hospital that patients or their families can access in real time if they experience lack of empathy or problems with communication related to their care.

#### CONCLUSION

The good news is that preventing avoidable patient deaths can largely be accomplished with solutions that are available today. But we all need to act now. Every week, we are losing nearly 4,000 of our family members, neighbors and friends to healthcare-associated infections and other forms of preventable deaths. If Congress creates laws that align the incentives of the healthcare ecosystem to encourage innovation, transparency, cooperation, implementation of evidence-based best-practices such as Patient Safety Solutions, and the creation of a Patient Data Super Highway, we can reduce, if not completely eliminate, preventable deaths.

We are excited to welcome Congress to the Healthcare Ecosystem and work with Congress on solutions to this problem and together achieve **ZERO Preventable Patient Deaths by 2020**.

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Following is a summary of Patient Safety Programs to Reduce Hospital Acquired Infections and Conditions. These are extremely helpful but are not replacement for what we have suggested above.

#### CMS

CMS has created a number of programs to improve Patient Safety.

The Innovation Center is engaged in a number of innovative projects and is working to develop new payment and service delivery models to improve patient safety.

The Partnership for Patients and its over 3,700 participating hospitals are focused on making hospital care safer, more reliable, and less costly through the achievement of two goals:

1. **Making Care Safer.** By the end of 2013, preventable hospital-acquired conditions would decrease by 40 percent compared to 2010.

2. **Improving Care Transitions.** By the end of 2013, preventable complications during a transition from one care setting to another would be decreased so that all hospital readmissions would be reduced by 20 percent compared to 2010.

CMS partners with AHRQ and CDC to develop an algorithm to identify claims-based markers of HAIs originating at surgical care settings. Programs are generally focused on hospital reporting or consumer-facing tools to make the hospital and provider quality more transparent to patients.

- *Inpatient Prospective Payment System Incentives (IPPS)*

- Hospitals are encouraged to treat patients efficiently and to avoid infections because they receive a MS–DRG-based payment for an inpatient stay.
- *Hospital Pay-for-Reporting*
  - Gives patients quality of care information to make more informed decisions about their healthcare and encourages hospitals and clinicians to improve the quality of inpatient care.
  - Hospitals that don't report on 10 specific conditions are penalized.
- *Hospital Value-Based Purchasing (VBP)*
  - A portion of hospital-base operating DRG payment amount will be contingent on actual performance, rather than reporting of measurement data, and must include hospital-associated infection rates.
- *Hospital Readmission Reduction Program*
  - Seven conditions make up almost 30 percent of Medicare spending on readmissions. CMS developed reporting measures for four of the seven.
  - The ACA includes penalties for hospitals that have excess readmissions based on the readmission measures developed by NQF.
- *Physician Quality Reporting System (PQRS)*
  - A set of 74 quality measures.
  - Four are related to hospital acquired infections.
  - Providers receive incentives for reporting and (starting in 2015) penalties for not reporting.
- *Physician Feedback Program and Value-Based Payment Modifier*
  - A Physician Value-Based Purchasing Program to improve Medicare beneficiary health outcomes and experience.
  - Uses payment incentives and transparency to encourage higher quality, more efficiently provided healthcare services.
- *Shared Savings/Accountable Care Organizations*
  - A coordinated care model for Medicare beneficiaries that is required to report on quality including HAI levels. ACOs with better quality and lower cost of care receive a percentage of the money saved by Medicare.
- *Hospital Compare*
  - Hospital Compare ([www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov)) is a Web site for consumers that provides information on how well hospitals provide care to their patients with certain medical conditions, including care related to the prevention of certain infections.
  - Uses at Hospital Pay-for-Reporting requirements.
- *Physician Compare*
  - Consumer-facing Web site that compares physicians using PQRS Data.
- *Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Facilities and Hospice Program*
  - These facilities are required to report new and worsening pressure ulcers and CAUTI events.
- *Value-Based Purchasing for Skilled Nursing Facilities and Home Health*
  - Quality reporting requirements for the prevalence of pressure ulcers.
- *Medicare Advantage*
  - Medicare Advantage Private Fee-for-Service and Medicare Savings Account plan must have an ongoing quality improvement program that meets the regulatory requirements.

#### AHRQ

AHRQ funds research to identify and promote effective HAI prevention approaches as well as to identify gaps in the HAI science that can be filled with additional research.

- *Comprehensive Unit-based Safety Program (CUSP)*
  - An Intensive Care Unit Safety Reporting System developed by the Johns Hopkins Quality and Safety Research Group.
  - Focused on Central line-associated bloodstream infections (CLABSI) and Catheter-associated urinary tract infections (CAUTIs).
- *Surgical Unit-based Safety Program*
  - An adaptation of the CUSP program focused on surgical site infections (SSI) and ventilator-associated pneumonia (VAP).
- *Patient Safety Organizations*
  - Encourages clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery.

## CDC

The CDC Prevention Epicenters Program is a network of academic centers with which CDC performs collaborative research on the epidemiology and prevention of HAI.

- Safety and Healthcare Epidemiology Prevention Research Development (SHEPheRD) program
  - Includes academic experts in the field, large healthcare facility networks interested in participating in HAI prevention research, and entities with healthcare information on large patient populations that can be used to measure outcomes and the impact of prevention efforts.
  - Over 2,500 hospitals and insurers covering more than 200 million lives are represented in the SHEPheRD program.
- National Healthcare Safety Network & Emerging Infections Program
  - Epidemiologic research that informs prevention efforts and provides estimates of national HAI burden and trends.

## MEDICARE

Medicare's "never events" policy that refuses payment for clinical mishaps that are so horrific they should never happen is helpful in reducing preventable deaths. Likewise, the current Medicare Hospital Acquired Conditions policy, which refuses payment for conditions in certain limited categories that develop after a hospital admission, is helpful in making hospital clinicians and administrations more aware of the financial consequences of avoidable conditions and errors. Beginning in fiscal year 2015, the ACA reduces payments to hospitals that have risk-adjusted HAC rates in the top quartile of hospitals, but more must be done. Evidence-based practices are available to address more conditions than are currently on the HAC list, however no new conditions have been added to the list in 2 years, despite advances in clinical evidence and technology. The Deficit Reduction Act of 2005 (DRA) requires a quality adjustment in Medicare Severity Diagnosis Related Group (MS-DRG) payments for certain hospital-acquired conditions. CMS has titled the provision "Hospital-Acquired Conditions and Present on Admission Indicator Reporting" (HAC & POA).

For discharges occurring on or after October 1, 2008, Inpatient Prospective Payment System (IPPS) hospitals do not receive the higher payment for cases when one of the selected conditions is acquired during hospitalization (i.e., was not present on admission). The case is paid as though the secondary diagnosis is not present. For instance, if a patient falls out of bed while in a hospital, the consequent broken hip was not present on admission, so the "complication" of "broken hip" would be demoted as a "Falls and trauma" HAC. The hospital would not be compensated for treatment of the injury. The intent of this sort of classification is to force hospitals to prevent such problems in the first place.

Pursuant to the Health Reform Law, beginning in fiscal year 2015, hospitals will face an additional 1 percent reduction in Medicare inpatient payments if they fall into the top 25 percent of national risk-adjusted HAC rates for all hospitals in the previous year. The CBO estimates this will reduce Medicare spending by \$1.4 billion over the 2015–19 period. (Established by PPACA § 3008 and 10309.)

The Hospital-Acquired Conditions payment provision applies only to IPPS hospitals. At this time, the following hospitals are **exempt** from the HAC payment provision:

- Critical Access Hospitals (CAHs),
- Long-Term Care Hospitals (LTCHs),
- Maryland Waiver Hospitals,
- Cancer Hospitals, Children's Inpatient Facilities,
- Rural Health Clinics,
- Federally Qualified Health Centers (FQHCs),
- Religious Non-Medical Health Care Institutions,
- Inpatient Psychiatric Hospitals,
- Inpatient Rehabilitation Facilities (IRFs), and
- Veterans Administration/Department of Defense Hospitals.

The law requires that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions under the MS-DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised,

again in consultation with CDC, from time to time as long as the list contains at least two conditions.

