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HEALTHCARE-ASSOCIATED INFECTIONS: A PREVENTABLE EPIDEMIC

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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HEALTHCARE–ASSOCIATED INFECTIONS: A PREVENTABLE EPIDEMIC

WEDNESDAY, APRIL 16, 2008

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 11:09 a.m., in room 2154, Rayburn House Office Building, Hon. Henry A. Waxman (chairman of the committee) presiding.

Present: Representatives Waxman, Kucinich, Davis of Illinois, Watson, Yarmuth, McCollum, Hodes, Sarbanes, Davis of Virginia, Burton, Shays, and Platts.

Also present: Representative Murphy of Pennsylvania.

Staff present: Andy Schneider, chief health counsel; Sarah Despres, senior health counsel; Steve Cha, professional staff member, Earley Green, chief clerk, Teresa Coufal, deputy clerk; Jesseca Boyers, special assistant; Ella Hoffman, press assistant; Leneal Scott, information systems manager; Kerry Gutknecht and Miriam Edel, staff assistants; Larry Halloran, minority staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Ashley Callen, minority counsel; Jill Schmaltz and Benjamin Chance, minority professional staff members; Patrick Lyden, minority parliamentarian and member services coordinator; and John Ohly, minority staff assistant.

Chairman WAXMAN. The meeting of the committee will come to order. Today we will examine an epidemic that causes about 2 million infections and 100,000 deaths each year and costs the Nation billions of dollars. This epidemic ranks sixth among the leading causes of death. It is largely preventable, and the sad fact is we are not doing nearly enough to prevent it.

The epidemic I am referring to is healthcare-associated infections. These are the infections that patients get when they are in the hospital, clinic, or even their doctor's office, receiving treatment for other illnesses.

Today's discussion will be limited to the infections patients get in the hospital. There are several types of healthcare-associated infections. Patients often need large catheters placed into their bloodstream. Improper procedures by physicians and nurses can contaminate these lines and cause bloodstream infections. When patients need surgery, improper procedures can lead to unnecessary infections of the surgical site.

Today's hearing will focus on what the Department of Health and Human Services is doing to address this epidemic. According to new findings by the Government Accountability Office, the Depart-

ment is not providing the necessary leadership. It has not identified for hospitals the most important infection-control practices, and it is not coordinating the collection of data from hospitals in order to avoid duplication and unnecessary burden.

The failure of HHS leadership is particularly regrettable because these illnesses, deaths, and costs are preventable. Moreover, the preventive measures don't require new technologies or large investments.

Thanks to the work of one of our witnesses, Dr. Peter Pronovost, and the efforts of Michigan hospitals, we know that by taking simple steps hospitals can significantly reduce the number of patients who become infected when they are receiving treatment for another condition. These steps are not expensive. Healthcare workers should wash their hands before inserting the catheter into a blood vessel. If a patient is going to undergo a surgical procedure, the hair around the surgical site should be removed with clippers, not a razor, so as to avoid nicks and cuts that can be routes of infection. Catheters should be withdrawn as soon as they are no longer necessary.

We are going to hear this morning from a hospital administrator whose hospital has taken these simple infection-control measures. He will explain that his hospital's infection rate dropped precipitously.

How many deaths could be prevented if all the hospitals took these simple steps? I asked the Society of Healthcare Epidemiologists to prepare an estimate of the number of deaths from healthcare-associated infections that could be prevented by using proven interventions. They noted that data was limited, and analyzed just four kinds of healthcare-associated infections. According to their analysis, we could prevent tens of thousands of deaths each year just by doing what we already know how to do.

Earlier this week the Institute of Medicine [IOM] reported that there would be a large cost savings if we simply put our knowledge into action. The IOM conservatively estimated that healthcare-associated infections result in extra costs of about $5 billion with a "B," billion per year to society as a whole.

Other infection-control measures may be promising, but are less well understood. For instance, two articles recently appeared in the top medical journals about screening for the drug resistant bacteria known as MRSA. One concluded that MRSA screening did work. One concluded it did not.

HHS needs to help hospitals understand which strategies do work. But hospitals should not wait while HHS sorts out all the evidence. They should adopt the simple measures that are already proven and give their patients the benefit of the lowest achievable risk of infection.

It is not too often that a prevention strategy comes along that is simple, inexpensive to implement, and proven to be effective in reducing the number of patients' deaths. The experience of the Michigan hospitals demonstrates clearly that this prevention strategy works.

Today we will try to understand why the Department of Health and Human Services is not doing more to lead in the dissemination and adoption of this strategy nationwide.

[The prepared statement of Chairman Henry A. Waxman follows:]

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Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
Healthcare-Associated Infections: A Preventable Epidemic
April 16, 2008

Today we will examine an epidemic that causes about two million infections and 100,000 deaths each year and costs the nation billions of dollars. This epidemic ranks sixth among the leading causes of death.

It is a largely preventable epidemic but we are not doing nearly enough to prevent it.

The epidemic I'm referring to is healthcare-associated infections. These are the infections that patients get when they are in the hospital, clinic, or even their doctor's office receiving treatment for other illnesses. Today's discussion will be limited to the infections patients get in the hospital.

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Today's hearing will focus on what the Department of Health and Human Services (HHS) is doing to address this epidemic. According to new findings by the Government Accountability Office, the Department is not providing the necessary leadership. It has not identified for hospitals the most important infection control practices, and it is not coordinating the collection of data from hospitals in order to avoid duplication and unnecessary burden.

The failure of HHS leadership is particularly regrettable because these illnesses, deaths, and costs are preventable. Moreover, the preventive measures don't require new technologies or large investments.

Thanks to the work of one of our witnesses, Dr. Peter Pronovost, and the efforts of Michigan hospitals, we know that by taking simple steps, hospitals can significantly reduce the number of patients who become infected while they are receiving treatment for another condition.

These steps are not expensive. Healthcare workers should wash their hands before inserting a catheter into a blood vessel. If a patient is going to undergo a surgical procedure, the hair around the surgical site should be removed with clippers, not a razor so as to avoid nicks and cuts that can be routes of infection. Catheters should be withdrawn as soon as they are no longer necessary.

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Other infection control measures may be promising but are less well understood. For instance, two articles recently appeared in the top medical journals about screening for the drug resistant bacteria known as MRSA. One concluded that MRSA screening did work, one concluded it did not. HHS needs to help hospitals understand which strategies do work.

But hospitals should not wait while HHS sorts out the evidence. They should adopt the simple measures that are already proven and give their patients the benefit of the lowest achievable risk of infection.

It's not too often that a prevention strategy comes along that is simple, inexpensive to implement, and proven to be effective in reducing the number of patient deaths. The experience of the Michigan hospitals demonstrates clearly that this prevention strategy works. Today we will try to understand why the Department of Health and Human Services is not doing more to lead in the dissemination and adoption of this strategy nationwide.

Chairman WAXMAN. Before we call on the witnesses, I want to recognize Mr. Tom Davis for an opening statement.

Mr. DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

A century and a half ago, Hungarian physician Ignaz Semmelweis noted that one in three women died from fever after giving birth in hospitals. He was the first to make the connection between basic hygiene practices by doctors and the deadly trend. When he instructed his students to wash their hands before examining patients, the maternal death rate fell to less than 1 percent.

Today we think of our healthcare system as highly advanced and technologically sophisticated. But hospital infection rates remain stubbornly and unacceptably high. The very complexity of modern healthcare delivery can give persistent microbes many more places to hide. Distracted by all the costly gadgets, effective and cheap low-tech solutions like basic hand hygiene can be overlooked and undervalued.

This year, in this country, 1.7 million patients will contract an infection in a healthcare facility; 98,000 of those patients will not survive. Those who do may face degraded health, unnecessary time away from work and family, and the additional costs of treating a preventable complication of their original care.

Ed Lawton is one of those survivors. Facing surgery in 1998, Mr. Lawton could not have foreseen the most dangerous threat to his health would be antibiotic-resistant infections acquired in the hospital. That contamination put his life in danger, and needlessly added years to the course of his recovery. Mr. Lawton is a constituent of mine and a victim of the painful, costly, and too often deadly epidemic of hospital-acquired infections. His sad saga brings meaning to the often lifeless statistics about our healthcare system's dirty secrets. We are grateful he could be here to testify today on the impact and implications of this intractable public health threat.

On top of the human suffering, treatment of hospital-acquired infections adds $5 billion to healthcare spending annually. In a system already strained to meet urgent needs, the $5 billion is wasted fixing preventable mistakes. Those resources could be used to treat vulnerable children, research or a cure for debilitating disease. Reducing the instance of infection would improve the quality of care, prevent needless suffering and death, and reduce waste.

It is a problem with known solutions, but the healthcare system has been largely ineffective at making progress. Why? One answer seems to be pervasive financial incentives that simply pay the bill for care-induced infections rather than reward prevention or punish carelessness.

In an effort to reverse that flow, the Department of Health and Human Services recently engaged the powerful fiscal tool available to the Federal Government in the healthcare marketplace: Medicare repayments. By withholding reimbursements for certain hospital infections, the Federal Government sends a powerful signal that healthcare spending should align more closely with quality outcomes, and the signal is being heard.

That change in Medicare policy helped pave the way for similar changes in private insurance reimbursement. At the request of the Minority, the Leapfrog Group will testify this morning. They represent large private purchasers of healthcare, and will discuss the

importance of incentives to focus spending on the quality, not just the quantity of care. We appreciate the chairman's willingness to include their testimony in today's hearing. It is still too early to know the impact of these reforms, and the opportunities for change have not been exhausted.

HHS has yet to maximize the use of various health surveillance data bases, expand the type of infections Medicare will no longer pay for, and partner with hospitals and payers to make infectious-control activities a priority. Health facility boards and CEOs need to be clear that infection prevention is an indispensable element in the standard of care. Cultural behavioral norms will have to change and money may have to be invested to implement infection-control guidelines. And hospital accreditation standards should reflect stronger anti-infection requirements, demanding more than just a plan, but an actual program that produces measurable outcomes to reduce contamination.

We do know that there are significant opportunities to effect change in hospital infection rates. The Centers for Disease Control and Prevention has developed detailed guidelines for infection control. We will also hear about private research into healthcareinterventions that have dramatically lowered infection rates. The answer may seem simple—a little soap, a drop of bleach—but the broad-scale changes needed to clean up healthcare institutions won't be easy. Hearings like this shine the disinfecting light of public discourse on a critical public health problem, and we look forward to today's testimony. Thank you.

[The prepared statement of Hon. Tom Davis follows:]

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

TOM DAVIS, VIRGINIA
RANKING MINORITY MEMBER

ONE HUNDRED TENTH CONGRESS

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Statement of Rep. Tom Davis
Ranking Republican Member
Committee on Oversight and Government Reform
"*Healthcare Associated Infections: A Preventable Epidemic*"
April 16, 2008

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Reducing the incidence of infection would improve the quality of care, prevent needless suffering and death, and reduce waste. It is a problem with known solutions. But the health care system has been largely ineffective at making progress. Why?

One answer seems to be perverse financial incentives that simply pay the bill for care-induced infections rather than reward prevention or punish carelessness. In an effort to reverse that flow, the Department of Health and Human Services recently engaged the most powerful fiscal tool available to the federal government in the health care marketplace – Medicare payments.

By withholding reimbursement for certain hospital infections, the federal government sends a powerful signal that health care spending should align more closely with quality outcomes.

And the signal is being heard. That change in Medicare policy helped pave the way for similar changes in private insurance reimbursement. At the request of the Minority, the Leapfrog Group will testify this morning. They represent large private purchasers of health care and will discuss the importance of incentives to focus spending on the quality, not just the quantity, of care. We appreciate the Chairman's willingness to include this testimony in today's hearing.

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Cultural behavioral norms will have to change, and money may have to be invested to implement infection control guidelines. And, hospital accreditation standards should reflect stronger anti-infection requirements, demanding more than just a plan but an actual program that produces measurable outcomes to reduce contamination.

We do know there are significant opportunities to affect change in hospital infection rates. The Centers for Disease Control and Prevention has developed detailed guidelines on infection control. We will also hear about private research into health care interventions that have dramatically lowered infection rates.

The answer may seem simple – a little soap, a drop of bleach – but the broad-scale changes needed to clean up health care institutions won't be easy. Hearings like this shine the disinfecting light of public discourse on a critical public health problem, and we look forward to today's testimony.

But it must be said the driving factor in the loss of value and confidence in Lehman's was the financial undertow created by falling home prices and resulting losses on mortgage-backed assets of all kinds. And central to that crisis in the twelve trillion dollar mortgage securities market were imprudent policies and cozy practices of the two government-sponsored housing finance giants Fannie Mae and Freddie Mac. We have asked that former Fannie Mae CEO Franklin Raines be invited to testify at a future hearing because that company's failure offers Congress lessons we dare not overlook.

Many in Congress did turn a blind eye to clear warnings of impending danger sounded as early as 1998. They missed golden opportunities to treat localized problems before they metastasized throughout the economic system. Out of well-intentioned zeal to promote home ownership, Members from both parties in both chambers not only tolerated but encouraged the steady erosion of mortgage lending standards. When an alarm sounded, Fannie and Freddie - holding low-income borrowers as political hostages - mobilized armies of expensive lobbyists to block calls for greater accountability and transparency. Using lobbying fees and campaign contributions, the mortgage giants bought their way around attempts by Senate and House banking committees to pierce their profitable pyramid scheme. The Clinton Administration was rebuffed by a Republican Congress; and this Administration had no more success with the Democratic Congress in advancing needed reforms. This Committee cannot ignore that sad history in our inquiries into the causes and effects of the current economic crisis.

Now that the $700 billion economic rescue bill has been enacted, the debate is no longer whether the federal government should intervene in the credit markets, but how that intervention should be managed to stabilize capital flows and protect taxpayers. Although it comes too late to help Lehman Brothers, the so-called "bail out" program will have to make wrenching choices, picking winners and losers from a shattered and fragile economic landscape. These hearings should help mark the landmines and potholes on the path to a restoration of trust and economic vitality.

Trust. There is a moral dimension to economics we often don't want to confront. Economics is a not an objective discipline, but a political art, grounded in certain assumptions about human nature and civilized behavior. As the process of "deleveraging" unfolds - breaking the economy's delusional addiction to debt beyond our reasonable means to repay - the goal has to be a restoration of the moral bond between labor and capital. We need to restore faith in production, savings, and investment over consumption, spending and speculation.

Our witnesses today can help us do that, and we appreciate their being here.

Chairman WAXMAN. Thank you very much, Mr. Davis.

I want to call forward our panel 1: Edward Lawton a survivor of hospital-acquired infections; Cynthia Bascetta, Director for Healthcare Issues, Government Accountability Office; Peter Pronovost, medical director, Center for Innovation in Quality Patient Care and Assistant Professor, Department of Anesthesiology and Critical Care Medicine at Johns Hopkins University School of Medicine; John Labriola, senior vice president and hospital director, William Beaumont Hospital, Royal Oak; Leah Binder, chief executive officer of the Leapfrog Group; Don Wright, M.D., Principal Deputy Assistant Secretary for Health, U.S. Department of Health and Human Services.