The current list of HACs is:

1. Foreign object retained after surgery.
2. Air embolism.
3. Blood incompatibility.
4. Pressure ulcer stages III and IV.
5. Falls and trauma, including:
  - a. Fractures,
  - b. Dislocations,
  - c. Intracranial injuries,
  - d. Crushing injuries,
  - e. Burns, and
  - f. Other injuries.
6. Vascular catheter-associated infection.
7. Catheter-associated urinary tract infection.
8. Manifestations of poor glycemic control, including:
  - a. Diabetic ketoacidosis,
  - b. Nonketotic hyperosmolar coma,
  - c. Hypoglycemic coma,
  - d. Secondary diabetes with ketoacidosis, and
  - e. Secondary diabetes with hyperosmolarity.

As specified by statute, CMS may revise the list of conditions that *could* include other causes of preventable deaths.

The CHAIRMAN. Thank you very much, Mr. Kiani.

And to all of you, thank you. We'll start a round of 5-minute questions, as soon as the clock gets reset. I've just got 1 minute—if you can reset that.

Mr. Kiani and all of you, I always spend the night before reading through the testimonies, and I always learn things. Mr. Kiani, I learned from your testimony a lot of things. But I didn't know the following hospitals are exempt from the hospital-acquired condition payment provision: critical access hospitals, long-term care hospitals, cancer hospitals, children's inpatient facilities, federally qualified health centers, inpatient psychiatric hospitals—I'm not going to read them all—inpatient rehabilitation facilities, Veterans Administration, Department of Defense hospitals.

I guess it's because they're paid differently. But surely there's some way that we can apply the HAC payment provision or something like that to those hospitals. Do you have any idea—I mean, they may not be paid the same, but we still have the same problems there. So how are we going to pull them into this whole umbrella system that we have?

Mr. KIANI. Well, I humbly suggest, despite, like I said, us all not carrying all the knowledge, that we need to create an incentive and disincentive program. If you take your car for service, and, accidentally, it gets set on fire, they're not going to charge you for the service you took it in for. They, in fact, try to replace your car. But, unfortunately, if someone goes into a hospital, especially those hospitals, and they acquire some condition, including dying from it, not only do they not get the child back or their loved one back, but government and other assurers have to pay the bill still for what they went in for.

So I believe we need something more dramatic and, this time, to include all of these different groups that you mentioned so that they all have the incentive to do the right thing, and also shield

them from malpractice litigation if they are putting steps in place to do the right thing.

The CHAIRMAN. Dr. Perlin, all the veterans hospitals are exempted from this, but what can we do with the veterans hospitals to bring them under some kind of a system like this?

Dr. PERLIN. Well, I'm no longer at VA, but I can share that VA, as in my current organization, HCA, uses something called a patient safety learning system to understand and to make continuous improvement.

Senator Harkin, members of the committee, when caregivers go to work, their goal, which is really what attracted them to healthcare, is to do the best job possible. Obviously, our shared goal is to prevent all avoidable harm. I think what we lack—and why I think the studies such as REDUCE MRSA are so powerful in the work with CDC—is insight into building a safer system.

Imagine a different scenario where there were simple tests or simple clinical markers that would identify sepsis more reliably. Building these sorts of system supports allows good but fallible individuals to come to the best understanding of disease and achieve best and safest outcomes for patients.

The CHAIRMAN. Well, it just seems to me that we've got a—I was kind of surprised that all of those entities were exempted from that, and I think that's something that we really ought to take a look at.

The other thing that you mentioned was all the silos that we have. And I mentioned this in my opening statement, about the lack of communication. People have different proprietary interest in certain software programs and things like that.

So someone is in a nursing home. They fall, they break their hip, they go to the hospital, and now the hospital does some surgery. But then they get an infection, they get MRSA, and things pile up. But no one seems to know how they talk to one another on this. How do we break that down?

Mr. KIANI. It's very simple, Chairman Harkin. I'm also CEO of Masimo Corporation, and I'll be first to say we've been guilty of hoarding our data so that one day perhaps we can do something more with it for our business. And I really have to admit it was the story of Mr. Staunton's son that made me realize that that can't go on anymore.

So I called up to all of my colleagues that we have to begin sharing our data. Let's not hide behind standards. Let's just agree to make a commitment to share our data.

Already, GE Healthcare, Cerner, Drager, and many companies have signed this commitment. If we can get the entire med tech space to sign this commitment, I am sure that one day, we'll have a real-time Patient Data Super Highway, and some smart person, either living today or coming to life soon, will create an algorithm that can tell when Mr. Staunton's son has all these issues and can warn, if not the caregiver, them about what's happening.

So I think it's just incentivizing them. Right now, we're providing incentives for meaningful use to technologies like EMR. And, unfortunately, some of them are not sharing their data. They share it with the hospital, but they will not share it with other of their so-called competitors, and, therefore, the hospital is not going to come

up with an algorithm that can be used at the nursing home or another hospital.

Usually, private industry—someone will come up with that algorithm. But if that data can't be accessed, there's no need to make the algorithm.

The CHAIRMAN. Thank you very much.

Mr. STAUNTON. If I may say, sir, just one point is that there's insufficient evidence and awareness about sepsis. Education and awareness can save lives. We know for a fact that since we spoke publicly about our case that we have saved families. Now, that hasn't cost us anything apart from emotion.

Can anyone here imagine if the U.S. Government and every agency started an education campaign on sepsis awareness, if every mom and dad and doctor were looking for sepsis the same as parents look for meningitis, that doesn't cost a nickel, but would save millions.

The CHAIRMAN. Thank you, Mr. Staunton.

Senator Alexander.

Senator ALEXANDER. Mr. Staunton, I join Senator Harkin in thanking you and your family for what you are doing, or as he said, turning your anguish into such constructive work on behalf of other people.

Dr. Perlin, Senator Burr asked a little while ago about whether there was a difference in the rate of infections when you go into a hospital and when you go into an ambulatory surgery center. You're in charge of a lot of hospitals. You're in charge of a lot of outpatient centers. Do you see a difference between the hospitals and the outpatient centers that you manage?

Dr. PERLIN. Well, first, I'd be remiss, Senator Alexander, if I didn't thank you for your terrific leadership in Tennessee. With what this country has to experience, we get the privilege of working with Senator Alexander across our great State, and thank you for that.

The ambulatory surgical center environment and the hospital environment are slightly different. Hospitals do concentrate the risk of patients who might be carrying other infections, but good infection control practices have to be used in both environments.

The truth is that our national data need to improve to determine what the rates are. But what we do know is that among patients who have surgery in hospitals—admittedly, the data are only good for there—that, sadly, between 1 in 10 and 1 in 3 acquire infections, and up to 5 percent of those are surgical site infections.

Now, toward understanding and preventing those, we're actually following up. The same study team that did REDUCE MRSA are working with CDC and others to actually implement a variety of strategies to try to make that rate of what we believe to be largely avoidable infections zero.

So I would encourage, first, better national surveillance of infection rates in those environments. There are likely similar problems in terms of infection prevention between both. Either way, the rates are too high, and the goal has to be zero. And we have, I think, a national need to ask CDC to help us get better data on that.

Senator ALEXANDER. Mr. Kiani has said that the goal should be by 2020 to prevent these infections. I have brought up in hearings here the importance of accountability. We're going through that with dealing with the tragedy with fungal meningitis in compounding pharmacies, a big part of which I think came about because of confusion about who's in charge, who's on the flagpole, who's responsible for this pharmacy or that pharmacy. We're about to work that out.

I use the example of Hyman Rickover, the admiral who told his submarine captains in the 1950s, "If you're in charge of the ship and you're in charge of the reactor, and if there's a problem with the reactor, your career is over." And we've never had a death from a reactor on a Navy submarine.

Now, you've had a lot of experience, both in government with the VA and with now privately managed hospitals. When we're dealing with lots of different institutions, we're always tempted here in Washington to say—for example, President Obama did the other day—the University of Tennessee is doing a good job of graduating its students in 4 years, and someone will say, "Well, if they did that, let's apply it to all 6,000 universities." The President didn't say that, but we're tempted to do that.

But we know it doesn't work when we just take a good idea and make everybody do it. Based on your experience, what can we do to fit into the strategy to reach Mr. Kiani's goal by 2020 without making it more difficult for hospitals and managers to reach that goal? And how can we put somebody on the flagpole? How can we make it clear who's accountable for reaching that goal by 2020 so that we don't have infections in hospitals when we go to get well and instead get sick?

Dr. PERLIN. First, let me start by saying that our immediate goal has to be no infections now, no preventable harm now. We've talked about a number of strategies that don't have to wait. Hand hygiene, members of this committee have already alluded to. The rates are really insufficient. There needs to be high reliability. And we need to hold ourselves accountable for dealing with high reliability type behaviors, which means hand hygiene before and after each and every patient encounter.

We can accelerate through a learning health system the ability to bring together not only large sets of data, as was mentioned, but to compare interventions and find out what works best. It gives us not only the ability to create new evidence, but also to apply it.

That's why in HCA we've applied the REDUCE MRSA universal decolonization across all of our intensive care units. That's why the CDC and others are building that into the infection management or infection control compendium right now.

This is really a remarkable change. That study was a 44 percent reduction on top of every other best practice found. When we have good science, we need to make sure that we apply the science consistently and rigorously. And performance measures are actually a very forceful mechanism of creating transparency and thus accountability. So we actually like the ability not only to have that transparency, but to identify where good performance is occurring.

The CHAIRMAN. Thank you, Dr. Perlin.

Thank you, Senator Alexander.

The vote has started. We have less than 15 minutes to go, but I'll recognize Senator Whitehouse.

Senator WHITEHOUSE. I want to thank you all for being here and again thank the Chairman and the Ranking Member for this really important and useful hearing.

There's been some suggestion that we need to get a lot of data, and I think that is correct. But it strikes me that while we're waiting for the data, there's a lot that we can get done right now that can begin now. I mentioned in my first round of questions the Rhode Island Quality Institute and its effort with the intensive care units across Rhode Island, every single one in.

That really didn't boil down to anything much more than the Pronovost checklist being applied and the nurses in the intensive care units being told and empowered and believing that it was within their job description to stop a procedure if the checklist wasn't being complied with. It broke up the doctor to nurse power structure a little bit, but it also created incredibly good morale among ICU nurses, virtually ended turnover, and it had this very salutary effect.

So it strikes me that those things are possible. They've been possible for a long time, and yet despite the proven success of the Pronovost principles, they haven't propagated as widely as possible. It strikes me that the incentives really matter—to give a hospital administrator the incentive, the push, to go into the intensive care unit and to say to the doctors there,

“Guys, there's going to be a new rule here, and that is that the nurses can call off anything that you're doing if you're not following these guidelines that we've established. You don't get to wing it. You don't get to cut corners.”

That's a tough conversation to have if you don't have an incentive behind it. If you could comment on that, I'd appreciate it.

Dr. PERLIN. First, let me applaud the work of the Rhode Island QIO. I know Laura Adams well, and she speaks of your support of that organization, and it really has done just extremely stunning and positive work.

You've indicated quite correctly that healthcare is a team sport. We need to have the tools of communication and the tools of empowerment. It was really in large part because of the work on what we call in HCA our MRSA ABCs that CDC came to us to do this REDUCE MRSA study. In fact, in part of the MRSA ABCs—which, by the way, included compulsive hand hygiene as a piece—there was the ability for members of the team to really stop the line. That meant that nurses were empowered.

We actually worked with the central line manufacturers, the producers of the devices, to actually put a card inside of that package that expressed the principles that Peter Pronovost and others used in the CUSP program so that even if people “knew that,” it was a reminder right in front of them. And someone could say, “Dr. Perlin, I know you always do this right, but just remember these are the five steps,” and that's incredibly important.

That creates an environment of shared accountability. You've alluded earlier to ways in which, sometimes inadvertently, hospitals, doctors, and others are misaligned. But alignment—the fact that this is a team-based sport, using the evidence that we have now,



being a learning health system creating new evidence—is demonstrated by great examples like Rhode Island and elsewhere.

Senator WHITEHOUSE. Thank you, Chairman.

The CHAIRMAN. Thank you, Senator Whitehouse.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you.

Ciaran, thank you for being here today and for offering your personal witness. I can't even imagine what you and your family have been through. And when we talked many months ago, you gave me an insight that I didn't have before, and I'm grateful for that. I'm glad that you've been able to have the strength to share your story with the country and also to motivate all of us to focus on this problem.

I know Ciaran, and I know Joe Kiani, and, Doctor, I don't know you. But I know how all three of you are committed to this.

I know we're really short on time. I just have one question for Ciaran and then Joe. We'll do some questions for the record.

But, Ciaran, how about any kind of report you can give us on kind of a state-by-state comparison or update? I know New York State, as you mentioned, has moved forward. But what's your best sense of that and what we can do to encourage States?

Mr. STAUNTON. Thank you, Senator Casey. We know, for example, that New York's regulations, the Rory Regulations in New York passed by Governor Cuomo, will save 7,000 to 8,000 lives a year. And that is one page, like that. That's what saves us. If that was nationally, every State, perhaps we could save a couple of hundred thousand people a year.

We also know that there is also in a number of hospitals what's called a checklist, a standardized protocol to facilitate quick and accurate diagnosis and fast and effective treatment as soon as any sign of sepsis arises. This has been used in a number of hospitals. Mortality rates have dropped by 50 percent.

If this was applied across the USA, it would save more than 150,000 lives a year. That's 400 people a day that could be saved. So what we're saying is, first and foremost, there has to be awareness. Sepsis is a medical emergency. If it's suspected, it can be treated, and there you save a lot of people.

Our son could have been treated. If my wife or I or anyone had heard the word, sepsis, as every parent here knows—you go through the list of what it might be, and that's where that would have come in.

So what we are saying today, Senator Casey, is that if Congress looks at this nationwide, what we did in New York, what it has done, and here's how much you can save—a hospital in Utah, for instance, brought their mortality rate down to 9 percent on sepsis and also saved \$36 million that year. So it saves them a lot of money.

What we would like to see Congress do is create a comprehensive educational resource so doctors, nurses, parents, patients, all of us can include sepsis as a possible diagnosis so when a patient shows up in an emergency room, like our son, Rory, that they suspect sepsis. And if you suspect sepsis, you save a life. And that's it. That's it. That's 400,000 people.

Someone said earlier we need numbers, not curves. This number is \$17 billion a year that sepsis is costing in care that can be saved. Awareness is what we are saying, and this is the first one. And thank you very much, Senator Casey.

Senator CASEY. Ciaran, thank you so much. And I would hope that a lot of our hospitals wouldn't wait for a law to be passed. But we'll continue to work with you on moving it forward.

I know we're really out of time, but, Joe, maybe in 1 minute, I wanted to ask you about the patient advocates and the role that they play. I know there's a lot more we could cover with you and with Ciaran and Dr. Perlin, but we're down to about 3 minutes to vote.

Mr. KIANI. Thank you. I'll be very brief. We talked about the silos that, unfortunately, have been amongst us all. One of the silos has been the patient advocates not being part of the equation. When we hear a number like 200,000, it's easy to just think of it as a statistic and not personalize it.

The patient advocate being in the room—I remind you of that one patient, whether it's Rory or it's Lenore Alexander's daughter back here—it reminds you not only of just how critical one life is, but it reminds everybody in the room, whether it's the med tech companies, hospitals, engineers, or doctors, that we have to unite to solve even one death, let alone over 200,000 a year.

Senator CASEY. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey.

Thank you all very much.

I'll just ask one question, Mr. Staunton, about those Rory's Regulations in New York. Did they go to all hospitals, even those I mentioned, that Mr. Kiani pointed out were exempt?

Mr. STAUNTON. Everything in New York is covered under the Rory's Regulations in New York. There are no exemptions in New York, sir. Everyone has to suspect sepsis.

The CHAIRMAN. I know we're very late. In fact, I'm going to miss a vote. Go ahead. I'll be right with you.

Do you know if other States have picked up on this?