As you come forward to take your seat, why don't you remain standing, because it is the practice of this committee that all witnesses that testify do so under oath. So I would like you to please raise your right hands.

Mr. DAVIS OF VIRGINIA. Mr. Chairman, could I ask unanimous consent to let Mr. Murphy of Pennsylvania, Mr. Tim Murphy, participate in the hearing?

Chairman WAXMAN. Without objection, we would welcome his participation. We are pleased to welcome you today.

[Witnesses sworn.]

Chairman WAXMAN. The Chair wants to note for the record all the witnesses answered in the affirmative. So you are properly under oath. And we want to welcome you to give your testimony. Your written statements that have been submitted in advance will be part of the record in full.

We would like to ask each of you to limit your oral presentation to around 5 minutes. We will have a clock, a buzzer over there that doesn't ring, but it does have a light. And when the green light is on it means your time is still going. For the last minute it will turn yellow. And then when the time is up, it will turn red. And when you see it red, I would hope you would conclude your remarks or summarize them very quickly.

Mr. Lawton, thank you so much for being here. I want to welcome you, and particularly note you are a constituent of Mr. Davis', and for being willing to share the unfortunate circumstances that befell you, which are going to be helpful to us to learn.

There is a button on the base of the mic, and be sure to pull it close enough so that it will all be picked up.

STATEMENTS OF EDWARD LAWTON, A SURVIVOR OF HOSPITAL-ACQUIRED INFECTIONS; CYNTHIA BASCETTA, DIRECTOR FOR HEALTHCARE ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE; PETER PRONOVOST, M.D., Ph.D., MEDICAL DIRECTOR, CENTER FOR INNOVATION IN QUALITY PATIENT CARE AND ASSISTANT PROFESSOR, DEPARTMENT OF ANESTHESIOLOGY AND CRITICAL CARE MEDICINE, JOHNS HOPKINS UNIVERSITY, SCHOOL OF MEDICINE; JOHN LABRIOLA, SENIOR VICE PRESIDENT AND HOSPITAL DIRECTOR, WILLIAM BEAUMONT HOSPITAL-ROYAL OAK; LEAH BINDER, CHIEF EXECUTIVE OFFICER, THE LEAPFROG GROUP; AND DON WRIGHT, M.D., MPH, PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF EDWARD LAWTON

Mr. LAWTON. Chairman Waxman, Ranking Member Davis, members of the House Committee on Oversight and Government Reform, distinguished and honored guests, my name is Edward Lawton, and today I sit before you, a survivor of healthcare-acquired MRSA, VRE, osteomyelitis, and klebsiella.

Today is very special not only because of the privilege of speaking before you, but because it is the 10th anniversary of my survival of the two most serious aforementioned healthcare-acquired infections. Ten years ago today, following two scheduled back surgeries, I lay in a hospital bed diagnosed with MRSA. Later, VRE and osteomyelitis would also be identified.

Ultimately, in 1998 I spent 9 months surviving what I characterize as the fog of survival. I had five back surgeries, many smaller procedures, injections too numerous to count, and more prescribed drugs than I can recall. Three of those surgeries necessitated debridement. My doctor was required to open me up three times over a period of 90 days and surgically remove contaminated tissue and foreign matter. Consequences of the infections had broader implications relating to nerve and skeletal damage and other health consequences, most of which you cannot see.

Returning home in late 1998, I spent the next 5½ years reconstituting my life, despite the fact that I could no longer independently stand or walk. Five open back wounds also diminished my homecoming. They never healed. A wound specialist advised me the wounds couldn't heal due to osteomyelitis. He said I could only be treated by more surgery, without assurances of resolution. I felt trapped, facing an inevitable consequence.

I survived, but according to CDC estimates approximately 99,000 others among the population of nearly 2 million patients nationwide, all diagnosed with healthcare-acquired infections, died that same year in America. In the past decade of my survival, approximately 20 million people were diagnosed with avoidable healthcare-acquired infections, with more than 1 million patients dying. Those are staggering statistics.

In 2004, I was rehospitalized. I had the surgery, and afterwards my doctor told me I would require additional surgeries to remove substantial infectious fluids in my body, along with the remaining rods and screws, all contaminated by klebsiella. I had two addi-

tional surgeries among other specialized care. My 6–1/2-year infection saga finally seemed over, along with the open back wounds.

In 2004, unlike my earlier hospitalizations, I insisted upon certain protective measures during my hospital stay. I had educated myself since 1998, and I refused to die because of someone's dirty hands or complacent attitude. This time I didn't contract a hospital infection. I have detailed my initiatives in my accompanying written statement.

In 1998, I witnessed and experienced unconscionable acts of hospital staff. If these well-trained, well-educated medical professionals had complied with their own standards and protocols, I probably would have walked into this hearing as a spectator rather than entering in a wheelchair as a witness.

Past years' testimony to Congress by former secretaries and assistant secretaries of the Department of Health and Human Services all consistently acknowledged the crisis of healthcare-acquired infections, yet well-educated and well-trained medical practitioners continued perpetuating the culture of complacency, ignoring the same rules we teach our children to follow before they sit at a dinner table.

Medical practitioners routinely claim that due to the inherent dangers of their work environment, healthcare infection-related deaths are unavoidable. Is that the interpretation of friendly fire? Consider that for 42 years, police officers in America have carried what is called the "rights card" so any interview with a suspect is preceded by the reading of the person's constitutional rights. Eight years ago Chief Justice William Rehnquist stated the advisement of rights was part of the national culture.

Why shouldn't medical practitioners carry anti-infection cards to protect the survival rights of patients by explaining fundamental hygienic protocols? I have created a sample for your review and consideration. Sadly, during my presentation today, someone died in America due to an infection they contracted in the hospital they trusted.

Finally, Americans ought to know what is occurring in their hospitals. We can research nearly anything on the Internet. Why don't we have the same right to check out a hospital before we risk our lives entering it?

Thank you for your courtesy. I hope my comments contribute to converting HHS sound bites into meaningful, proactive workplace attitudes, ending the scourge of healthcare-acquired infections.

Chairman WAXMAN. Thank you very much, Mr. Lawton.

Mr. LAWTON. Thank you, sir.

[The prepared statement of Mr. Lawton follows:]

House Committee on Oversight

and

Government Reform

Prepared, written statement by Edward F. Lawton

April 16, 2008

Chairman Waxman, Ranking Member Davis, Members of the House Committee on Government Oversight and Reform.

In my oral statement before this committee, I provided a brief synopsis of the severely debilitating experiences I sustained in 1998 and subsequent years, due to healthcare acquired infections. I've little doubt that hospital workplace complacency and inattentive hygienic attitudes by well educated and well trained hospital staff caused my life threatening situation, and subsequent, disabling lifestyle.

As I've prepared to speak with you today, I've given a great deal of thought to how I could possibly convey to you, the degree and scope of suffering and mental trauma I experienced due to avoidable and frankly, preventable healthcare acquired infections.

I'm unsure that I can or will, adequately convey in words, what occurred to me in 1998 which has affected me for the rest of my life. Clearly, my naiveté, unquestioning faith and high expectation that hospitals and those working within them were consummate

professionals focused on their patients, contributed to my misunderstanding of a serious threat I had yet to encounter.

SOME PERSONAL INSIGHT

Through most of my life up until the age of 41 years of age, I'd experienced minimal contact with healthcare professionals other than mostly routine physical examinations, typical dental appointments and as a child, orthodontic care. I was raised with two brothers and despite our having the various, common, childhood illnesses, my family was fortunate in that we all lived relatively disease free until we grew older. Both of my parents were deceased in their 70's, primarily due to serious and chronic illnesses.

As a young adult, my personal, primary health care experiences were associated with my military service and again, most of those experiences related to periodic physical examinations and regulatory compliance issues, none of which I believe, exposed me to healthcare acquired infections.

Because I served many years in overseas assignments, I was not around my family when serious health issues began affecting their lives. I regret I was never with my parents or grandparents when they became seriously ill, requiring hospitalization prior to their deaths.

I believe if I'd spent time with them while they were hospitalized, I would have begun to understand what really occurs in hospital settings, and maybe, I might have been better prepared when I was hospitalized. Perhaps I would have eased some of their pain which now, gnaws on me, knowing what I do about hospitals and the

dangers therein. One major concept I have learned with all my own contemporary hospitalizations and interactions with numerous healthcare providers, is that ***situational awareness is the key to survival.***

MY LIFE CHANGES FOREVER

My life changed in 1990 while I was serving overseas in the Republic of the Philippines. Beginning in the spring of that year, I began experiencing pain in my right leg and my back. The problems intensified and my military health care consisted primarily of an x-ray, some Tylenol and heat treatments. The diagnosis based upon my symptoms at the time, was sciatica.

After months of growing pain, I was sent to Manila for an MRI as the technology didn't exist at our base hospital. Following my return to Clark AB, I recall an orthopedic surgeon reviewing the films and looking at me, stating emphatically, "you're on the next aerovac to the United States. You have a serious spinal problem."

My initial serious surgery and first experience with a healthcare acquired infection occurred at the military hospital at Lackland AFB in San Antonio. The spinal surgery, what could be done, was "successful." The neurosurgeons did their jobs well, and I later walked out of the hospital. However, I recall in the post-operative period of my recovery, I contracted some type of infection which extended my hospital stay for a limited period.

I returned to the Philippines for a month long, rest and recovery period. I wasn't working at the time, but I did occasionally go to the

office after hours. I was a branch chief with seven criminal investigators under my supervision. There wasn't any question I couldn't abandon my duties merely because I was "resting and recovering."

The Air Force returned me to the United States for follow-up treatment in late January, 1991. What occurred between February and early June, 1991, was my participation in a cutting edge, developing treatment called Proton Beam Radiation.

I received nearly 7900 rads of radiation at the Lawrence Berkeley Laboratory, at the time, state of-the-art technology for my extremely rare, cancer. I handled the treatment well and actually commuted between the lab and Fairfield, California, two to three times per week. I was billeted temporarily, at a hotel near Travis AFB.

My return to Clark AB in early June, 1991 was preempted by the eruption of Mt. Pinatubo, a volcano that had been dormant for approximately 500 years. I actually arrived at the base on the last incoming military aerovac before non-essential, flight operations ceased due to the volcanic threat.

Within five days, I was required along with around 15,000 others to relocate to Naval Air Station Subic Bay. After 11 days, my wife and family departed and a week afterwards, I departed on the USS Midway, ultimately arriving at Fairchild AFB, Washington State.

When advised of the plans to leave Subic by ship, I enlisted the aid of a senior non-commissioned officer who had worked with me, to assist me with my two bags during our return to the Continental

United States. You see, I was unable to carry anything heavy because of my recent surgery and post-operative radiation.

I was reassigned to San Antonio, Texas because of the extensive, healthcare facilities in the military community.

I retired in 1993 from the Air Force and my wife and I relocated to Northern Virginia. I was employed in a new career when my medical situation became active again

Between 1991 until late, 1997, I regularly had semi-annual MRIs to monitor my health situation. Fortunately, the recurrence of my illness was identified before it got out of hand in September, 1997.

CONTEMPORARY HOSPITALIZATION & EXPERIENCES

In February 1998, I was hospitalized at one of two large, New York hospitals. My physician, a neurosurgeon with specialized spinal skills, operated on my spine twice that month. I believe I was in a recovery mode for several weeks before being transferred to a different hospital for physical therapy.

The committee is aware of my general medical experiences during this period, thus I won't repeat them in this statement. However, it was during the physical therapy period that I was initially diagnosed with what I later learned was MRSA.

I received treatments for the infection and eventually, was discharged in May to return home. I couldn't walk when I left the hospital, although I had expectations I would eventually.

At home, I soon began suffering more pain and as I've previously reported to the committee; I was hospitalized locally for a

serious abscess, and soon rehospitalized in NY. I remained hospitalized in NY for another 3 ½ months, undergoing three major back surgeries in an attempt to resolve the infection problem which was now identified as Vancomycin Resistant Enterococcus (VRE) and Osteomyelitis, a bone infection.

Since my wife lived in Virginia, I only saw her periodically, on every other Saturday. She'd exhausted her all leave during my initial hospitalization from February to May; she had a job and couldn't take an indefinite leave of absence but even if she could, hotel costs in NYC were cost prohibitive to us.

THE "UNOBVIOUS" PROBLEMS AFFECTING PATIENTS IN A HEALTHCARE ENVIRONMENT

Being alone in the hospital was what I discovered to be the first serious threat to my well being. How do I describe to you how it felt lying in a hospital bed with serious, life threatening resistant infections? True, I was monitored by the nurses; I received medicine and the doctors made their rounds. From an outsider's perspective, it appeared that I was receiving the care and attention I needed, and so I thought.

When my mother visited me for two weeks during my second hospitalization in 1998, I soon realized how fortunate it was she came to be with me. Besides uplifting my spirits just by being there, she soon observed several anomalies. She initially observed that when the bed sheets on my bed were routinely replaced by some of the

nursing staff, the clean sheets were literally dragged upon the dirty floor while the bed was being made.

Because some nursing assistants were shorter in height, they'd lower my hospital bed in order to be able to reach across it. Because of my wounds, I couldn't get out of bed, thus, I'd be forced to roll from one side to the other during the sheet replacement process. I never saw what was occurring because I was always facing the opposite wall, holding onto the bed rail, in pain and on medication.

When making my bed, the partially unfolded, clean sheet, hanging over the side of the bed, would drag on the floor. It would be lifted eventually during the process and some of it was tucked under the mattress while I lay on the remaining portion. Were it not for my mother, I don't know how long or how often this process of dragging clean sheets on the floor would have continued and there I was, trying to recover from infected back wounds! (I also never knew for how long this occurred prior to my mother's visit.)

During her visit, my mother asked me several times why the linen bag in my room, used for dirty linen, was not emptied daily. Once during her visit, there were so many dirty sheets and towels in the bag, the smell became discomforting. I asked my 72 year old mother to drag this heavy bag out of my room and leave it in the hall. I figured someone would find it and maybe, they would get the message! I don't remember anyone ever coming into the room and asking about the bag in the hallway.

I absolutely believe any patient has a better chance of survival, merely by having a trusted family member or friend in the room. From my experiences, it became very apparent that the adage, "you

can't see the forest because of the trees," was a reality among hospital staff when it came to hygienic procedures and my care.

In 1998, I recall that my room was visited by housekeeping personnel who would spray some type of fluid on hard surfaces of my room, apparently to disinfect them. I never knew what they were using nor did I even know whether the cloths or towels they used were clean ones, or if they'd been used in another patient's room. Frankly, both my physical and mental conditions were so debilitated; I never thought to ask the question.