Mr. STAUNTON. Not yet, sir. There is hope that we may take it—I know there's been some hearings in Connecticut, Rhode Island, and Florida. But we would—

The CHAIRMAN. When did New York adopt these regulations?

Mr. STAUNTON. January the 1st of this year.

The CHAIRMAN. Interesting. I'm going to check on that.

Mr. STAUNTON. And we'll provide your staff with a copy of it, sir. Your staff has been excellent. Thank you very much.

[The information referred to may be found in additional material.]

The CHAIRMAN. I appreciate it very much.

Thank you all very much. I'll just close where I started. These hospital-acquired conditions and infections is something that we can win. We can win this. We've got to break down these silos. We've got to have transparency. We've got to have communication, software that talks to one another. We need the kind of regulations in every State so that they recognize sepsis.

MRSA can lead to sepsis. So we've got to take a look also at MRSA, as Senator Isakson was talking about.

With this, I thank you all very much. I'm sorry we're going to have to rush off from this hearing. But thank you for all you're doing, and we look forward to continuing our dialogue with you with written questions.

Thank you all very much. The committee will stand adjourned.  
[Additional material follows.]

## ADDITIONAL MATERIAL

### PROPOSED REGULATIONS: NEW YORK STATE DEPARTMENT OF HEALTH

#### PROPOSED RULE MAKING: AMENDMENT OF SECTIONS 405.2 AND 405.4 OF TITLE 10 NYCRR (HOSPITAL SEPSIS PROTOCOLS)

Publication Date: 02/13/2013

Comment Period Expiration: 04/01/2013

#### PROPOSED TEXT AND STATEMENTS

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2800 and 2803 of the Public Health Law, Sections 405.2 and 405.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraphs (6) and (7) of subdivision (f) of section 405.2 are amended and a new paragraph (8) is added to read as follows:

(f) CARE OF PATIENTS. The governing body shall require that the following patient care practices are implemented, shall monitor the hospital's compliance with these patient care practices, and shall take corrective action as necessary to attain compliance:

\* \* \*

(6) hospitals which conduct, or propose to conduct, or otherwise authorize human research on patients or other human subjects shall adopt and implement policies and procedures pursuant to the provisions of Public Health Law, article 24-A for the protection of human subjects; [and]

(7) hospitals shall have available at all times personnel sufficient to meet patient care needs[.]; and

(8) *hospitals shall have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care as required by subdivision (a) of section 405.4 of this Part.*

New paragraphs (4), (5), (6), (7) and (8) are added to subdivision (a) of section 405.4 to read as follows:

405.4 Medical staff.

(a) MEDICAL STAFF ACCOUNTABILITY. The medical staff shall be organized and accountable to the governing body for the quality of medical care provided to all patients.

\* \* \*

(4) *The medical staff shall adopt, implement, periodically update and submit to the Department evidence-based protocols for the early recognition and treatment of patients with sepsis, severe sepsis and septic shock ("sepsis protocols") that are based on generally accepted standards of care. Sepsis protocols must include components specific to the identification, care and treatment of adults and of children, and must clearly identify where and when components will differ for adults and for children. These protocols must include the following components:*

(i) *a process for the screening and early recognition of patients with sepsis, severe sepsis and septic shock;*

(ii) *a process to identify and document individuals appropriate for treatment through severe sepsis protocols, including explicit criteria defining those patients who should be excluded from the protocols, such as patients with certain clinical conditions or who have elected palliative care;*

(iii) *guidelines for hemodynamic support with explicit physiologic and biomarker treatment goals, methodology for invasive or non-invasive hemodynamic monitoring, and timeframe goals;*

(iv) *for infants and children, guidelines for fluid resuscitation with explicit timeframes for vascular access and fluid delivery consistent with current, evidence-based guidelines for severe sepsis and septic shock with defined therapeutic goals for children;*

(v) *a procedure for identification of infectious source and delivery of early antibiotics with timeframe goals; and*

(vi) criteria for use, where appropriate, of an invasive protocol and for use of vasoactive agents.

(5) The medical staff shall ensure that professional staff with direct patient care responsibilities and, as appropriate, staff with indirect patient care responsibilities, including, but not limited to laboratory and pharmacy staff, are periodically trained to implement sepsis protocols required pursuant to paragraph (4) of this subdivision. Medical staff shall ensure updated training when the hospital initiates substantive changes to the protocols.

(6) Hospitals shall submit sepsis protocols required pursuant to paragraph (4) of this subdivision to the Department for review on or before July 1, 2013. Hospitals must implement these protocols no later than 45 days after receipt of a letter from the Department indicating that the proposed protocols have been reviewed and determined to be consistent with the criteria established in this Part. Hospitals must update protocols based on newly emerging evidence-based standards. Protocols are to be resubmitted at the request of the Department, not more frequently than once every 2 years unless the Department identifies hospital-specific performance concerns.

(7) **COLLECTION AND REPORTING OF SEPSIS MEASURES.**

(i) The medical staff shall be responsible for the collection, use, and reporting of quality measures related to the recognition and treatment of severe sepsis for purposes of internal quality improvement and hospital reporting to the Department. Such measures shall include, but not be limited to, data sufficient to evaluate each hospital's adherence rate to its own sepsis protocols, including adherence to timeframes and implementation of all protocol components for adults and children.

(ii) Hospitals shall submit data specified by the Department to permit the Department to develop risk-adjusted sepsis mortality rates in consultation with appropriate national, hospital and expert stakeholders.

(iii) Such data shall be reported annually, or more frequently at the request of the Department, and shall be subject to audit at the discretion of the Department.

(8) **DEFINITIONS.** For the purposes of this section, the following terms shall have the following meanings:

(i) *sepsis* shall mean a proven or suspected infection accompanied by a systemic inflammatory response;

(ii) *severe sepsis* shall mean sepsis plus at least one sign of hypoperfusion or organ dysfunction; and

(iii) *septic shock* shall mean severe sepsis with persistent hypotension or cardiovascular organ dysfunction despite adequate IV fluid resuscitation.

**REGULATORY IMPACT STATEMENT**

**Statutory Authority**

Public Health Law ("PHL") Section 2800 provides that "[h]ospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the State . . . , the department of health shall have the central, comprehensive responsibility for the development and administration of the State's policy with respect to hospital related services . . . ."

PHL Section 2803 authorizes the Public Health and Health Planning Council ("PHHPC") to adopt rules and regulations to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

**Legislative Objectives**

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by promoting the efficient provision and proper utilization of high quality health services at a reasonable cost.

**Needs and Benefits**

Sepsis is a range of clinical conditions caused by the body's systemic response to an infection and affects about 750,000 people in the United States each year. The mortality rate is alarming—between 20 percent and 50 percent—and the rate largely depends on how quickly patients are diagnosed and treated with powerful antibiotics to battle the bacteria racing through their systems.

In New York State the number of **severe** sepsis cases increased from 26,001 in 2005 to 43,608 in 2011—an increase of 68%. Similarly, the number of sepsis cases in New York State increased from 71,049 in 2005 to 100,073 in 2011, an increase of 41%. Sepsis mortality is significant and ranges widely from one hospital to another. In New York, sepsis mortality ranges between 15 percent and 37 percent. A patient may have a greater chance of dying from sepsis if care is provided by an institution ill-prepared to deal with this illness or from providers not thoroughly trained in identifying and treating sepsis.

The likelihood of death following initial diagnosis of sepsis is more than 20%, and the window for administering effective treatment is short. Mortality rates from severe sepsis are on a similar scale to lung, breast, and colon cancer, and it is one of the leading causes of death in the intensive care unit. Sepsis kills more people than HIV/AIDS, prostate cancer, and breast cancer combined.

The 28-day mortality rate in sepsis patients is comparable to the 1960s hospital mortality rate for patients of acute myocardial infarction (“AMI”). Over recent years, there has been an improvement in the awareness and management of AMI, resulting in a decline in mortality, while sepsis remains an unacknowledged killer.

The number of severe sepsis cases is expected to grow at a rate of 1.5% annually, adding an additional one million cases per year in the United States alone by 2020. This will increase total mortality and increase the burden on health care resources. The increase is mainly due to the growing use of invasive procedures, immune system modifying therapies and increasing numbers of elderly and high-risk individuals, such as those with diabetes, cancer and HIV. Older people are at an increased risk of sepsis as they are more vulnerable to infections due to aging, co-morbidities, use of invasive procedures, and problems associated with institutionalization. Individuals with diabetes, cancer, and HIV are at increased risk due to immune system and other dysfunction caused by their disease or its treatment.

Sepsis places a significant burden on health care resources, accounting for 40% of total ICU expenditures. Sepsis costs our health care system an estimated \$17 billion annually, and the average cost of treating the condition is \$50,000. (See [http://www.nigms.nih.gov/Education/factsheet\\_sepsis.htm](http://www.nigms.nih.gov/Education/factsheet_sepsis.htm).)

The rapid diagnosis and management of sepsis is critical to successful treatment. The sepsis patient is usually already critically ill and requires immediate attention to avoid rapid deterioration; therefore, it is necessary to treat the patient at the same time as confirming the diagnosis. Due to the challenges of diagnosing and treating this complex condition, approximately 10% of sepsis patients do not receive prompt appropriate antibiotic therapy, which increases mortality by 10 to 15%.

In the absence of adoption of protocols as required by these regulations, it is estimated that New York will see dramatic increases in cases of sepsis and sepsis mortality as the numbers of persons who are at risk continue to increase.

Hospitals can significantly impact sepsis morbidity and mortality by adopting standard protocols. For example, since the implementation of Kaiser Permanente’s Northern California sepsis program mortality has been reduced for patients admitted to hospitals with sepsis, by more than 40 percent—and saved more than 1,400 lives. Similarly, Regions Hospital in Minnesota reports that initiatives launched in 2005 led to more than a 60 percent drop in sepsis mortality by 2011, and Intermountain Health Care reports a reduction in its sepsis mortality rate from 25% to 9%, saving 85 lives and \$38 million annually. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012.)

In particular, these regulations will promote the early identification and treatment of sepsis at general hospitals by focusing on the following areas:

- **Recognition** of risk factors, signs and symptoms of sepsis;
- **Resuscitation** with rapid intravenous fluids and administration of antibiotics upon diagnosis of sepsis;
- **Referral** to appropriate clinicians and teams as appropriate;
- **Measurement** and evaluation of current practices for purposes of informing future policy; and
- **Quality Improvement** measures that will permit development and dissemination of best practices through clinical and administrative information sharing.

The Department of Health (“the Department”) will publish guidance to assist facilities in developing protocols that include an appropriate process for screening all patients to ensure early recognition of patients with possible sepsis and, once possible sepsis has been documented, establishing clear timeframes for administration of antibiotics and full protocol implementation. At a conference of stakeholders, including hospital systems, convened by the Department in 2012, it emerged that the current best practice is to pursue administration of antibiotics and fluid resuscitation within 1 hour of a diagnosis of sepsis, with full implementation of sepsis proto-

cols within 3 hours for severe sepsis and 6 hours for septic shock. Given continual advancements in medical research and practice, these timeframes could change and accordingly will be set forth in guidance which will be updated as appropriate.

These regulations, requiring hospitals to adopt protocols to identify and treat sepsis, and another set of regulations requiring hospitals to provide patients and their parents or other medical decisionmakers with critical information about the patient's care and to post a Parent's Bill of Rights, were inspired by the case of Rory Staunton, a 12-year-old boy who died of sepsis in April 2012. Both sets of regulations, together known as "Rory's Regulations," will help New York State set a "gold standard" for patient care.

#### COSTS

##### **Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity**

Costs to the regulated entities are expected to be minimal and to be primarily associated with the following: (a) adoption of and compliance with evidence-based protocols; (b) reporting information to inform risk-adjusted sepsis mortality measures; and (c) training staff to implement the sepsis protocols. It is likely that hospitals will realize overall cost savings as a result of early identification and treatment (see below).

In fact, many hospitals throughout the State are currently implementing sepsis initiatives. The Greater New York Hospital Association ("GNYHA") and the United Hospital Fund ("UHF") have launched a joint program called the "Strengthening Treatment and Outcomes for Patients Sepsis Collaborative;" the *North Shore-LIJ Health System* recently launched an education program to train emergency and critical care nurses on how to identify sepsis at its earliest stages and provide treatment to improve patient outcomes; and the Healthcare Association of New York State ("HANYS") has organized a collaborative to improve the identification and management of sepsis and test the value of collaborative improvement projects versus traditional medical and clinical staff education. This regulation will build on and support these initiatives going forward.

Research conducted nationally suggests the possibility of a significant return on investment. As noted, Intermountain Health Care in Utah has reported savings of \$38 million per year due to its sepsis program, and reports more favorable reimbursement from insurers for identifying potential septic patients faster and treating them in the intensive care unit earlier. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012.)

In New York State, Stony Brook University Medical Center ("SBUMC") reports that a recent campaign to reduce sepsis mortality was extremely successful, resulting in a 49 percent reduction in mortality and a decrease in length of stay for patients with severe sepsis. This resulted in a cost savings of more than \$740,000 for the 153 severe sepsis patients at SBUMC in 2010. (See <http://www.naph.org/Homepage-Sections/Explore/Innovations/Preventing-Hospital-Acquired-Conditions/Stony-Brook-Reduces-Sepsis-Mortality.aspx>.) Similarly, a recent sepsis initiative at South Nassau Communities Hospital resulted in a 44% reduction in sepsis mortality (See HANYS Quality Institute, *Healthcare Association of New York State, Leading the Quest for Quality 2011 Profiles in Quality and Patient Safety*.) Similar savings to those reported by SBUMC are likely.

##### **Costs to Local and State Government**

There is no anticipated fiscal impact to State or local government as a result of this regulation, except that hospitals operated by the State or local governments will incur minimal costs, offset by savings, as discussed above.

##### **Costs to the Department of Health**

There will be minimal additional costs to the Department of Health associated with the following: review of protocols submitted by hospitals to the Department; general programmatic oversight; development of measures to evaluate the impact of these regulations as they relate to the adoption of evidence-based sepsis protocols; and creation of a data system for purposes of analysis and reporting.

##### **Local Government Mandates**

Hospitals operated by State or local government will be affected and be subject to the same requirements as any other hospital licensed under PHL Article 28.

##### **Paperwork**

Consistent with these regulations all hospitals will be required to submit evidence of the following:

(a) adoption of an evidence-based sepsis protocol initially and then once every 2 years after that.

(b) information sufficient to evaluate each hospital's adherence to its own sepsis protocol, including adherence to timeframes and implementation of all protocol components for adults and children;

(c) data, as specified by the Department, to permit the evaluation of risk-adjusted severe sepsis mortality rates.

#### **Duplication**

These regulations do not conflict with any State or Federal rules. Implementation of these regulations represents the first time New York State has required that facilities submit indication of adherence to evidence-based protocols for the early detection and treatment of sepsis and to report outcomes (risk-adjusted mortality). Thus, there is no duplication.

#### **Alternative Approaches**

There are no viable alternatives. Implementation of these regulations is predicated on strong evidence indicating the effectiveness of implementing evidence-based protocols. In addition to requiring that all hospitals throughout the State develop and implement evidence-based sepsis protocols, the regulations will require submission of data to the Department. This will allow the Department to monitor adherence to protocols, measure the impact of the protocols through risk-adjusted mortality statistics, and use the data and information obtained to inform the development of quality improvement initiatives.

#### **Federal Requirements**

Currently there are no federal requirements regarding the adoption of sepsis protocols or for reporting adherence to protocols or risk-adjusted mortality.

In December 2012, the National Quality Forum included a proposed measure of adherence to treatment bundles for patients treated for sepsis. This measure, which is currently under consideration, would focus on patients 18 years of age and older who present symptoms of severe sepsis or septic shock who are eligible for the 3-hour (severe sepsis) and/or 6-hour (septic shock) early management bundle. The regulations proposed by the Department to measure adherence with established sepsis protocols will seek to be in alignment with the NQF measure when adopted.

#### **Compliance Schedule**

These regulations will take effect upon publication of a Notice of Adoption in the *New York State Register*.