I can't speak to the frequency of the housekeeping visits; however, I recall that one woman who came to my room was always in a hurry, often completing her duties seemingly in seconds. In and out so quickly, I recall she would typically drag the cloth across the window sill or possibly, a bed rail before departing the room.

There are many surfaces in a hospital room which are easily and routinely contaminated on a daily basis. I believe if I'd seen the checklist of the housekeeper's duties in my room, I would have noted the shortcuts I believed she was taking.

I don't know how to clearly explain how difficult it is to be a patient on a crowded and busy, hospital ward, and report an anomaly or problem to an attending physician or nurse. I never felt they were interested to avail themselves of additional, impromptu issues, especially when it involved a colleague.

I will acknowledge that everyone assigned to a ward is generally very busy, but their focus on patient related tasks often, seemingly missed the inherent necessities of safe and proper, hygienic protocols.

Ultimately, in the case of the housekeeper, I was forced to write a letter to the hospital administrator explaining my observations; I then rewrote it in my journal to insure I had a copy. I don't recall who I asked, but someone assisted me in getting my letter to the hospital administrator. The housekeeper was eventually replaced, and for the next week or two, several nurses assigned to my ward, challenged me for "unnecessarily getting their friend in trouble."

The bigger issue which I later learned was a serious problem in hospitals, pertained to hand washing. I can seldom recall medical staff physically washing their hands before checking my wounds or administering an injection or some other treatment. The scenario then, as it is today when I have local, medical appointments, is for medical personnel to reach into an open box and put on their hands, **non-sterile gloves,** which typically sit on a shelf in a patient's hospital room or a doctor's examination room.

I've learned over time that those gloves are not worn to protect the patient; they are worn to protect staff from exposure to a possible contaminant from a patient, even if the patient has no such diagnosis.

So what is done to specifically protect patients? The answer is simply, nothing!

Why should anyone be surprised when the CDC publishes their reports such as their March-April 2001 report entitled, *Feeding Back Surveillance Data To Prevent Hospital-Acquired Infections*, which states in part, "Hospital-acquired infections affect approximately 2 million persons each year?"

In 1998, I wasn't well informed on the issue of healthcare acquired infections. I hadn't researched the subject nor had anyone briefed me in advance on the dangers I was about to face.

MY PROACTIVE ACTIONS

In 2004 when I was rehospitalized, I was more informed and prepared to deal with the conditions I knew I'd face. I actually physically feared going back to the same hospital I'd been in previously, but my doctor had privileges there, and thus, I had no choice.

Before being admitted, I contacted The Joint Commission, defined by **Wikipedia**, an online encyclopedia, as "a private sector, US-based non-profit organization," whose mission is "*To continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.*". [http://en.wikipedia.org/wiki/Joint_Commission]

I was seeking any available information on their findings and observations regarding the hospital's Infectious Disease Surveillance and Training Programs, along with the findings of any Joint Commission inspections within the prior two or three years.

Despite the fact The Joint Commission's publicized mission statement states that it "evaluates and accredits more than 15,000 health care organizations and programs in the United States," to "*To continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related*

services." [http://www.jointcommission.org/AboutUs/Fact_Sheets/joint_commission_facts.htm], the information provided to me was substantially lacking in specifics. Moreover, when I telephoned The Joint Commission and specifically inquired about health acquired infection rates; the nature of the hospital's surveillance program or how it administered training to staff regarding healthcare acquired infections, I was told the information was either "unavailable" or "not releasable to the public."

So much for transparency in reporting by this non-profit agency, whose 29 member Board of Commissioners, is comprised primarily of members of the health care industry.

When I was admitted to the hospital, I personally hand carried a case of sterile gloves and this time, I didn't allow anyone to touch me unless I knew they washed their hands with soap and water; and occasionally, I prepared the sterile gloves for their use! Imagine being hospitalized in a neurosurgical ward, generally alone and without family by your side, having to instruct healthcare providers to do their job safely.

In 2004, I wasn't afraid to confront a nurse or resident about whether they understood the danger they subjected me to when they grabbed the non-sterile gloves to inspect my back wound. Admittedly however, I wasn't as aggressive with my doctors. I was more discreet with any admonishments, but on several occasions, I did ask them to wear my clean gloves and absolutely not those contaminated ones, sitting in the open box!

Prior to this hospitalization, I'd coordinated with the hospital's Infectious Disease Office to have a dedicated, blood pressure cuff unit assigned to my room. I didn't want my vitals routinely taken by equipment that was commonly utilized on the ward for many other patients, all with various illnesses and potential, bacterial infection.

Once, around 5:30 in the morning, I was awakened by a medical technician literally taking my blood pressure with a unit he'd brought into my room and not the one sitting 18" from my bed. When I challenged him, he said he knew nothing about the dedicated unit.

I told this technician that he'd better review my charts; that I was at risk for infection and he was seriously endangering my life. About an hour later, he returned to my room, apologizing and acknowledging he hadn't read the documentation before administering the morning test!

Additionally, I'd requested that the number of medical students accompanying the residents during their daily rounds be limited to two students when visiting my room. I sought a reduction of unnecessary personnel in my room that could inadvertently and unintentionally, transmit bacteria onto my person or any of the furniture, putting me at greater risk.

I even coordinated with the hospital to prohibit the newspaper lady on Sunday mornings from bringing the papers into my room. Newsprint is very dirty and I recalled in 1998 that when the paper was delivered, it was often placed upon my bed or on the table where my food tray was delivered.

My primary doctor considered my initiatives contrary to the interests of the hospital as a "learning institution" for medical students.

I responded that I considered it my responsibility to protect myself from the kind of serious problems and risks I'd previously experienced in the hospital.

A PERSONAL RECOMMENDATION

If I were a hospital administrator, I would require my infectious disease unit to periodic, 100% bacteria samplings of the open boxes containing gloves in every room in every ward in my hospital. Starting with these test results, I believe I could influence personnel working in the wards or any other hospital environments involved with patients, about the importance and necessity of hand washing vs. the use of non-sterile gloves.

WE POSSESS THE SOLUTION TO THE PROBLEM

In preparing for this hearing, I extensively reviewed many government documents and past media articles. I am sure this committee is well acquainted with the countless, detailed US Government reports on the history of healthcare acquired infections and their existence which go back decades. I searched the CDC website using the term, "healthcare *acquired* infections," and received a response with 3,140 hits.

Clearly, there is no shortage of detailed information on this subject, including countless articles on the importance of hand hygiene, but sadly, most of it is written in such complicated terms, it appears these reports and studies have been written by rocket scientists. Who can understand such complex documents, except other rocket scientists, or perhaps, the engineer who invented my VHS remote control?

I possess one CDC report dated October 25, 2002, entitled, "Guideline for Hand Hygiene in Health-Care Settings," and it puts forth recommendations by a US Government, hand hygiene task force. **The document is 56 pages in length – all this to explain the fundamentals of hand washing**, something we routinely teach our children.

It's no wonder that healthcare practitioners either don't or can't comply, or even make a minimal effort to follow government regulations or recommendations. The recommendations either can't be understood, or many are so complex, they would take hours to read and decipher.

Our government employs or contracts countless thousands of medical experts in all facets of the profession, who for decades, have been explaining in minutia, the threat to our nation which seemingly, is being ignored. Yet how many expert **trainers** does the government or our nation's hospital administrators employ, insuring practitioners thoroughly understand and comply with their workplace procedures, including hygiene protocols?

HAVE WE REALLY CONNECTED THE DOTS

Following the September 11th, 2001 attacks, there was an outcry in our nation about why no one allegedly "connected the dots," which many allege, contributed to so many deaths and the economic and infrastructure disaster our nation experienced.

It seems to me that with respect to healthcare acquired infections, the dots have been repeatedly connected and documented over the years by many medical experts and Members of Congress. Countless reports have been commissioned and publicized, yet the threat and more importantly, the recurring deaths and financial consequences in our national war on healthcare acquired infections, continues, unabated!

In 2004, the CDC published their annual report entitled, "Deaths – Leading Causes."
http://www.cdc.gov/nchs/datawh/statab/unpubd/mortabs/lcwk9_10.htm

This report lists the top 15 causes of death in America that year, and of those listed causes, only five exceed the estimated 99,000 healthcare acquired infection related deaths, that CDC also estimates, occurred in America.

All but suicide, 11th on the list, were non preventable causes. Healthcare acquired infections ARE preventable!

The CDC, in its many published, however complex documents, emphasizes great attention and concern about this national threat. Even its website has an extensive and well documented "campaign," encouraging "Increased awareness of the problem of antimicrobial

(*infection related*) resistance in healthcare settings." [http://www.cdc.gov/drugresistance/healthcare/default.htm

However, the website hasn't been updated since September 15, 2005, or so it states. What has the CDC been doing the past three years to expand and reinforce its campaign?

In its' March-April 2001 Special Issue entitled, "Feeding Back Surveillance Data to prevent Hospital Acquired Infections," cited earlier, the CDC report states in part:

> "The Centers for Disease Control and Prevention (CDC's) National Nosocomial Infections Surveillance (NNIS) system has been serving as an aggregating institution for **30 years**. The NNIS system is a **voluntary**, hospital-based reporting system established to monitor hospital-acquired infections and guide the prevention efforts of infection control practitioners."

Why would this serious national issue, acknowledged for decades as an indiscriminate killer of thousands of Americans, be left up to the *voluntary* cooperation of our nation's medical practitioners who manage and operate the very same facilities where this horrific enemy hides? Clearly, any surveillance system in America ought not to be voluntary and more importantly, findings ought to be public, just like countless other mortality data.

I urge this committee to connect **all** the dots; to take the appropriate steps and enjoin not only our national leaders, but our national healthcare administrators and practitioners in a proactive, collaborative, 21st Century effort, to truly fight and end healthcare acquired infections in our country. We possess the knowledge and capabilities to fight this enemy; we possess the educational and

professional expertise to overcome and destroy it. The only question is whether we have the will to fulfill the mission!

Sample exhibit submitted to the House
Committee on Oversight and
Government Reform

By

Edward F. Lawton
April 16, 2008

Draft v.1 (Apr-2008)

Patient Infection-Protection Briefing

Before administering any medical care, you are assured the following important procedures are enforced:

1. As your medical provider, I will wash my hands with soap and hot water or alcohol-based gel before touching you.
2. Any medical equipment I may utilize in the course of your care is clean, because I have personally cleaned it.
3. Any other medical staff member including medical students entering this room, have washed their hands with soap & hot water.
4. If you are an inpatient, I will take every precaution to insure you are not unnecessarily touched by anyone's clothing or attire.
5. It is your right to have a clean room, wiped down daily to protect you from exposure to deadly bacteria.
6. At anytime, you have the right to report any deviation of any of the above procedures to the nearest supervisor.

Sample form

The use of this card is intended to insure that medical personnel protect patients from avoidable, healthcare acquired infections (HAI). Failure to follow the procedures on the reverse of this card may result in punitive action.

All patients have the right to be protected from HAIs. It is the intent of this medical facility to insure all personnel know and understand this policy.

If you have any questions, contact your supervisor or department head.

Fm ___ (name of institution)

Chairman WAXMAN. Ms. Bascetta.

STATEMENT OF CYNTHIA BASCETTA

Ms. BASCETTA. Mr. Chairman, Mr. Davis, and other members of the committee, thank you for the opportunity to discuss our report, completed at your request——

Chairman WAXMAN. There is a button on the base of the mic.

Ms. BASCETTA. It is on. It is probably not close enough.

Chairman WAXMAN. Pull it a little closer.

Ms. BASCETTA [continuing]. To discuss our report, completed at your request, on healthcare-associated infections in hospitals.

Common HAIs, such as bloodstream, surgical site, and urinary tract infections can be deadly. And evidence is mounting that they also take an economic toll on our healthcare system and on the hospitals in which they occur.

But patients should not have to accept HAIs as a necessary risk of medical treatment. In fact, some hospitals have dramatically lowered their HAI rates by using new infection-control techniques and by enforcing others, like hand washing, which was proven to save patients' lives more than 100 years ago.

Our report identified ongoing HHS activities that could help reduce HAIs. CDC has issued 13 guidelines for hospitals that contain almost 1,200 recommended practices. And 500 of them are strongly recommended. However, only a few of them are incorporated by CMS and accrediting organizations in the required standards for hospitals.

Second, HHS has multiple HAI data bases, but none provide a complete picture about the magnitude of the problem. Some of the data bases are limited by nonrepresentative sampling, and reporting differences impede combining the data to better understand the extent of HAIs and to measure progress in reducing rates.

A good example is the lack of linkage between one data base on surgical infection rates and another on surgical processes of care, even though these data bases cover some of the same patients.

Third, both AHRQ and CDC fund research aimed at reducing HAIs. However, there is little evidence of their collaboration to maximize the return on research dollars and avoid duplication.

And finally, CMS has included some HAI-related measures in its pay-for-performance program for hospitals and has targeted three preventable HAIs for which it will eliminate Medicare patients beginning this October. But it is too early to tell how effective this will be and how many conditions can be tackled through the payment system.

Despite these actions, we believe that HHS is not exploiting its leverage to reduce or eliminate HAIs. We concluded that leadership from the Secretary is required for HHS to bring to bear the multiple ways for influencing hospitals to tackle the HAI problem. However, an official from HHS told us that no one within the Office of the Secretary is responsible for coordinating infection-control activities across the Department.

In light of the prevalence and the serious consequences of HAIs, this lack of leadership has already resulted in lost opportunities to take concerted action to reduce the suffering and death caused by these infections. We made two recommendations that, if imple-

mented, could help HHS gain sufficient traction to be more effective.

First, we recommended that the Secretary identify priorities among CDC's recommended practices and determine how to promote their implementation. This would include whether to incorporate selected practices into CMS's conditions of participation for hospitals. In its comments on our draft report, CMS said that it welcomed the opportunity to work with CDC on this matter. CDC has categorized the practices on the basis of the strength of scientific evidence, but work by AHRQ suggests that cost, complexity, organizational obstacles, and other factors are necessary in considering how to set priorities.

Making headway is important because the large number of practices and the lack of departmental-level prioritization has hindered efforts to promote their implementation. Clear priorities could assist CMS and the hospital accrediting organizations in determining whether additional recommended practices ought to become part of the required infection-control standards for hospitals. And it could also help hospitals themselves monitor their own efforts to reduce HAIs.

Our second recommendation was for the Secretary to establish greater consistency and compatibility of HAI data collected across HHS to increase information available, including reliable national estimates. HHS's comments acknowledged the need for greater consistency and compatibility and identified actions that CMS would take, as well as noted that CDC has recently begun working toward greater alignment with CMS. We encourage HHS to act quickly so it can draw a more complete picture of the HAI problem.