Contact Person: Katherine Ceroalo, New York State Department of Health, Bureau of House Counsel, Regulatory Affairs Unit, Corning Tower Building, Room 2438, Empire State Plaza, Albany, NY 12237, 518-473-7488, 518-473-2019-FAX, [REGSQNA@health.state.ny.us](mailto:REGSQNA@health.state.ny.us).

#### **REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS**

#### **Effect of Rule**

The provisions of these regulations will apply to the 228 general hospitals in New York State, including 18 general hospitals operated by local governments. Three general hospitals in the State are considered small businesses. These hospitals will not be affected in any way different from any other hospital.

#### **Compliance Requirements**

Compliance requirements are applicable to those three hospitals considered small businesses as well as the 18 hospitals operated by local governments. Compliance will require: (a) adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measures.

#### **Professional Services**

Professional services are not anticipated to be impacted as a result of the following: (a) reporting the adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measure.

#### **Compliance Costs**

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) adopting and complying with evidence-based protocols; (b) reporting information to inform risk-adjusted Sepsis mortality measures; and (c) training



staff to implement the sepsis protocols. This will apply to those hospitals (three) defined as small businesses.

#### **Economic and Technological Feasibility**

It is economically and technologically feasible for small businesses to comply with these regulations.

#### **Minimizing Adverse Impact**

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. More specifically impacted entities will have a minimum of 90 days following adoption of these regulations to have sepsis protocols in place and at least 6 months before information to inform risk adjusted mortality measures will have to be reported to the Department.

#### **Small Business and Local Government Participation**

These regulations have been discussed with hospital associations that represent hospitals throughout the State, including those that are small businesses and operated by local governments, who are supportive of this initiative.

#### **Cure Period**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

### **RURAL AREA FLEXIBILITY ANALYSIS**

#### **Effect of Rule**

The provisions of these regulations will apply to general hospitals in New York State, including 47 general hospitals located in rural areas of the State. These hospitals will not be affected in any way different from any other hospital.

#### **Compliance Requirements**

Compliance requirements are applicable to those hospitals located in rural areas. Compliance will require: (a) adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measures.

#### **Professional Services**

Professional services will not be impacted as a result of these regulations.

#### **Compliance Costs**

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) adopting and complying with evidence-based protocols; (b) reporting information to inform risk-adjusted Sepsis mortality measures; and (c) training staff to implement the sepsis protocols. This will apply to those hospitals located in rural areas of New York State.

#### **Minimizing Adverse Impact**

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. More specifically impacted entities will have a minimum of 90 days following adoption of these regulations to have sepsis protocols in place and at least 6 months before information to inform risk-adjusted mortality measures will have to be reported to the Department.

#### **Rural Area Participation**

These regulations have been discussed with hospital associations that represent hospitals throughout the State, including those that are located in rural areas, who are supportive of this initiative.

### **JOB IMPACT STATEMENT**

Pursuant to the State Administrative Procedure Act (SAPA) section 201-a(2)(a), a Job Impact Statement for this amendment is not required because it is apparent from the nature and purposes of the proposed rules that they will not have a substantial adverse impact on jobs and employment opportunities.

RESPONSE BY PATRICK CONWAY, M.D., MSC TO QUESTIONS OF SENATOR MURPHY

*Question 1.* Considering that hospitals are a prime arena for priority attention in reducing Healthcare-associated infections (HAIs), have you considered the role of antimicrobial copper surfaces in reducing infections acquired in a hospital setting? The research surrounding the use of copper on certain surfaces where pathogens can live, such as bed rails and door knobs, is intriguing to me as we examine ways that we can reduce Healthcare-associated infections (HAIs) and unnecessary hospital readmissions. Are you familiar with the research in this area? And do you consider this application of copper surfaces to be a useful tool for reducing infections?

Answer 1. We are familiar with the research in this area, and we are committed to the reduction of infections in hospitals and other patient care settings. This research is still in its very earliest stages, and more research is needed. You are correct in describing this approach as “intriguing.” The approach is very innovative and holds great promise. We will continue to interact with national and international authorities on infection control to inform our policies in supporting the work to reduce HAIs.

*Question 2.* You mentioned in your testimony the role that Quality Improvement Organizations (QIOs) play in reducing healthcare associated infections. How would this important work change if CMS were to move from the current State-based model to a regional network?

Answer 2. The important role that QIOs play in working with hospitals and other providers to reduce HAIs will not in any way be reduced. Moreover, we believe that additional flexibility in defining the geographic areas for the QIOs activities will enhance system efficiencies, streamline the QIO work, and allow targeting of program expertise in a way that will most effectively establish and spread best practices. As the science of quality improvement continues to evolve rapidly, we believe that the QIO program should evolve as well to more effectively reduce and prevent HAIs and other events of harm, and further enhance quality-improvement initiatives.

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NATIONAL CENTER FOR EMERGING AND ZOO NOTIC INFECTIONOUS  
DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION,  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
ATLANTA, GA, 30333,  
*September 24, 2013.*

DEAR MR. CHAIRMAN: On September 24, 2013, the Centers for Disease Control and Prevention (CDC) testified at a hearing before the Committee on Health, Education, Labor, and Pensions entitled “U.S. Efforts to Reduce Healthcare-Associated Infections.” This letter provides responses for the record to questions posed by certain members of the committee, which we received on November 7, 2013.

CDC works 24–7 to save lives and protect people from harm. CDC has prioritized the prevention of healthcare-associated infections (HAIs) as one of the agency’s Winnable Battles—public health priorities with large-scale impact on health and with known, effective strategies to address them.

HAIs include a variety of infections ranging from those related to specialized intensive care procedures like mechanical ventilation, to infections caused by lapses in basic safe practices, like re-using disposable syringes or inappropriate cleaning of equipment. HAIs are associated with increased mortality and greater cost of care, and can occur in any healthcare setting—hospitals, long-term acute care, dialysis clinics, ambulatory surgical centers, nursing homes/skilled nursing facilities, and even doctors’ offices. In the worst cases, HAIs can lead to sepsis, a dangerous body-wide inflammation that can result in organ failure and death. Primary prevention of HAIs stops a root-cause of sepsis.

CDC’s portfolio of activities is critical to improving the capacity of healthcare facilities and States to detect HAIs and protect patients and communities.

If you have further questions, please contact Michael Craig at [MCraig@cdc.gov](mailto:MCraig@cdc.gov).

Sincerely,

BETH P. BELL, M.D., M.P.H.,  
*Director.*

RESPONSE BY BETH BELL, M.D., M.P.H. TO QUESTIONS OF SENATOR HARKIN,  
SENATOR CASEY, SENATOR HAGAN, AND SENATOR MURPHY

SENATOR HARKIN

*Question.* Has CDC/CMS reviewed the DOD-funded copper clinical trial results? If so, what is their opinion? Do they believe the use of copper furnishings in hospitals has significant potential for reducing bacterial loadings or harmful healthcare infection rates?

Answer. CDC has reviewed the DOD-funded copper clinical trial results by Salgado et al.<sup>1</sup> This study demonstrated a significant reduction in HAIs and/or colonization with healthcare pathogens. Antimicrobial copper has been repeatedly shown to result in moderate reductions in environmental surface contamination, although it is not known what degree of bacteria reduction is necessary to affect HAI or colonization outcomes.

HAI elimination is a priority at CDC and we are always looking for new and innovative ways to increase the safety of health care, including surface treatments such as silver alloys and copper. CDC recommendations for new practices or technologies are based on peer-reviewed scientific evidence of both effectiveness and safety, as well as an assessment of potential unintended consequences of such innovations. Adjunct measures such as copper products would not replace standard infection control practices, but they might play a useful role in reducing infections in health care settings. However, additional research will be needed before any recommendations can be made on the appropriate role of using copper to reduce HAIs, and CDC is interested in pursuing work in this area.

SENATOR CASEY

*Question 1.* Is the CDC working with medical providers and the public to raise awareness of sepsis?

*Question 2.* If so, what steps have been taken, or what programs exist, to encourage timely diagnosis of sepsis?

*Question 3.* Is the United States learning from best practices that have been adopted around the world—including in the EU—to diagnose and monitor sepsis?

I understand that CDC has recommended reducing unnecessary antibiotic usage as a means of addressing the rise of antibiotic resistance bacteria.

*Question 4.* Do U.S. patients often receive preventive antibiotics while they're awaiting diagnostic test results that may take hours or days? And how can the United States ensure that at-risk patients are monitored for the development of sepsis without being given unnecessary antibiotics?

Answers 1–4. Primary prevention of HAIs stops a root-cause of sepsis. Eliminating HAIs is a priority for the Department and its Federal agencies, evidenced by the “HHS Action Plan to Eliminate Health Care-Associated Infections: Road Map to Elimination.”<sup>2</sup> CDC data indicate that at any given time, approximately 1 in 20 hospitalized patients has an HAI and over 1 million infections occur each year across healthcare settings. In the worst cases, some HAIs can lead to sepsis, a dangerous body-wide inflammation that can result in organ failure and death.

Using multiple detect-and-protect strategies, CDC's world-class experts target HAIs and the drug resistant pathogens that can cause them, including:

- monitoring HAIs and evaluating their risk factors, establishing benchmarks and targets, and tracking prevention progress toward those goals,
- detecting and responding to emerging and urgent threats through outbreak investigation and laboratory science,
- developing guidelines for HAI prevention and filling gaps in knowledge through applied research,
- implementing prevention strategies with Federal and State partners.

CDC promotes primary prevention of sepsis by preventing HAIs from occurring in the first place. Some examples include the promotion of vaccination and smoking cessation to prevent community-acquired pneumonia or the careful insertion of central venous catheters in hospitals to prevent bloodstream infections.

However, the reality is that infections do occur despite our best prevention efforts. CDC is working to understand and ultimately prevent mortality and morbidity from severe sepsis. Researchers in CDC's Emerging Infections Program (EIP) are working to characterize which patients develop severe sepsis, their underlying conditions, the infectious causes, and when during their interaction with healthcare those patients

<sup>1</sup> <http://www.ncbi.nlm.nih.gov/pubmed/23571364>.

<sup>2</sup> <http://www.hhs.gov/ash/initiatives/hai/actionplan/>.

most often develop sepsis. This important work will identify strategies for enhancing primary diagnosis prevention for those patients identified with severe sepsis.

Adding to the body of knowledge about sepsis, researchers at CDC's Harvard Prevention Epi-Center are working to better understand ways to identify patients most likely to benefit from a set of specific interventions (called a "bundle") for treating severe sepsis. The goal of this project is to focus resources, reduce unnecessary antibiotic use, improve performance measurement, and improve tracking of national risk-adjusted mortality. Meanwhile, researchers at CDC's Washington University Prevention Epi-Center are tracking historic rates of sepsis defined by both electronic health records and administrative coding (billing) data. While most recent reports of increasing rates of sepsis have been based upon billing data, such a comparison may reveal findings suggesting that while U.S. hospitals are doing a better job at diagnosing and coding for sepsis (and therefore show an increase in billing codes for sepsis), actual rates of sepsis defined via clinical parameters have remained stable.

The United States and European Union (E.U.) continue to consult with each other regarding best practices for diagnosing and monitoring sepsis. This is principally done as part of the ongoing activities of the Transatlantic Task Force on Antimicrobial Resistance (TATFAR). In implementing the recommendations for collaboration in the initial TATFAR report,<sup>3</sup> the United States and E.U. have addressed the issue of sepsis diagnostics and monitoring. Specifically, the United States and E.U. held a joint workshop entitled, "*Challenges and Solutions in the Development of New Diagnostic Tests to Combat Antimicrobial Resistance*" in September 2011, Brussels, Belgium. The workshop brought together experts from healthcare, government, and industry with an aim to identify factors impacting the development, approval, introduction and appropriate use of new diagnostic tools for invasive bacterial infections (i.e., sepsis) in both inpatient and outpatient settings. In addition, the U.S. CDC and the E.U. CDC (ECDC) regularly correspond on the topic of antimicrobial resistant surveillance activities and results including surveillance for pathogens causing sepsis and associated antimicrobial resistance. CDC and ECDC conduct quarterly conference calls to discuss surveillance strategies, new findings and trends.

Timely transatlantic communication and common actions are fundamental to respond to emerging threats and critical trends due to antimicrobial resistance. To improve communication and properly disseminate information within the United States, E.U. and partner public health agencies and ministries of health, CDC and ECDC drafted and approved terms of reference (ToR) on how international communication and actions about critical antimicrobial resistance surveillance results will occur and what information should be communicated. As described in the ToR, communications include a procedure for notification of the identification of novel resistant phenotypes, as well as quarterly conference calls in which CDC and ECDC subject matter experts discuss new resistance data and critical trends. These calls were initiated in 2012 and allow experts to exchange information on resistance and also on surveillance programs and protocols. As a result, each agency has gained better insight into the current state of antimicrobial resistance and is fostering new collaborations.

Finally, the question regarding being sure that patients who need antibiotics receive them early on while avoiding unnecessary antibiotic use highlights a concern we share. Currently, empiric antibiotics (i.e., non-prophylaxis and non-culture directed or therapeutic) account for a significant proportion of all antibiotics administered in U.S. hospitals and such early empiric use is necessary to reduce mortality from serious infections in individual situations. In light of this necessity, our principal antibiotic stewardship strategies to improve antibiotic use do not involve restrictions on such early empiric use, but rather encourage clinicians to communicate in the medical record why the antibiotics are being used and perform an "antibiotic time out" after 48–72 hours when culture results become available, reassessing whether the antibiotics are still needed. To advance the availability of tools to aid in clinical decisionmaking, both CDC's Chicago and University of Pennsylvania Prevention Epicenters are performing research on biomarkers, such as procalcitonin, that can assist in determining whether a patient requires, or continues to require, antibiotic coverage owing to a higher likelihood of active infection.

*Question 5.* What else is the CDC doing to help hospitals deal with infections that are resistant to antibiotics?

*Question 6.* How is the CDC keeping up with diseases to ensure they are not becoming resistant to antibiotics?

<sup>3</sup><http://www.cdc.gov/drugresistance/pdf/tatfar-report.pdf>.

Answers 5–6. Preventing infections negates the need for antibiotic use in the first place, and scientific evidence shows that reducing antibiotic use in a single facility can reduce resistance in that facility. Taken on a national scale, infection prevention efforts can significantly decrease resistance. To help prevent infections, CDC:

- conducts research to find new ways of preventing infections;
- provides the Nation with infection prevention guidelines and tools to prevent infections;
- serves as the Nation's reference laboratory to identify microorganisms; and
- offers the Nation's largest HAI infection tracking system, the National Healthcare Safety Network (NHSN), allowing facilities and States to identify and address problem areas.

CDC works to prevent antibiotic resistance in healthcare settings by providing a system to track resistance and prescribing patterns at national, regional, and local levels; providing guidance to healthcare facilities interested in better antibiotic use; and working to prevent all patient infections through infection control guidelines, assistance implementing these guidelines, and laboratory expertise. As more hospitals submit data to the new NHSN Antibiotic Use and Resistance (AUR) Module, they will be able to track and benchmark antibiotic resistance in all bacteria, as well as track antibiotic usage. CDC's NHSN is used by healthcare facilities to electronically report infections, antibiotic use, and resistance. Data currently submitted by hospitals to NHSN provide facilities, States, and regions with the ability to track and benchmark antibiotic resistance (AR) in bacteria responsible for many HAI. This information will allow facilities to target areas of concern, to make needed improvements and to track the success of their efforts. In addition, NHSN allows CDC to perform and report national assessments of antibiotic resistance.

CDC uses national, regional, and local surveillance data to: (1) detect and track emerging AR pathogens; (2) identify situations where multidrug resistant pathogens are increasing; and (3) work with State health department and healthcare facilities to prevent infections and respond to outbreaks of antibiotic resistance. Under the Prevention Fund, CDC has piloted regional collaborative projects to detect emerging AR problems and implement infection control measures to prevent spread of AR pathogens. CDC works with State public health departments to improve and strengthen their clinical and public health laboratories to detect AR pathogens accurately.