Although we found CDC, CMS, and AHRQ officials discussed HAI data collection with each other, they were not taking steps to integrate any of the existing data bases by, for example, creating linkages or standardizing patient identifiers. We believe this would enable HHS to do a better job connecting the dots regarding how hospitals can reduce these often preventable infections. That concludes my comments.

Chairman WAXMAN. Thank you very much for the report and for your testimony today.

[NOTE.—The Government Accountability Office report entitled, "Health-Care-Associated Infections in Hospitals, Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections," GAO–08–283, March 2008, may be found in committee files.]

Chairman WAXMAN. Dr. Pronovost.

STATEMENT OF PETER PRONOVOST

Dr. PRONOVOST. Mr. Chairman, Mr. Davis, and members of the committee, thank you for having me here today.

The suffering that Mr. Lawton incurred ought never happen, nor should the excess costs that he incurred because of that.

I would like to share my reflections on why I think it happened and what we might do about it. There was a promising violinist who was a mother of two who woke up one night with tingling in her hand and slurred speech. She had a CAT scan that showed a large brain tumor. The surgeons did a very technical test to meas-

ure her blood flow, that showed that where they planned on cutting was the part of her brain that actually allowed her to play the violin. And based on that technical test, they changed how they were going to cut, and she woke up with no deficit and is playing the violin now.

That case is one example of the dramatic benefits we have had, as the U.S. public, from investments in biomedical research. And that is one of many. Our life expectancy since 1955 is up from 69 to 78 years. AIDS is now virtually a chronic disease. Many cancers, including childhood cancers, are curable. And, indeed, a recent report said the United States is more productive in research than the entire European Union. And yet that same healthcare system infects Mr. Lawton, leaves surgical equipment in patients, overdoses children with heparin, and kills 98,000 people a year. And when we hear this, how could we possibly explain this discrepancy?

And perhaps most concerning is the recent Commonwealth report that showed that the United States ranks dead last in measures of quality and access and efficiency among the 29 other countries in the Organization for Economic Cooperation and Development. And when I think about this, how could it happen, without trivializing it, the basic issue is that we have failed to view the delivery of healthcare as a science. That science or traditional biomedical science has funded looking at genes and finding new therapies, but once we find them or at least have a hunch, knowing whether they really work in the real world or whether patients get them hasn't been a priority.

Indeed, we spend a dollar for biomedical research for every penny that we spend on research into safety and healthcare delivery. And so it is entirely predictable and understandable that we are ranked as the world's preeminent biomedical sciences and yet are dead last in outcomes and quality.

Now, the public has seen the benefits when we do make some small investments. I was fortunate enough to lead a project funded by the Agency for Healthcare Research and Quality, which, by the way, the direct costs were about 350,000 a year for 2 years. We summarized the CDC guidelines and made a checklist to reduce those infections and pilot-tested it at my hospital, Johns Hopkins.

We then partnered with the Michigan Hospital Association Safety Center at 127 ICUs in Michigan to put it in. We didn't know that we could move all these infections from the "inevitable" bucket to the "preventable," but we thought we needed to try. The results were, frankly, breathtaking and were published in the New England Journal of Medicine and subsequently in the New Yorker. We virtually eliminated those infections.

The median rate of infections was zero in those hospitals; the overall rate was reduced by 66 percent. And those rates now have stayed that low for 4 years after this infection. The estimates are that annually it was saving somewhere around 1,800 lives and nearly $200 million in costs, all for an investment of 350,000.

Unfortunately, though, there is far too few of those programs that exist. We don't have a funding mechanism to develop those programs, nor do we have funding to train people who can lead them. But what it showed for us is when they are done well, there is a hunger for it.

The hospitals in Michigan are saying, what is the next program we can put in? They want one for surgical-site infections or surgical safety, to tackle MRSA and VRE in a meaningful way. And other States, including Oregon and California, Arizona, and Ohio are asking, Could we come and do this? So we really need HHS leadership.

Importantly, though, there seems to be barriers for this, that indeed OHRP charged that this study violated the protection of human subjects and that the study ought not continue. They subsequently allowed us to continue in Michigan, but there is not at all clarity about what is going to be required to prevent these infections in Ohio and California or for the myriad of other quality improvement programs that the country so desperately needs.

And so I would ask the committee to consider four concrete things that I think can make the difference.

The first is, I think, supplying some support for AHRQ to make this program national, and to develop a pipeline of other programs that the country is hungry for, to do in a scientifically sound way. I think you could urge HHS to clarify from OHRP what are the requirements to do these so that we don't risk running afoul of regulations.

I think we need to increase funding for biomedical research, and especially alter that ratio of a dollar to a penny. It is appalling. Imagine what would happen if it was a dollar to a dime or a dollar to a quarter.

And finally, we need to have programs to treat more people; so there are many more people, like myself or my colleagues, who can do these in a more robust way.

Your committee through this has the opportunity to save more lives this year than we have in the last decade. And it is going to take courageous leaders who are going to do this. And I hope your committee can move us beyond the far too common rhetoric of high-quality, low-cost care to make that a reality.

We have a program that works, that the return on investment is almost ridiculous, and we need leadership to make that happen—so that Mr. Lawton becomes a rare, rare exception. Thank you.

Chairman WAXMAN. Thank you very much.

[The prepared statement of Dr. Pronovost follows:]

Testimony before Government Oversight Committee

Statement of Peter J. Pronovost, MD, PhD, FCCM
Professor and Director, Quality and Safety Research Group
Medical Director Center for Innovations in Quality Patient Care
Johns Hopkins University

April 16, 2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

Chairman WAXMAN. Mr. Labriola.

STATEMENT OF JOHN LABRIOLA

Mr. LABRIOLA. Good morning, Chairman Waxman and committee members. My name is John Labriola. I am the hospital director of William Beaumont Hospital in Royal Oak, MI. And thank you for the opportunity to offer comments on this most important subject.

You had asked us to prepare and respond to some questions about healthcare-associated infections dealing with implications, barriers, costs and benefits. And, hopefully, our written testimony has done that.

I just show you we had prepared a book last year. This book really represents a compendium of all of the different initiatives that we do at the hospital. The purpose of the book was to show to our staff and our board and leadership what is being done. But I think, more importantly, it was prepared to demonstrate our commitment to this culture of safety that exists in our hospital.

It is interesting that the mention of culture was brought up earlier by Mr. Lawton. So in our case, it is the combination of all of these activities, and more to develop, that will improve care.

We are a very large hospital. We have a very high patient census, both in terms of inpatient admissions and surgeries. We are one of the largest hospitals in the country. The culture of safety that I mentioned is a result of decisions that were made by our hospital and medical leadership and supported by our board many, many years ago. They established as an expectation, as a core belief, the importance of safety for each and every patient in our hospital. To create this culture has required will and courage. It represents a commitment to challenge and change, when necessary, the traditional beliefs and approaches to care that are found in our hospital, and really throughout the healthcare system.

We feel that at its core, patient safety is about the dignity and respect of our patients. There are no alternatives. It is difficult for me to isolate a cost for patient safety. To us it is not a program or an approach, it is embedded in the way we deliver care. It is how we hire our staff. It is how we train our staff. It is part of our expectation of our staff. We take words like "teamwork" and "collaboration" very seriously. We ensure that all of our staff, from our very skilled intensivists and nurses, our house staff, our support staff, work together in a prescriptive manner that defines and ensures that all treatments and care for our patients is appropriate.

We have conducted over 40,000 briefings, done before every surgery, to go over checklists so that everyone on the surgical team confirms the patient, the site, what is to be done by all the team members.

Behaviors of engagement and empowerment are emphasized and supported by all members of our leadership team so that anyone can stop a procedure if they feel something is not being done correctly.

The Institute of Medicine's compelling reports have been a call to action for all of us in healthcare. There is so much more to do and improve in all of our systems and processes. So for us, the adoption of the principles that surround Keystone, which is what

Dr. Pronovost was referring to, were very easy for us to support and embrace; we, along with all the other hospitals in Michigan.

The Keystone Michigan project has been a tremendous benefit to us. Our patients are someone's family member, their loved ones. When they are in our care they are to be protected. That is why we have taken this so seriously, and why we need to do what we have done.

Thank you for giving me the opportunity to talk about Beaumont and its wonderful staff.

Chairman WAXMAN. Thank you very much, Mr. Labriola.

[The prepared statement of Mr. Labriola follows:]

Testimony to the Oversight and Government Reform Committee

John Labriola, Senior Vice President and Hospital Director

William Beaumont Hospital - Royal Oak Michigan

April 16, 2008

Beaumont Mission

We will provide the highest quality health care services to all of our patients efficiently, effectively, and compassionately, regardless of where they live or their financial circumstances.

Beaumont Vision

We will rank among the nation's leading institutions in the provision of health care services, patient safety, medical education and financial performance.

William Beaumont Hospital, Royal Oak is a 1,061-bed major academic and referral center with Level 1 trauma status and Michigan's first Magnet-designated hospital for nursing excellence. Beaumont ranks first in the United States for inpatient admissions and second for its number of surgeries. Beaumont is a regional health provider with 91 medical and surgical specialties with more than 3,100 physicians. Beaumont also has two other community hospitals, and numerous community-based medical centers, and nursing centers.

Beaumont is a major teaching facility that has 37 accredited residence and fellowship programs with 380 residents and fellows. Beaumont is partnering with Oakland University, in Rochester Michigan to establish a private medical school to open in 2010.

Beaumont Rankings:

U.S. News & World Report's "Best Hospital" listed in 9 medical specialties
AARP - Best Employers for Workers 50 and Over
Marcia & Eugene Applebaum Surgical Learning Center Accredited by the American College of Surgeons
One of 41 U.S. Hospitals on Leapfrog Group's 2007 Top Hospitals list for quality and safety
One of America's "50 Best Hospitals 2008" by Healthgrades for superior clinical outcomes

Beaumont 2007 Statistics

Number of licensed beds 1,061 Royal Oak Campus
Number of 2007 admissions 58,212
Number of surgeries 54,120
Number of adult intensive care units 5, totaling 100 adult ICU beds
Second highest Medicare admission hospital in the United States

The Beaumont Story

William Beaumont Hospital, Royal Oak has long recognized the need for and supported an aggressive infection prevention and control program. Hospital leaders believe that we have an obligation to prevent and control healthcare associated infections and to protect our health care workers. This is even more important today than in decades in the past. Beaumont has a Centers for Disease Control (CDC) trained medical epidemiologist knowledgeable of epidemiological and scientific principles and in statistical analysis. We believe that an effective infection prevention and control program can reduce rates of health

care associated infection and are cost-effective. We have provided administrative support, resources, and an organizational commitment to a culture of safety. Reports on the effectiveness of our infection control programs are provided to our Infection Control Committee, Medical Evaluation Committee, Medical Executive Board, and our Board of Directors.

In health care today, we are faced with new communicable diseases such as HIV and hepatitis C and re-emerging infections such as, pertussis (whopping cough), measles, mycobacterium tuberculosis, as well as changing pathogens such as a new toxigenic strain of Clostridium difficile. We have heightened the importance of infection control. However, as the population ages and treatments continue to advance, patients are more susceptible to infectious diseases. Organisms previously treatable with antibiotics are becoming more resistant. Infection prevention and control has many challenges; challenges we must face and address. New lifesaving technology confers new risks of infection.

The results of our infection control program have been extraordinary with institutional health care infection rates well below our peer groups, and the rates of other hospitals reported voluntarily to the Centers for Disease Control with anonymity protected. Between 2000 and 2007 our overall health care associated infection rate was approximately 1% or 2.1 per 1,000 patient days, a rate significantly below other large tertiary care hospitals with rates of more than 4% or 5 per 1,000 patient days. Each year, potential problem areas specific to our hospital are reviewed, analyzed, and a plan is created to further reduce rates of infection. We have been largely successful because our infection control personnel are proactive in developing programs and policies to address our specific needs.

Since 1999, when the Institute of Medicine's compelling report on medical errors was unveiled, there have been only a few measurable improvements in patient outcomes and the safety culture in hospitals. The Michigan Health & Hospital Association (MHA) Keystone ICU Project in the State of Michigan demonstrates how broad-based collaboration can improve care not only at an individual hospital or patient level, but for all hospitals and patients in the state of Michigan. The MHA Keystone Center brings together hospitals, national experts, and best practices to improve patient safety by addressing the quality of health care delivered at the bedside.

The Keystone Center for Patient Safety & Quality

The MHA Keystone Center for Patient Safety and Quality was created in March 2003 as a not-for-profit division of the MHA Health Foundation in response to growing concern about patient safety and health care quality and in recognition of the unique willingness of Michigan hospitals to collaborate to improve care. To date, Keystone has been funded by grants, MHA-member hospitals and Blue Cross and Blue Shield of Michigan (BCBSM). The original Agency for Health Care Research and Quality (AHRQ) matching grant was for $1,000,000. The hospitals contributed a match of in-kind contribution of staff time. Keystone now represents the largest regional partnership of intensive care units assembled in a single initiative. The MHA Keystone Center has partnered with safety experts from Johns Hopkins University, the Centers for Disease Control and Prevention, and others to bring this work to the State of Michigan.

The MHA Keystone Projects allow hospitals to apply local wisdom to implement best-practice interventions to prevent harm to patients. This work requires dedicated participants, leadership support, resources, and physician engagement to achieve measurably improved outcomes and sustained results. Engagement of frontline staff to change behavior is the key to implementing and sustaining any successful change in practice.

Through the Michigan Health and Hospital Association Keystone Center for Patient Safety and Quality, Michigan hospitals have launched groundbreaking programs to reduce errors and improve the quality of patient care in the state of Michigan. While participation in the Keystone projects is voluntary in

Michigan, this effort demonstrates the serious commitment of the MHA and its member hospitals to provide the safest, most effective care to all Michigan residents. Michigan hospitals have a proven track record of accountability through voluntary reporting. Voluntary reporting efforts have allowed us to devote our time correcting problems and implementing changes, rather than on laborious data collection. Voluntary non-punitive reporting encourages ownership, transparency and action. The MHA Keystone projects emphasize sharing of information, challenges, and successes among Michigan hospitals in a non-competitive manner through the exchange of ideas among health care systems so that we can assist each other in providing better and safer care.

At Beaumont Hospital, Royal Oak, we have been involved in all of the Keystone statewide collaboratives, the first being the Keystone ICU Project which focused on providing safer ICU care. Beaumont was an early adopter of the Keystone ICU Project. Our clinicians endorsed the use of evidence-based protocols, and the approach defined by the Keystone ICU Project. It has been estimated that the average patient in the ICU has 1.7 errors in his or her care per day in the ICU. The Keystone ICU Project gave us the infrastructure to improve our safety culture, lower infection rates and enhance teamwork and communication.

Our Keystone ICU team consists of an intensivist, the registered nurse caring for the patient, pharmacist, respiratory therapist, resident, and other key disciplines such as the infection control practitioner, care management, and physical therapy. This model for collaborative rounding provides an opportunity for our resident staff to learn behaviors such as team building and communication preparing them for their future in medicine.