CDC's EIP and Epidemiology and Laboratory Capacity collaborate with State and national partners on AR surveillance and special studies for invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) and multidrug-resistant, gram-negative organisms.

CDC laboratories detect new and emerging pathogens (e.g., by using DNA analysis) to compare and maintain a repository of clinically relevant isolates. CDC's specialized national reference laboratory tests bacteria samples from around the country to detect new and emerging resistance patterns that affect patient health. This provides an early warning of new resistance that has the potential to spread across the Nation, requiring public health action. Additionally, CDC recently conducted a survey in collaboration with EIP sites to estimate the number of HAIs and to better understand antibiotic use in U.S. hospitals. This is CDC's largest EIP survey in more than 30 years and will make improved estimates of the burden of HAIs in the United States, discover which pathogens are causing infections and how many are resistant to antibiotics, and identify antibiotic use patterns that may be contributing to resistance. The survey will complement NHSN data by addressing all HAIs in all types of hospital patients and will be used to inform national policies and recommendations that target HAI prevention and antibiotic preservation. Two publications will be released on the results of this survey. The first will focus on the HAI prevalence and the second will focus on results related to antibiotic use. Formal results will be published in spring 2014 and late 2014 respectively.

SENATOR HAGAN

*Question.* Despite the important work done by a variety of health care providers, published reports indicate that some continue to be exposed to blood-borne pathogens and bacterial infections due to unsafe medical injection practices including the reuse of needles and/or syringes, mishandling of medication vials and containers, reuse of single-dose vials, and reuse of insulin pens. The CDC has clear guidelines for are injection practices. Last summer, the GAO shed light on this issue in their report "HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action Is Needed." This report noted the work of the CDC to promote education and awareness on this topic. However, this report focused solely on unsafe injection practices in ambulatory surgery centers (ASCs). But we know that unsafe medical

injections are happening in other settings as well such as VA Medical Centers, assisted living facilities, dental clinics, correctional facilities, and inpatient hospitals.

What steps need to be taken to ensure that all healthcare providers are aware of and adhering to current injection safety guidelines across all healthcare settings?

Answer. Investigations undertaken by State and local health departments and the CDC have identified instances of improper use of syringes, needles, and medication vials during routine healthcare procedures, such as administering injections. These unsafe practices have resulted in a wide range of adverse events, including the transmission of bloodborne viruses, like hepatitis C, to patients. Between 2001 and 2011, over 40 outbreaks of viral hepatitis or bacterial infections resulting from unsafe injection practices occurred in various healthcare settings, most commonly in non-hospital settings. These outbreaks resulted in the notification and infection testing of over 130,000 patients and over 630 confirmed infections. It should be noted that these numbers are likely to be an under-estimate due to inherent challenges with outbreak detection and investigation. These unfortunate events serve as a reminder of the serious consequences of failure to maintain strict adherence to safe injection practices during patient care. Injection safety and other basic infection control practices are central to patient safety, as well as prevention of needle-stick injuries to providers and other healthcare personnel.

CDC is working with partners, other Federal agencies, and State and local health departments to provide educational and promotional materials in an effort to improve adherence to CDC safe injection practices and prevent transmission of bloodborne pathogens and other infectious diseases in all healthcare settings. CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) developed evidence-based recommendations on Safe Injection Practices applicable in all healthcare settings as part of Standard Precautions and can be found in the 2007 Guideline for Isolation Precautions. CDC and HICPAC further developed guidelines specifically targeting infection control practices in outpatient healthcare settings, including those related to safe injection practices. CDC is collaborating with the Safe Injection Practices Coalition (SIPC) on the One and Only Campaign, an educational campaign to promote safe injection practices by raising awareness among patients and healthcare providers about safe injection practices. Currently CDC and SIPC have partnered with five States (CO, NC, NJ, NV, and NY) to help disseminate the messages and materials of the One & Only Campaign, conducting educational outreach, state-based activities and further promotion of the campaign.

CDC continues to respond to a steadily increasing number of requests from State health departments and healthcare facilities for assistance in investigating infections and outbreaks potentially stemming from unsafe injection practices or related breakdowns in safe care. Support from CDC includes technical guidance and consulting from epidemiologists, onsite assistance with field investigations, and laboratory assistance. Varying availability of health department resources and potential reticence by health departments and facilities to alert CDC of potential outbreaks continue to affect CDC's ability to accurately and effectively monitor unsafe injection practices and related adverse events.

#### SENATOR MURPHY

*Question.* To date, efforts to address antibiotic resistance have been primarily focused on encouraging the development of new antibiotics. CDC's recent report also identifies the need to develop new diagnostic tests for identifying resistant bacteria. What steps do we need to take to encourage investments in research and development in order to advance diagnostic capabilities in this area?

Answer. CDC recommends four core actions to address the public health concern of antibiotic resistance:

1. Prevent infections in the first place and stop the spread of resistant infections from person-to-person.
2. Track resistance to monitor progress.
3. Improve antibiotic use/stewardship.
4. Develop new drugs and diagnostic tests.

CDC is the primary reference laboratory supporting State health departments and U.S. health care facilities in timely identifying dangerous or emerging antimicrobial resistance.

Given the scope of the threats that we face, CDC needs to equip our scientists and State public health laboratories with the best available tools to rapidly identify these threats and accelerate our Nation's response to them. New technologies will allow us to uncover hidden outbreaks (including those caused by antimicrobial resistant pathogens), stop them sooner, and save lives. To that end, the President's fiscal year 2014 Budget proposed an Advanced Molecular Detection (AMD) initiative

that would equip CDC's scientists with two powerful technologies—molecular sequencing and bioinformatics—to help solve complex disease outbreaks. With new technology CDC can find outbreaks we are currently missing, find outbreaks sooner, stop them faster, and identify ways organisms are spread so we can better prevent them. These techniques would also help us to identify how pathogens spread so we can better target our prevention efforts. Genetic sequencing of pathogens, if funded, will revolutionize how CDC investigates and controls disease outbreaks, including those caused by antibiotic resistant strains.

This funding will support research designed to improve our understanding of the molecular mechanisms of resistance and will support the development of new clinical diagnostic tests to detect AR pathogens to improve clinical decisionmaking and speed up the implementation of infection control strategies. These investments will allow CDC to: lead core laboratory activities to assess optimal patient treatment; serve as a national and international antimicrobial resistance reference laboratory; perform antimicrobial susceptibility tests; and respond to diagnostic needs for new and emerging healthcare-associated pathogens.

Specifically, culture-based laboratory diagnostics are slow and insensitive. Polymerase-chain-reaction-based tests are costly and provide limited information. AMD will enable CDC to establish leading capability to adapt the next generation of rapid, semi-automated, point-of-care molecular tests to meet evolving public health needs. As a result, the agency will significantly enhance its ability to pinpoint early threats and outbreaks; develop new diagnostic tests during outbreaks; better characterize infections, including those caused by highly resistant healthcare-associated pathogens, such as *Clostridium difficile*, MRSA, and CRE; and increase the level of detail and quality of information for biosurveillance and response activities. To that end, the President's fiscal year 2014 budget proposal is an important step in helping to ensure that CDC can adequately track, rapidly detect, and respond to these alarming threats.

RESPONSE BY JONATHAN PERLIN, M.D. PH.D., MSHA, FACP, FACMI TO QUESTION  
OF SENATOR CASEY

*Question.* The REDUCE MRSA study specifically looked at strategies to reduce transmission of MRSA. Are there any similar efforts underway to better identify and treat sepsis?

*Answer.* We are advancing up our own version of the national “Survive Sepsis” campaign. That said, the state-of-the-art doesn't yet allow early identification of when sepsis will occur. We propose that collaboration with CDC and academic colleagues could allow us to mine “big data” to discover earlier predictors of sepsis.

As I testified, current science allows us to intervene aggressively when we see fire. We need to be able to smell smoke, or even advance to preventing fires.

I am happy to discuss or elaborate further. Again, my thanks to the committee for the privilege of presenting our work and for their leadership in this important area.

[Whereupon, at 12 p.m., the hearing was adjourned.]