We implemented an organized approach to improving quality and patient safety in our ICUs by doing the following:

Keystone ICU Project

1. Implementing a Comprehensive Unit-Based Safety Program (CUSP) to educate staff on the science of safety. This is an 8-step safety program that begins and ends with staff assessments of safety in the workplace. CUSP advocates open communication and collaboration between all levels of staff from senior leadership to entry level staff.

2. Improving team communication through the development of a daily goals checklist. We have implemented daily multi-disciplinary rounding to include all participants in patient care. With the addition of a pharmacist to our daily rounding team, we are able to address medication appropriateness, and compatibility, and discuss evidence-based treatment. Infection Control Practitioners are also able to reinforce proven methods of prevention.

3. Reducing catheter-related blood stream infections which increase morbidity, mortality, and cost of care. We implemented the use of a standardized central line checklist that ensures that we are compliant with evidence-based practices and have followed all of the infection control practices accordingly. We evaluated the contents of our central line equipment cart and added full-barrier draping to help maintain a sterile field and reduce complexity of the procedure.

4. Improving the care of ventilated patients in the ICUs to ensure that best practices were consistently applied in the care of these patients. These best care process include: Elevating the head of the bed 30 degrees which reduces the frequency of pneumonia; appropriate use of peptic ulcer disease prophylaxis which reduces the risk of upper gastrointestinal bleeding; daily interruption of sedative drug infusions to decrease the duration of mechanical ventilation; daily screening of respiratory function to determine if the patient could be removed from the ventilator.

5. Improving the identification and implementation of early goal-directed therapy to treat patients with sepsis by reducing complexity and creating independent redundancy. This helps to ensure that patients with severe sepsis and septic shock receive the care they should in the intensive care unit with evidence based clinical guidelines.

Beaumont Results

Every day, 247 people die in the United States as a result of health care associated infections which is equivalent to over 90,000 deaths a year. At Beaumont we have taken direct action to prevent infections. For example, we have implemented several successful initiatives in our institution targeted to reduce the most serious types of health care associated infections, such as central venous catheter-associated bloodstream infections, and mechanical ventilator-related lower respiratory tract infections in our adult ICUs as part of our Keystone work. Prior to the implementation of Keystone, our rates were already well below our peer group. We have experienced a 53% reduction in blood stream infections and a 44% decline in ventilator-related lower respiratory tract infections in 2007 when compared to 2006. Through hospital-wide efforts, infections associated with peripherally inserted central catheters also decreased from 1.8% to 1.4% (22%). Through our antimicrobic stewardship program, we have been able to reduce unnecessary antibiotic exposures to our patients and reduce rates of antibiotic resistant organisms.

Keystone Hospital Associated Infection (HAI) Project

In addition to the ICU Project, we participate in a second MHA Keystone statewide Project that focuses on reducing hospital-associated infections in general. Hospital associated infections add to patient morbidity, mortality and costs of care. It's estimated that 5 to 10% of inpatients develop an infection, which is roughly 2 million patients a year, at a cost of $4.5 to $5.7 billion nationally. We have implemented several interventions with our staff to reduce infections. We, along with over one 100 Michigan hospitals, have voluntarily committed to work together in this statewide collaborative to reduce the patient's risk of infection. Between 2007 and 2009, we will be fully implementing additional interventions to reduce infections.

1. Appropriate hand hygiene. Hand hygiene is the primary measure to reduce infections. We have developed an aggressive hospital-wide awareness and marketing campaign to remind our health care providers of the importance of hand washing, and have installed hand hygiene stations in patient care and public areas throughout the hospital for staff and visitor use. We are beginning to observe remarkable results. Hand hygiene has already improved from 40-50% compliance to rates in excess of 85%. We continue to strive for 100% compliance. Hand hygiene is considered the leading measure to reduce the transmission of pathogens in health care settings. The importance of this simple procedure is often times not recognized by health care workers. Though the act of washing your hands is simple, the lack of compliance among health care providers is problematic throughout the world.

2. Reduction of blood stream infections - We have empowered our staff to speak up if they perceive a breakdown in sterile technique during catheter placement. We have implemented an ICU protocol using a standardized checklist that is completed prior to every catheter insertion to ensure the adherence of proper precautions to prevent infections. The checklist is used throughout our hospital.

3. Reduction of indwelling bladder catheter use to prevent urinary track infections (UTI) - With this being the most common hospital-associated infection, our hospital is endorsing the concept of an aggressive hospital-wide effort to minimize bladder catheter-associated UTIs. We now have approved indications for placement of a bladder catheter requiring a physician order and are developing a nurse-initiated urinary catheter discontinuation protocol. Prompt removal can minimize the risk of catheter-associated UTIs that increases every day a catheter remains in place.

Keystone Surgery

As a result of the benefits realized in the intensive care units, we expanded Keystone into other clinical areas. Our third MHA Keystone collaborative is geared toward improving care and safety for our surgical patients in the peri-operative setting. Our objective is to improve communication and collaboration among caregivers by conducting preoperative briefings and debriefings. We are focusing our efforts on reducing surgical site infections, mislabeled specimens, and preventing the National Quality Forum's "Never" events of wrong site surgery and retained foreign objects. Beaumont is leading the pilot to test the Keystone Surgery interventions that will be launched to nearly 80 other hospitals across the State of Michigan on April 28, 2008.

During the 18-month testing period, we have developed and implemented pre-operative briefings and debriefings. The OR briefing is a one-to-two minute discussion that takes place in the OR among all surgical team members before the case begins. Its purpose is to check critical information and promote open communication by all team members during the operation. Topics that are discussed include the operative plan, patient risks, potential hazards, safety concerns, and operating knowledge of the equipment needed for each case. To date we have implemented this procedure in all of our operating room suites, and have performed more than 40,000 briefings and debriefings.

We have improved our delivery of perioperative antibiotics to patients and continue to examine risk factors for surgical site infections. By implementing interventions, we were able to achieve an additional 11% reduction in sternal wound infections in patients undergoing coronary bypass grafting, a patient population at very high risk for infection.

Barriers To Reduce Healthcare Associated Infections

We face many challenges in our efforts to improve patient safety and outcomes. In health care, there is a tremendous need for standardization of practices and procedures, institution of evidence-based practices, and consistent data collection and reporting standards. There is a need to create safer systems of care. According to the Institute of Medicine, it takes 17 years for evidenced-base guidelines to translate to actual bedside practices. The Keystone projects provide a method for rapid and effective patient safety improvements, where evidence-based interventions are implemented and the outcomes are reviewed. While this work is financially beneficial, more importantly it is just the right thing to do for any patient in any hospital. Health care leaders need to support clinical practice and operational changes and own the challenge of providing safer care. Health care workers need to understand that everyone is important in our system and plays a vital role in reducing infections by following infection prevention safety practices and procedures.

As a health care leader, I recognize that understanding and effectively addressing quality and safety issues requires a strong strategic commitment to improvement and sustainability. As part of our commitment to constantly improving our care, we have made implementation of the Keystone projects a key hospital-wide objective. We have taken lessons learned from our intensive care units, and have adapted them to practices in our non-ICU medical and surgical areas. Our work should continue to lower infection rates, and provide safer care with evidence-based practices. As health care providers, we also need to learn and adopt safety ideas and techniques from other industries, as we continue to transform our current health care model.

Costs to Implement

William Beaumont Hospital, Royal Oak has more than a 50-year history of building an infrastructure for patient safety and quality. At Beaumont, we take patient safety very seriously. We take organizational and leadership responsibility for patient safety, and as a health care system we strive to build a culture of safety through open communication, and empowerment of our staff. The cost to implement the Keystone project has been minimal for our hospital. One full-time registered nurse was added for project facilitation, and a pharmacist was added to the intensive care area to address medication appropriateness, compatibility, and discuss evidence-based treatment regarding therapy. Another infection control practitioner was added to assist with surveillance, educational programs and data collection. Investments to reduce infection have been made by hospitals and must continue during a time when they are also faced with growing needs for investment in supplies, equipment, medications, staffing and other resources. Health care systems are also facing costs associated with the need to create more private rooms for patients requiring contact isolation precautions as well as the need for more airborne isolation rooms and other costs of airflow and negative pressure, and exhaust changes. The adoption of new technology of proven scientific value comes with tremendous cost for hospitals.

Infection control programs should be designed around the needs of individual hospitals. The threat of mandates may add to the additional costs. For example, requiring that all patients be screened for MRSA rather than allowing infection control programs to adopt screening policies to best fit their own needs would be cost prohibitive. Mandated programs may have components that are not applicable to all hospital settings and are inflexible in interpretation. Often with mandated programs there are unrealistic goals and they become bureaucratic nightmares. Mandated programs can be extremely costly and place an unnecessary financial burden on hospitals. A collaborative approach, such as that in Michigan, allows hospitals to take ownership of safety interventions and to share best practices in order to achieve similar goals despite different systems. A "one size fits all" approach is not ideal.

Financial Savings

In general, the magnitude of a hospital's infection rate is strongly correlated to two factors: (1) the underlying risk of its patients, and (2) the effectiveness of its infection control program. Our ability to maintain infection rates 50% below our peers, despite caring for comparable or even sicker patient populations, attests to the effectiveness of our hospital-wide programs. Every time we prevent a patient from developing an infection this results in reduced length of patient stay, hospital costs, and more importantly, reduced patient mortality and morbidity. Patients that develop an infection typically stay an average of 7 hospital days, resulting in added costs of at least $7,850 per infection, and have an associated 15% attributable mortality. If our infection rate met the CDC average, there would be an additional 850 infections, $6.7 million in cost, and 125 patient deaths at our hospital. We initiated an active surveillance system to identify high-risk patients with MRSA and VRE. Through these efforts, we lowered hospital-associated MRSA, VRE, and C difficile infection rates significantly below those reported by other tertiary care hospitals. We were able to remove isolation precautions from 188 patients (1,586 patient bed days) which resulted in savings of $125,000.

Patient Impact

As a health care system we strive for continuous improvement. We identify potential problem through the review of reliable and rigorous data. We perform epidemiologic studies to determine the reasons for problems discovered, implement control measures, provide feedback to all concerned, and measure the impact of our interventions. These actions result in reductions in both health care associated infections and improved healthcare worker safety results. We continuously monitor our compliance with scientifically validated methods of infection prevention. We provide education to our staff and patients. We also recognize the importance of studies to improve quality of care and research to reduce health care

associated infections. By maintaining involvement in each of these areas, our patients benefit greatly as attested by our low rates of hospital-associated infections.

Conclusion

Patient safety is an organizational priority at our hospital. Significant resources are allocated to support this commitment. Just as in retooling of any industry, we must first invest in change to see the benefits of improved quality and efficiency downstream. Hospitals in Michigan have been investing in this work. State and national funding sources are needed for this work to continue and spread throughout the country. As a nation, there is a national call for greater transparency in health care that must be answered. We need federal support for studies to improve patient outcomes and to assess novel strategies to enhance patient safety. We must strive for continuous quality improvement and never accept the status quo. Much attention on the national level has focused on issues such as mandatory reporting of hospital-associated infections and the need for additional regulations. Mandatory reporting and bureaucratic programs are not the answer to improving our health care system. These programs place a heavy burden on an already flawed system. We have found that quality improvement and patient safety efforts are best left in the hands of a motivated clinical team at the point of care where success motivates excellence.

We would like to acknowledge our nursing, medical, and support staff for their dedication in implementing the Keystone Project.

Chairman WAXMAN. Is it Binder or Binder?

Ms. BINDER. Binder.

Chairman WAXMAN. Binder. Ms. Binder, we are pleased to have you with us. And there is a button on the base. Yes.

STATEMENT OF LEAH BINDER

Ms. BINDER. Thank you. Thank you, Chairman Waxman, Representative Davis, and members of the committee for the opportunity to testify today on the problem of hospital-acquired infections.

I am the CEO of the Leapfrog Group, which is a member-supported nonprofit organization representing a consortium of major companies and other private and public purchasers of healthcare benefits for more than 37 million Americans in all 50 States. As our founders envisioned it, Leapfrog triggers giant leaps forward in safety, quality, and affordability of healthcare; hence, our name.

And we have two key business principles underlying our work and underlying what I will talk about today in terms of our perspective on hospital-acquired infections.

One is transparency. Healthcare quality data should be made public, understandable, and accessible, supporting informed decisionmaking by those who use and pay for healthcare.

And two, common sense alignment of payment with patient outcomes. Financial incentives and rewards should be used to promote high-quality, high-value healthcare that produces the best possible outcomes for patients. We call this value-based purchasing.

Leapfrog conducts an annual survey of hospitals, called the Leapfrog Hospital Survey. It is completed by about 1,300 hospitals, which represent more than 60 percent of the inpatient beds in the country. Several items on the Leapfrog survey address whether hospitals have deployed proven methods to reduce hospital-acquired infections. Unfortunately, last year we found that 87 percent of the hospitals completing the Leapfrog survey do not take the recommended steps to prevent avoidable infections.

Leapfrog also applies our principles of transparency to call for changes in the way hospitals handle medical errors and infections. We call for hospitals to apologize to victims, something Mr. Lawton did not receive and deserved.

We also call for hospitals to conduct root-cause analyses, publicly report these events, and waive all charges related to them. Many health plans now ask hospitals to adhere to these principles, and we are confident they will soon be standard practice.

The statistics, as we have discussed today, are breathtaking. Infections kill almost twice as many people as breast cancer and HIV/AIDS put together. Despite the overwhelming impact of these preventable infections on U.S. citizens, eradication has not been prioritized to the same extent as other very important issues.

We believe that hospital-acquired infections are emblematic of a larger problem in our healthcare system. We as governmental and private sector payers have not traditionally aligned financial incentives with patient well-being, and unfortunately in some ways we get what we pay for. We pay for this surgery, that medication, this x-ray, without tying the payment to quality outcomes for the pa-

tient. We pay the same even when errors occur that jeopardize the patient's health or life. Indeed, we pay more for poor performance.

On average, hospital-acquired infections add over $15,000 to the patient's hospital bill, amounting to over $30 billion a year wasted on avoidable costs. We must assume that money is concentrated on hospitals with the worst record of hospital-acquired infections.

As a former executive in a hospital network, I can say I know firsthand the pressure to direct resources within the hospital system toward the high-profit, new surgical suite, and not toward the unreimbursed infection-control program. We as purchasers have an obligation to take some of that pressure off.

Leapfrog has been pleased to support HHS Secretary Leavitt's efforts to foster increased healthcare transparency and promote a healthcare market that recognizes and rewards quality. We have worked with some very dedicated and visionary colleagues throughout HHS, from AHRQ to CMS and CDC. Unfortunately, many of their efforts and many of the components of Secretary Leavitt's vision are not being prioritized and coordinated effectively enough at this point. We offer the following recommendations.

Federal agencies must view this problem as a priority. We must measure the right things. We must be measuring patient outcome. We do not have enough measures to actually tell us if a particular procedure or a particular protocol we are measuring leads to the outcomes we seek.

We must tie payments with outcomes. And that is something that we have been working with CMS jointly on in many ways.

We would like to see much more aggressive actions, as outlined in my written testimony. We must work together to improve transparency. Hospital Compare is an excellent Web site, but we believe it needs more outcomes-oriented measures, and would like to work more closely with the Department to see that happen.

We also need to acknowledge and support voluntary efforts by hospitals across the country, such as Mr. Labriola's. They are very impressive efforts. They are very powerful. And they are not supported in terms of payment or in terms of the kind of recognition that good hospitals deserve. The recognition is money in the bank, too, because hospitals are often in competitive marketplaces, and people deserve to know if one hospital is really putting the effort out to achieve the right outcomes for patients.

And finally, we would like to grant HHS more authority around value-based purchasing. We, among private sector employers, would like to commend Congress for your bold step in the Deficit Reduction Act of 2005 toward redressing the current perverse payment system.

In November 2007, HHS submitted a plan for the implementation of value-based healthcare purchasing as requested in section 5001(b). Our employer members unequivocally support CMS's plan to replace the current payment structure with this new program that includes both public reporting and financial incentives for better performance as tools to drive improvements in clinical quality, patient-centeredness, and efficiency.

The proposed rule change would implement payment reforms, strongly recommended by both the IOM and MedPac. We would like to see if there is anything that could come out of today's work;

and your work as the committee would be more support for this proposed rule change. Thank you.

Chairman WAXMAN. Thank you, very much, Ms. Binder.

[The prepared statement of Ms. Binder follows:]

TESTIMONY TO THE HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
APRIL 16, 2008

LEAH F. BINDER, MA, MGA
CHIEF EXECUTIVE OFFICER
THE LEAPFROG GROUP

Thank you Chairman Waxman, Representative Davis, and members of the Committee for the opportunity to testify today on the problem of hospital acquired infections. I will offer a brief analysis of the problem and some recommendations for effective response.

About Leapfrog
I am Leah Binder, CEO of The Leapfrog Group, a member-supported nonprofit organization representing a consortium of major companies and other private and public purchasers of health care benefits for more than 37 million Americans in all 50 states. These employers formed Leapfrog to encourage significant change in the quality and safety of health care in America. As our founders envisioned it, Leapfrog triggers giant "leaps" forward in safety, quality, and affordability of health care—hence our name. We have two key business principles underlying our work:

1) *Transparency*: Healthcare quality data should be made public, understandable, and accessible, supporting informed decisionmaking by those who use and pay for healthcare, and
2) *Common sense alignment of payment with patient outcomes*: Financial incentives and rewards should be used to promote the high-quality, high value health care that produces the best possible outcomes for patients. We call this value-based purchasing.

Leapfrog conducts an annual voluntary survey of hospitals, called the Leapfrog Hospital Survey, which is completed by over 1300 hospitals representing more than 60% of inpatient beds in the country. Survey results addressing quality and patient safety are published, and regional employer coalitions as well as health plans and others use those results to structure rewards and incentive programs. Several items in the survey address hospital acquired infections, including prevention of aspiration and ventilator associated pneumonia, central venous catheter related bloodstream infection prevention, surgical site infection prevention, and hand hygiene.

Unfortunately, last year we found that 87% of hospitals completing the survey do NOT take the recommended steps to prevent avoidable infections. You may view survey results on our website, www.Leapfroggroup.org.

Leapfrog also applies our principles of transparency and payment incentives to call for changes in the way hospitals handle medical errors, hospital-acquired infections, and what we call "never events." We call for hospitals to apologize to victims, conduct root-cause analyses, publicly report events, and waive all charges related to events. Many health plans now ask hospitals to adhere to these principles, and we are confident this will soon be the standard of practice for all hospitals.

Leapfrog's use of public reporting to drive market competition and our application of payment incentives to reward and improve quality and value have caused a stir in the

health care world. These basic market concepts of competition and value have been the bedrock business principles for centuries, and health care shouldn't be exempt from such accountability. Nonetheless, until Leapfrog was formed in 2000 by a coalition of business groups on health and employers, the two concepts of public reporting and payment incentives had not been systematically applied together to motivate change in the healthcare system.

The roots of the problem

As you've heard from other speakers, each year two million people—one out of every 20 people who obtain care at an American hospital contract an infection during their care; 90,000 of them die. To put that into context, infections kill almost twice as many people as breast cancer and HIV/AIDS put together. Despite the overwhelming impact of these preventable infections on US citizens, eradication has not been prioritized to the same extent as these other issues. It is long past time for bold action and real, focused leadership to address hospital acquired infections-it is a public health emergency, and scores of lives are lost while we delay implementing well-understood preventions.

Hospital-acquired infections are emblematic of a larger problem in our health care system: we don't align financial incentives with patient well-being. We as governmental and private sector payers have traditionally structured payment to hospitals to compensate individual protocols and procedures no matter how those procedures they turn out. We pay for this surgery, that medication, this X-Ray without tying payment to quality outcomes. Even with DRGs we pay for bundles of procedures regardless of quality, and until recently, we pay even if they are done so mistakenly they jeopardize the patient's life and health. Indeed, medical errors result in *increased* payments to hospitals to cover the additional treatment needed to remedy the error. On average, hospital acquired infections add over $15,000 to the patient's hospital bill, amounting to over $30 billion a year wasted on avoidable costs. We must assume that money is concentrated at hospitals with the *worst* record for hospital acquired infections. This perverse payment system impedes the implementation of critical quality processes.

We as purchasers in both the public and private sectors must continue working together to rapidly realign incentives to encourage systemic change in the delivery of care and to reward good outcomes. As a former executive in a hospital network, I can say this is not a mere theoretical point. When resources grow scarce and the future seems uncertain amid ongoing state and federal reforms, hospitals face understandable temptation to direct resources to the high-profit new surgical suite and not their unreimbursed infection control program.

The private-sector employers would like to commend Congress for your bold step in the Deficit Reduction Act of 2005 towards redressing the current perverse payment system. In November 2007, HHS submitted a plan for the implementation of value-based health care purchasing as requested in Section 5001(b) Our employer members unequivocally support CMS' plan to replace the current payment structure with this new program that includes both public reporting and financial incentives for better performance as tools to drive improvements in clinical quality, patient-centeredness, and efficiency. The proposed rule-change would implement payment reforms strongly recommended by both the IOM and MedPac. Unfortunately, Congress did not grant HHS this authority in the Medicare legislation passed in December, 2007. One of the most valuable steps this committee could take would be to grant the HHS Secretary the authority to implement this proposed rule. This action would not only help stop the occurrence of hospital-

acquired infections, but also bring us a major step closer to attaining the larger goals of improving overall health care quality and efficiency.

We are on the right track in integrating public and private sector strategies to influence transparency and value-based payment reform, but progress is unacceptably slow. Leapfrog was pleased to support HHS Secretary Leavitt's efforts to foster increased health care transparency and promote a health care market that recognizes and rewards quality through its value-based purchasing plans. Unfortunately, many of the components of Secretary Leavitt's vision are not being prioritized within HHS to effectively generate change. The private purchasers understand the complexities of coordinating the efforts with this mammoth agency, but we agree with the GAO's contention that meaningful, nationwide reductions in hospital-acquired infections are only achievable if HHS makes this an agency-wide priority. One example where a lack of coordination has slowed implementation of changes that would help reduce hospital acquired infections is apparent in the recently released plan for establishing Patient Safety Organizations. These entities are meant to serve as a vehicle to collect and act upon information about incidences of hospital-acquired infections, but the proposed regulations are so onerous and misaligned that this good idea is likely to fail before it begins.

Recommendations

The good news about addressing hospital acquired infections is that unlike breast cancer or HIV/AIDS, we know quite a bit about the cure. The problem is that we have not aligned incentives and rewards to make hospitals more effective at getting to that cure.

We offer the following recommendations.

1) *Federal agencies must view the problem as a priority.* Given the health risk to Americans, hospital-acquired infections deserve top-priority attention. Agencies addressing the issue should be tasked to coordinate effort, and invest in improved data interoperability to identify the problem and measure progress. Such coordination is difficult in federal agencies without leadership to assure its high level of priority on a day to day basis. We recommend that the agency be asked to establishing a rigorous inter-agency plan including milestones and an aggressive timeline for implementation.
2) *Measure the right things.* Our propensity for focusing exclusively on a hospital's procedures exacerbates problems like hospital acquired infections, which are not about any one procedure but about the overall function of the hospital. We must have more measures that demonstrate whether and how well a hospital and/or provider is making systemic change to improve outcomes for patients.
3) *Tie payment to outcomes.* Once we measure patient outcomes, we are positioned to offer incentives and rewards to hospitals that achieve them. We congratulate CMS for working toward this goal in its Medicare performance standards, but again would like to see progress expanded, accelerated, and integrated with federal health agencies. Leapfrog produced an evidence-based payment framework we can use in the private sector, and it would help CMS achieve this quickly, but we have not been able to access data from Medicare to apply it to the public side. We stand ready to help
4) *We must work together to improve transparency.* The results of good measures need to be made public in a usable format to enhance healthy market

competition. Hospitals that achieve excellence and/or show dramatic improvement ought to be rewarded not only with financial gain, but also with public recognition, which is money in the bank for hospitals in competitive markets. The CMS Hospital Compare website is a good start, but does not include enough outcomes-based measures and indicators we believe are essential.

5) *Acknowledge and support voluntary efforts by hospitals across the country.* If it were easy to prevent infections, there wouldn't be any. In fact, it is extraordinarily difficult to systematically prevent infections in a hospital. People who provide care in hospitals do not want to see patients suffer and sometimes die of preventable afflictions, but they can be overwhelmed by competing priorities. By rewarding and acknowledging hospitals that demonstrate results, we clear the way for providers to bring the full force of their ingenuity and caring toward solving the problem. We should support providers with the best possible research on reduction of Hays, financial incentives that help support the level of effort, and support for information technology and other systems improvements to help hospitals be most effective in improving patient outcomes.

Thank you for the opportunity to testify, and for your leadership and fast action in addressing this critical issue.

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Chairman WAXMAN. Dr. Wright.

STATEMENT OF DON WRIGHT

Dr. WRIGHT. Good morning, Chairman Waxman, Ranking Member Davis, and other distinguished members of the committee. I am Don Wright the Principal Deputy Assistant Secretary for Health in the U.S. Department of Health and Human Services, Office of Public Health and Science. Thank you for this opportunity to appear before you on behalf of HHS to discuss our efforts to reduce the rates of healthcare-associated infections.

There are several operating divisions within the Department that have taken lead roles in addressing this important public health challenge. These include the Center for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services. There are also a number of examples of how these agencies have worked collaboratively on this important issue.

We do recognize that there has been significant progress made in several areas. However, HHS also recognizes more work and leadership are necessary to enhance patient safety.

I want to take this opportunity to highlight some of our activities within the Department that relate to or address healthcare-associated infections. The CDC leads and supports a range of infection-prevention activities on behalf of HHS. For example, the agency produces evidence-based guidelines that serve as the standard of care in U.S. hospitals, and guides to clinical practices of healthcare providers.

The Healthcare Infection Control Practices Advisory Board, an advisory committee to HHS and CDC, has provided recommendations for the development of evidence-based guidelines for the prevention of healthcare-associated infections. And most recently, the CDC published guidelines to prevent the emergence of antimicrobial resistance and stop transmission of methicillin-resistant staphylococcus aureus [MRSA], and other antimicrobial-resistant pathogens in healthcare settings.

A second way the Department works to prevent healthcare-associated infections is through the Agency for Healthcare Research and Quality, the lead agency for patient safety. In 2007, AHRQ invested nearly 2 million in reducing HAIs through its program, Accelerating Change and Transformation in Organizations and Networks, a field-based research mechanism designed to promote innovation in healthcare delivery.

AHRQ awarded five task orders to ACTION partners to support infection mitigation activities at 72 hospitals. For 12 months, teams at each participating hospital will implement clinical training using AHRQ-supported evidence-based tools for improving infection safety. The findings from the HAI initiative will provide information on the barriers and challenges to improving and sustaining infection safety.

In addition to these activities, there are interagency initiatives that have recently been launched to reduce the rates of healthcare-associated infections. For instance, in fiscal year 2008, AHRQ was awarded 5 million to implement a new initiative, in collaboration with both the CDC and CMS. To identify gaps in prevention, diag-

nosis, and treatment of MRSA-related infections across the healthcare system.

CDC plans to use this new knowledge and findings to update multidrug resistant organism prevention, Healthcare Infection Control Practices Advisory Committee recommendations, to modify MRSA clinical management recommendations as appropriate, and to advise prevention implementation campaigns on how best to prevent MRSA infections. CMSexpects that the MRSA Initiative project results will enhance the quality of care for Medicare beneficiaries and, in general, public health.

Although we have a number of interagency activities in place, we also know that there is a need to establish greater consistency and compatibility of healthcare-associated infection data. That is why the CDC and other HHS agencies have made a concerted effort to establish compatibility of healthcare-associated infection data across the Department. CDC and CMS are working collaboratively toward a common set of data requirements for monitoring both healthcare-associated infections and adherence to their prevention guidelines. Presently, they are working together on data requirements for measurement of MRSA and toward an agreement on the surgical procedures that should be monitored as part of public reporting of surgical-site infection rates.

Before I close, I wanted to also mention the novel approach to reducing healthcare-associated infection through payment policy incentives. This is commonly referred to as value-based purchasing, and is currently being undertaken by CMS. The Deficit Reduction Act required CMS to select certain conditions for which Medicare will no longer pay an additional amount when that condition is acquired during a hospitalization.

CMS has collaborated closely with CDC on the selection of these conditions, with particular attention to identifying evidence-based guidelines that are consistent with CDC's recommended practice. Thus, the Medicare payment provision is closely tied to CDC's prioritized practices.

On Monday of this week, CMS announced additional steps to strengthen the tie between the quality of care provided to Medicare beneficiaries and payment for those services provided when they are in the hospital by proposing to expand the list of conditions. The proposed regulation builds on efforts across Medicare to transform the program to a prudent purchaser of healthcare services, paying based on quality of care, not just quantity of service.

You have just heard me discuss activities related to the prevention of HAIs, payment policy incentives, and also surveillance and monitoring of healthcare-associated infections. However, I think it is also important to note that we recognize that the implementation of healthcare institutions of quality improvement protocols can significantly reduce the number of healthcare-associated infections. I know you join me in saying that quality improvement research needs to continue to improve patient safety for all Americans. What I hope to convey during today's testimony is that the reduction of healthcare-associated infections to enhance patient safety and reduce unnecessary cost is a top priority for HHS. HHS looks forward to working with all stakeholders, public and private, in meeting its

shared responsibility to reduce healthcare-associated infections. I will be pleased to answer any questions that you might have.

Chairman WAXMAN. Thank you very much for your testimony.

[The prepared statement of Dr. Wright follows:]

Testimony
Before the House Oversight and Government Reform Committee
United States House of Representatives

HHS's Role in Reducing Rates of Healthcare-associated infections and Facilitating Quality Improvement Research

Statement of
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Introduction

Good morning Chairman Waxman, Ranking Member Davis and other distinguished Members of the Committee. I am Dr. Don Wright, Principal Deputy Assistant Secretary for Health in the Office of Public Health and Science at the U.S. Department of Health and Human Services (HHS). I am pleased to be here to describe HHS' efforts to reduce the rates of healthcare-associated infections (HAI). There are several agencies within the Department that have taken lead roles in addressing this important public health challenge, including the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). There are many examples of how these agencies have worked collaboratively on this issue. Though there has been significant progress in several areas, HHS recognizes more work and leadership is necessary to enhance patient safety in this regard. HHS recognizes the work of the Government Accountability Office in its recent proposed report to the Committee, *Health-Care-Associated Infections in Hospitals*, which looks at HHS prevention practices and data related to healthcare-associated infections.

Today, I will focus my remarks in four specific areas: 1) activities related to prevention of healthcare-associated infections; 2) activities related to surveillance and monitoring of healthcare-associated infections; 3) payment policy decisions (value-based purchasing) to create incentives to reduce healthcare-associated

infections; and 4) regulatory approaches to facilitate quality improvement research.

Prevention of healthcare-associated infections

CDC, on behalf of HHS, leads and supports a range of infection prevention activities at the national, regional and local levels. CDC's healthcare-associated infection prevention activities include developing evidence-based practice guidelines, assessing institution- and provider-level barriers and best practices for adoption of effective practices, developing and disseminating educational materials and toolkits to assist in translating policy into practice, and identifying and evaluating novel prevention strategies.

CDC produces evidence-based guidelines that serve as the standard of care in U.S. hospitals and guide the clinical practices of physicians, nurses and other providers. An advisory committee to HHS and CDC, the Healthcare Infection Control Practices Advisory Committee (HICPAC), has provided recommendations for the development of evidence-based guidelines for the prevention of healthcare-associated infections, including bloodstream infections, surgical site infections, healthcare-associated pneumonia, urinary tract infections, antimicrobial-resistant infections, and tissue safety issues. Most recently, CDC published guidelines to prevent the emergence of antimicrobial resistance and stop transmission of methicillin-resistant *Staphylococcus Aureus* (MRSA) and other antimicrobial resistant pathogens in healthcare settings, and published an

updated edition of the broader guideline "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007" that serves as the principal foundation of infection control practices in the United States. Overall, these guidelines represent over a thousand evidence-based recommendations which, while large in number, address the vast complexity of modern medical care. All of the recommendations are prioritized according to the quality of evidence available to support them.

CDC guidelines are translated into practice in several ways, and have served as the basis for national healthcare quality initiatives such as the Institute for Healthcare Improvement's 100,000 Lives Campaign and the CMS Surgical Care Improvement Project, which bundles together these guidelines to create best practices to reduce healthcare-associated infections. These collaborations help to standardize clinical practice, translate policy into practice, and reduce healthcare-associated infections. In addition, several of these evidence-based recommendations have been incorporated into The Joint Commission standards for accreditation of U.S. hospitals and have been endorsed by the National Quality Forum.

In addition, CDC provides funding to a network of academic centers, called the Prevention Epicenter Program, that work in a collaborative manner to identify novel ways to improve infection control and healthcare quality, assess the effectiveness of existing prevention strategies, including the prevention of MRSA

and other resistant organisms, and pilot new implementation tools to bring CDC guidelines to the bedside. Collaborations with the Epicenters resulted in demonstrating improved detection of surgical site infections, decreased inappropriate use of antimicrobial agents, reduced bloodstream infection rates in intensive care units, and decreased infections caused by MRSA and vancomycin-resistant *enterococci*.

There have been several successful regional initiatives in which projects were funded by HHS agencies to increase implementation of CDC guidelines to prevent bloodstream infections. CDC collaborated with the Pittsburgh Regional Healthcare Initiative to prevent central line–associated bloodstream infections, among intensive care unit patients in southwestern Pennsylvania, which resulted in a 68% decline in bloodstream infection rates over a four-year period. AHRQ funded the Keystone Initiative in Michigan that resulted in a 70 percent decline of central-line associated bloodstream infections when CDC guidelines were fully implemented.

CDC has provided direct support, through in-kind technical assistance and extramural funds, as well as assistance to external partners involved in healthcare-associated infection prevention initiatives to translate successful pilot projects at the local level into regional and ultimately national implementation programs. These partners include the Veterans Health Administration of the Department of Veterans Affairs, Institute for Healthcare Improvement, state and

regional initiatives, and other multi-center prevention collaboratives. CDC funded and collaborated with the VA Pittsburgh Healthcare System to use CDC recommendations to prevent MRSA infections; these efforts led to greater than 60 percent reductions in MRSA rates. Influenced by their success, other hospitals in southwestern Pennsylvania are now collaborating on a regional MRSA prevention initiative, and the Veterans Health Administration has launched a national MRSA prevention initiative involving every Veterans Affairs Medical Center in the country. The prevention successes demonstrated in southwestern Pennsylvania have also served as the model for other national and regional initiatives, including one in southeastern Pennsylvania; a statewide initiative coordinated by the Maryland Patient Safety Center; a group of hospitals funded by the Robert Wood Johnson Foundation to prevent MRSA infection in participating hospitals in Pennsylvania, Maryland, Montana, and Kentucky; and a national initiative by the Voluntary Hospital Association members.

Additionally, CDC launched a national evidence-based educational Campaign to Prevent Antimicrobial Resistance in Healthcare Settings that targets healthcare providers. The Campaign focuses on preventing antimicrobial resistance in healthcare settings by promoting four strategies targeting various patient populations including: hospitalized adults, dialysis patients, surgical patients, hospitalized children, and long-term care residents.

A second way the Department works to prevent HAI is through the Agency for Healthcare Research and Quality, the lead agency for patient safety. AHRQ is active in mitigating healthcare-associated infections through provider education efforts.

Specifically, AHRQ has focused its attention on the implementation of evidence-based safe practices through its Partners in Patient Safety (PIPS) grants program. One example of such a safe practice implementation project was led by a team of Johns Hopkins University researchers working with all of the Michigan hospitals to implement proven practices to reduce serious infections acquired by patients in intensive care units (ICU's). The dramatic reductions in serious ICU infections prompted replication in hundreds of hospitals across the country and were described as "one of the most important advances in intensive care in a generation."

In 2007, AHRQ invested close to $2 million in reducing HAIs through its program, Accelerating Change and Transformation in Organizations and Networks (ACTION) program, a field-based research mechanism designed to promote innovation in healthcare delivery. In September 2007, AHRQ awarded five task orders to ACTION partners to support infection mitigation activities at 72 hospitals. For 12 months, multi-disciplinary teams as each participating hospital will implement clinician training that uses AHRQ supported evidence-based tools for improving infection safety. The goal of the training is to facilitate changes in

clinical behaviors and habits, care processes, and the safety culture within hospitals. The finding from the HAI Initiative will provide information on the barriers and challenges to improving and sustaining infection safety.

In addition to these activities, there are two notable interagency initiatives that have recently been launched to reduce the rates of healthcare-associated infections.

In FY 2008, AHRQ was awarded $5 million in appropriated funds to implement a new initiative in collaboration with both CDC and CMS to identify gaps in the prevention, diagnosis, and treatment of MRSA-related infections across the health system and to fund research, implementation, measurement, and evaluation practices that mitigate infections. The three agencies completed an analysis of their individual ongoing MRSA efforts nationwide, the needs of specific populations and venues, the availability of resources and the likelihood of success. While some information is known about MRSA, much remains unknown about the epidemiology in selected settings (acute care, community care, and long term care), prevention of colonization and infection, diagnosis in non-hospital settings, and effective treatment for eradication in all settings. The inter-agency group proposed 7 projects that would address identified gaps through multiple, specifically targeted projects rather than investing the entire appropriation in one single project. Funds will be awarded through existing contract mechanisms during FY 08 and the studies are expected to be completed

in 2 – 3 years. Study results will be widely disseminated via AHRQ publications and at professional conferences. In addition, the Agency will develop and disseminate tool kits for a variety of professional and consumer audiences based on the project study findings. CDC plans to use the new knowledge and findings to update multi-drug resistant organism prevention HICPAC recommendations, to modify MRSA clinical management recommendations as appropriate, and to advise prevention implementation campaigns on how best to prevent MRSA infections or hospitalizations. CDC plans to base future surveillance, research, and investigations on the knowledge generated in part from these studies. CMS expects that the MRSA Initiative projects results will enhance the quality of care for Medicare beneficiaries and, in general, public health.

Second, the Office of Public Health and Science in the Office of the Secretary has launched a departmental initiative to increase influenza vaccination amongst healthcare workers. Influenza is a serious disease that accounts for an average of 36,000 excess deaths and over 200,000 hospitalizations annually in the United States. Healthcare workers can acquire influenza from patients or transmit influenza to patients and other staff. Despite the documented benefits of healthcare worker influenza vaccination on patient outcomes and healthcare worker absenteeism, and on reducing influenza infection among staff, vaccination coverage among healthcare workers remains low (i.e., <45 percent), and well below the Healthy People 2010 objective of 60 percent. Healthcare workers are a high priority for expanding influenza vaccine use, as recommended

by the Advisory Committee on Immunization Practices. Accordingly, the Assistant Secretary of Health has launched an interagency taskforce to discuss current activities promoting and/or providing healthcare worker influenza vaccination for the 2008-2009 flu season. The first specific objective of the taskforce is to increase vaccination of HHS healthcare workers. These personnel work predominantly in the Indian Health Service (IHS), National Institutes of Health (NIH), Federal Occupational Health (FOH) and at CDC. The taskforce also hopes to promote vaccination of non-federal healthcare workers who work at federally funded healthcare sites, such as the Health Resources and Services Administration's (HRSA) community health centers and the Office of Population Affairs' (OPA) family planning clinics. The second objective of the taskforce is to increase vaccination of the broader healthcare workforce by partnering with Federal agencies (DoD and VA), health profession associations, advocacy organizations, and private stakeholder organizations to raise awareness of this important issue.

Surveillance and Monitoring

CDC has developed and validated both standardized definitions for tracking healthcare-associated infections and mechanisms for comparing facilities and regions that are now used by most hospitals in the United States and by many hospitals around the world. CDC leads several activities to track and prevent healthcare-associated infections. The National Healthcare Safety Network (NHSN), formerly the National Nosocomial Infection Surveillance (NNIS) System,

is a web-based tool for hospitals and state health departments to measure healthcare-associated infections and is an integral part of many prevention strategies. It is built and maintained using Public Health Information Network (PHIN) components and standards, including security infrastructure for PHIN systems, messaging services, and vocabulary and data exchange standards. NHSN offers many options to hospitals and local health authorities, and provides hospitals with an accurate measure of infections attributable to a patient's hospital stay as well as information which can drive infection prevention efforts at the hospital level. Additional options to be released in 2008 to facilities and states participating in NHSN include the ability to measure MRSA among both inpatients and outpatients to help the facility prioritize staffing and prevention efforts. CDC's surveillance systems, including NHSN, provide the means for building the future infrastructure to capture data from electronic sources in an automated fashion, which in turn could provide accurate, timely measures to direct local prevention efforts and track the effectiveness of prevention programs. Participation in NHSN has increased in the past few years, and the Network is expected to continue to expand in order to accommodate local, state, and federal reporting initiatives for healthcare-associated infections. CDC is currently providing support to more than 1300 hospitals in16 states that are using NHSN to fulfill state reporting requirements.

CDC and other HHS agencies have made concerted efforts to establish greater consistency and compatibility of healthcare-associated infection data collected

across the Department. CDC and CMS are working collaboratively toward a common set of data requirements for monitoring both healthcare-associated infections and adherence to their prevention guidelines. CDC and CMS are also working together on data requirements for measurement of MRSA as part of CMS's Ninth Scope of Work for the Quality Improvement Organization (QIO) program. The likely outcomes of this effort will be wider use of CDC's NHSN by hospitals participating in the QIO program and dual use of NHSN data by CDC and the QIOs. CDC and CMS also are working toward agreement on the surgical procedures that should be monitored as part of public reporting of surgical site infection rates.

Another example of Inter-agency cooperation has been in the area of surgical improvement. Building on the efforts of the National Surgical Quality Improvement Program (NSQIP), implemented by the Veteran's Health Administration, AHRQ funded the implementation of NSQIP in civilian hospitals. Due to the program's success, CMS is using NSQIP as the basis for the Surgical Improvement Project (SCIP) which is being supported as a national implementation effort thorough the QIOs. AHRQ and CDC continue to actively support this CMS- led effort, an example of effective cooperation among various federal agencies building one another's efforts for improving healthcare.

HHS has several different surveillance systems tracking healthcare-associated infections. However, it is important to note that these data collection programs

are designed for very different purposes. For example, the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU), a CMS program, is designed for participating hospitals to report several infection-related measures. These measures are currently publicly reported on CMS' Hospital Compare website to promote value-driven healthcare and quality transparency, and provide information by hospital to the public (in contrast, NHSN provides estimates of national burden from HAI's but does not provide information on individual hospitals). The Medicare Patient Safety Monitoring System (MPSMS) is a surveillance project designed to identify the rates of specific adverse events within the Medicare population using inpatient medical records and administrative data selected as part of the Medicare Hospital Payment Monitoring Program (HPMP). As a result, the MPSMS, a large national randomly selected set of charts serves as its sample (25,533). Additionally, the MPMS data is used by AHRQ for its National Healthcare Quality and Disparity Reports (NHQR/NHDR), particularly for data on HAIs. The MPSMS is the most reliable data on rates for specific HAIs in the Medicare population.

CMS is working to improve the collection of healthcare-associated infection data. CMS is currently evaluating replacing the current coding system, ICD-9-CM, with an updated system, ICD-10. Identifying hospital-acquired conditions requires clear and detailed diagnosis codes. The current coding system, ICD-9-CM,has numerous instances of broad and vague codes which has made it difficult for CMS to identify cases with a hospital-acquired condition. ICD-10 codes are more

precise and capture information using medical terminology used by current medical practitioners. CMS plans to be ICD-10 ready by 2011.

Measurement and data efforts at AHRQ also enhance our capacity to track HAIs at the national, state, and community level. The AHRQ Patient Safety Indicators (PSIs) are a set of indicators based upon readily available hospital inpatient administrative data. The AHRQ PSIs provide information on potential in-hospital complications and adverse events following surgeries, procedures, and childbirth. Select AHRQ PSIs provide the ability to assess hospital acquired infections (e.g. post-op sepsis, selected infections due to medical care and others).
Through AHRQ's partnership with 39 states in the Healthcare Cost and Utilization Project, which includes data on 90 percent of the hospital discharges in the country, AHRQ can track variations in HAI across regions and over time using these PSIs. AHRQ summarizes information from these hospital discharge data, along with NHSN and CMS data in the annual National Healthcare Quality Report and National Healthcare Disparities Report.

AHRQ has also been collaborating with CDC and CMS, as well as other agencies, in another effort that involves greater consistency and compatibility of HAI data: the development of common definitions and reporting formats to support implementation of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). This effort, spearheaded by AHRQ, includes CDC, CMS, FDA, NIH, HRSA, and the IHS within the Department and the Departments of Defense

and Veterans Affairs. Proposed regulations for PSQIA were published in February that, when final, will allow implementation of this landmark legislation that creates uniform, national confidentiality and privilege protections for clinicians and entities performing patient safety activities. Secretary Leavitt has asked AHRQ to provide "common formats" as technical assistance to newly designated patient safety organizations (PSOs), so that patient safety data gathered among and across PSOs are comparable and can be aggregated for faster learning. Compatible data reported to HHS will be included in AHRQ's annual National Healthcare Quality Report. Among the common formats being developed are those for HAIs, and, with CDC participating in the effort, AHRQ will ensure that the clinical content of the formats is consistent with that of the CDC's National Healthcare Safety Network. These data formats can be used as measurement tools across the health care community, not solely within the PSO context.

Payment Policy Incentives

A novel approach to reducing healthcare-associated infections through payment policy incentives is commonly referred to as value-based purchasing. Currently, CMS is seeking legislative authority to implement a value-based (VBP) purchasing program for Medicare inpatient hospital payments that ties 5% of hospital payments to the hospital's actual performance. Payments would be based on improving a hospital's quality of care as well achieving absolute levels of quality of care.

The Deficit Reduction Act (DRA) required CMS to select certain conditions for which Medicare will no longer pay an additional amount when that condition is acquired during a hospitalization. The Secretary was asked through the Act to identify at least two conditions that are: (a) high cost or high volume or both; (b) result in the assignment of a case to a Diagnosis Diagnostic Related Group that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines. CMS has collaborated closely with CDC on the selection of these conditions, with particular attention to identifying evidence-based guidelines that are consistent with CDC's recommended practices. Thus, this Medicare payment provision is closely tied to CDC's prioritized practices.

In the Inpatient Prospective Payment System FY2008 final rule, of the eight selected conditions for the hospital-acquired provision, three conditions involved nosocomial infections. Specifically, catheter-associated urinary tract infections, vascular catheter-associated infections, and a surgical site infection, mediastinitis after coronary artery bypass graft surgery, were selected. Beginning October 1, 2008, Medicare cannot assign these selected conditions to a higher paying DRG unless they were present on admission. In addition, CMS is seeking public comment on additional hospital-acquired conditions, which will include several healthcare-associated infections. Also this week, CMS announced a proposal to expand the list of conditions.

As a prerequisite for implementing this Medicare payment provision, the DRA also requires hospitals to begin reporting present on admission (POA) indicator data to identify whether the selected conditions are acquired during a hospitalization. Beginning October 1, 2007, hospitals were required to begin submitting information on claims specifying whether diagnoses were present on admission. POA data will be needed to determine whether payments should be made for the selected healthcare-associated infections. CMS' collection of POA data will generate increased information about hospital-acquired conditions, including infections, which can be used by CDC and others to develop and disseminate reliable national estimates of these conditions.

Quality Improvement Research

HHS recognizes that the implementation by healthcare institutions of evidence-based quality improvement protocols can significantly reduce the number of healthcare-associated infections. The Department realizes that quality improvement research needs to continue to improve patient care and safety for all Americans. The key federal regulations that apply to some quality improvement research are the HHS human subject protection regulations at 45 CFR part 46. These regulations include the Basic HHS Policy for the Protection of Human Research Subjects (also known as the Federal Policy for the Protection of Human Subjects), which is codified at subpart A of 45 CFR part 46 and identifies requirements involving institutional review board (IRB) review and

informed consent of subjects and other measures designed to protect the rights and welfare of human subjects in research.

Recent media accounts have raised questions about whether the regulations apply to quality improvement activities. The HHS regulations for the protection of human subjects in research do not apply to most quality improvement efforts, but they do apply to some of them. Institutions need to correctly identify which quality improvement activities do not fall under the regulations and which ones do fall under those regulations, so that the appropriate protections for human subjects can be put into place. To determine whether these HHS regulations apply to a particular quality improvement activity, the following questions should be addressed in order: (1) does the activity involve *research* as defined in the regulations[1] (45 CFR 46.102(d)); (2) does the research activity involve *human subjects* as defined in the regulations[2] (45 CFR 46.102(f)); (3) does the human subjects research qualify for any of the six *exemptions* described in the

[1] "***Research*** **means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."** (45 CFR 46.102(d))

[2] "***Human subject*** **means a living individual about whom an investigator (whether professional or student) conducting research obtains**
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.
Intervention **includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.** ***Private information*** **includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."** (45 CFR 46.102(f))

regulations[3] (45 CFR 46.101(b)); and (4) is the non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable Federalwide Assurance approved by HHS' Office for Human Research Protections (OHRP). Some quality improvement activities fall outside of the regulations at each of these four decision points. Domestic institutions may voluntarily extend their Federalwide Assurance to cover all human subjects research conducted by the institution, regardless of the source of support for the research. These regulations only apply to quality improvement activities

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[3] **"Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:**
(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture." (45 CFR 46.101(b))

involving non-exempt human subjects research that are conducted or supported by HHS, and to non-exempt human subjects research conducted by an institution that has chosen on its Federalwide Assurance to extend the applicability of the regulations to all its non-exempt human subjects research. These are the same criteria that are used to determine whether other public health-related practices, such as public health surveillance or evaluation activities, require the regulatory protections appropriate to human subjects in research.

The regulations provide substantial flexibility in a number of ways related to how those quality improvement activities that are covered by the HHS human subjects protection regulations can satisfy the regulatory requirements. That flexibility includes various alternatives for cooperative arrangements for IRB review, the use of expedited review procedures, and the option to waive informed consent. This flexibility allows institutions to adjust the degree of oversight to the level of risk in the planned activity.

First, under the regulatory provisions for cooperative arrangements for IRB review, the HHS regulations allow one IRB to review and approve research that will be conducted at multiple institutions. An institution such as a community hospital participating in a research activity has the option to rely upon IRB review from another institution by designating that IRB on its Federalwide Assurance, submitting a revised assurance to OHRP with this designation, and having an IRB Authorization Agreement with the other institution. In this way, multiple institutions can share the review conducted by one IRB.

Second, if the human subjects research activity involves no more than minimal risk (defined in the regulations) and fits one of the categories of research eligible for expedited review provided under the regulations, the IRB chairperson or another member designated by the IRB chairperson may conduct the review. This allows the institution to go forward with the review of minimal risk activities instead of having to wait until the next meeting of the convened IRB to review the research plan.

Third, the HHS regulations allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research under certain conditions. An IRB can agree to requests to waive informed consent in the following circumstances: (a) the risk to the subjects is minimal; (b) subjects' rights and welfare will not be adversely affected by the waiver; (c) conducting the research without the waiver is not practicable; and (d) if appropriate, subjects are provided with additional pertinent information after their participation. This provision provides the flexibility to determine whether or not informed consent should be obtained.

Conclusion

The reduction of healthcare-associated infections to enhance patient safety and reduce unnecessary costs is a top priority for HHS. Through prevention activities, surveillance and data monitoring initiatives, value-based purchasing,

and guidelines to facilitate quality improvement research, the Department is tackling this public health challenge in many different ways. There are many examples of inter-agency collaboration in this area throughout the Department. HHS looks forward to working with all stakeholders – public and private – in meeting its shared responsibility to reduce healthcare-associated infections.

Thank you for the opportunity to testify today; I am happy to take any questions you may have.

Chairman WAXMAN. And I want to thank all of you for your presentation to us. You seem to be of one mind that there is something we can do about a problem that is an extraordinary one in costing lives and money, that could be prevented.

Maybe I will start off the questions. You might have heard bells. We are being called to the House floor for some votes. We will break in a minute. But let's see how far we can get.

Let me try to understand the scope of this problem. According to the Centers for Disease Control's best estimates, there are 1.7 million hospital-associated infections which lead to 100,000 deaths each year. And these are largely preventable infections. And they come at a price. They come at a price not only to the person infected, who may lose his or her life, they come at a price to the government, to employers, to members of the family. The Institute of Medicine said we could save $5 billion. Now, most people who die of these infections don't have it on their death certificate that they died of a hospital infection. They usually have something else reported typically as the cause of death.

But if we were able to look at this chart that I am going to put up on the screen, or one that is already standing on the pedestal there, what we have seen is that if you look at hospital-associated infections, it would be the sixth leading cause of death, higher than even diabetes. But unlike other causes of death, this is one we know how to reduce.

Dr. Pronovost, you now have several years of experience working with the hospitals in Michigan. You have a checklist for these hospitals to follow. If all hospital ICUs in every State were to use the same checklist, how many lives do you estimate we could be saving?

Dr. PRONOVOST. Mr. Chairman, the number of deaths from this particular type of infection is 28,000 a year. And the costs are somewhere between $2 and $3 billion a year for these catheter-related infections. I would add, though, that our knowledge of both how to measure and the extent to which we could actually prevent these infections for other infections is less mature. For these, though, there is no doubt that we used to think they were all inevitable. Now we know they are virtually all preventable. The others, though, I think the science still has to mature to say how much of them—certainly some, but I don't know that we are comfortable in saying what percentage are.

Chairman WAXMAN. Now, the GAO did an evaluation of our efforts in that regard. And Ms. Bascetta, you found that we just seem to have a very haphazard way of approaching the problem from the government's perspective. What would allow us to make sure that all the hospitals are doing the same thing that Dr. Pronovost and the hospitals say they want to be able to do?

Ms. BASCETTA. Well, I think there are some basic infection-control measures that are known that should be taken by all hospitals. And then another important point to remember is that it is important for hospitals to assess their own particular risks. Some of them may need to prioritize things differently than others. So we don't necessarily want them to all be tackling exactly the same problem, although there are certainly common approaches that they should take.

And our belief is that HHS could be doing a much better job bringing to bear its collective expertise from CDC and AHRQ and CMS to use these various leverage points to influence hospitals to take the measures that they need to take.

Chairman WAXMAN. What is the problem? Three separate agencies at HHS are not talking to each other, or are they taking too long at each of these agencies to figure out what recommendations to make, and make sure that the hospitals are following them?

Ms. BASCETTA. Well, although they all seem to have a sense of urgency about the problem, collectively they haven't achieved what we call "traction" in our report. And we think it is because, although they talk to one another, most of their discussions are so far in the nature of updating one another about their independent actions or their independent data bases. There isn't the synergy that is needed to ratchet up the attention to how they can strategically attack the problem and how they can get the word out to hospitals about their expectations and about what hospitals can do.

Chairman WAXMAN. We want this hearing to be a constructive hearing, because after this hearing is over we want to see action, using low-cost technology in proven ways to reduce these infections to save lives.

Dr. Pronovost, you developed a checklist. It looks like the government is giving a very long list of things for hospitals to do, but you had a simple checklist. Why aren't hospitals just following your checklist?

Dr. PRONOVOST. Well, in part, because as you alluded to, the typical way of summarizing guidelines is to make these often elegant but 200 to 300-page documents that clinicians don't read. They are too busy. And so we summarized the very detailed CDC guidelines into five key points and packaged them in a way. But what we were lucky enough to do, with some funding from AHRQ, was to find the science. And it is really almost social science of how do you get behavior change. How do we make something in a way that clinicians buy into? And part of it is having rigorous measurements so they believe the results.

In this case we measured infections quite robustly, having good evidence on which to act on, and then using some internal levers—payment system is one of them—that they are encouraged to say, I have to do the right thing. And we have made it easy for them.

Chairman WAXMAN. Thank you. My time has expired. Mr. Davis.

Mr. DAVIS OF VIRGINIA. We have a quick vote coming up. Let me ask Mr. Lawton—thank you for being here. The Leapfrog Group recommends that when a patient is a victim of a medical error or an infection, hospitals should apologize to the victims, conduct root-cause analysis, publicly report events, and waive all charges related to them. Did the hospital that treated you take any of those steps after your infection in 1998?

Mr. LAWTON. Not that I can recall.

Mr. DAVIS OF VIRGINIA. Would those steps have impacted your experience at the hospital?

Mr. LAWTON. Well, it would have helped me. The experiences I went through, from what I remember—and I try not to remember—were fairly traumatic. And I kind of suffered through all of them. But I mean, the folks were nice. I know everybody was busy

trying to help people in the hospital. But I really didn't feel that a lot of attention was given to that. It was just part of the process. They were going through their day-to-day activities and my situation——

Mr. DAVIS OF VIRGINIA. Just mailing it in. Thank you.

Ms. Binder, one of the outcomes that must be avoided is that in good-faith attempts to reduce infections, the Federal Government and the payers overburden hospitals with bureaucracy to the point that energy is spent fulfilling requirements versus improving care. That is also the balance.

Are there opportunities for the private sector and the Federal Government to collaborate to avoid overburdening hospitals?

Ms. BINDER. Yes. And we have been working on collaborating on exactly that issue for some time now, and continue to do so. The key issue, as I stated in my testimony for the Leapfrog Group, is that we are measuring—whatever measures we ask hospitals to report—are measuring outcomes of care. Our focus is on whether or not the patient improves or how the patient does. The patient outcomes should be preeminent.

Ms. BASCETTA. The patient outcome should be preeminent.

Now, it is very difficult sometimes to find a measure that will address patient outcomes. But if a measure will looked at, for example, a procedure in a hospital setting, then we ought to have evidence that procedure leads to positive patient outcome. So one of the issues that we have been working with our colleagues on the Federal Government with and our employer members, is to identify measures that are outcome-oriented and to apply those in the public setting in a transparent way so people are aware of how patients do when they go to one hospital versus another. And I think we do have more work to be done. Hospital Compare, as stated, the employers are not comfortable that it has enough outcome-oriented measures. We would like to see more of that.

Mr. DAVIS OF VIRGINIA. Dr. Pronovost, part of the frustration with infection controls, that in some areas there is evidence of effective interventions that reduce infection rates, but those interventions just aren't widely implemented. How do you explain this gap, where we have the knowledge but it is just not happening on the ground?

Dr. PRONOVOST. That is absolutely the case. And if you listen to this testimony, it is remarkable; that must be one of the few things that everyone on the panel agrees with. We all are acknowledging there is a problem. We want to help it. I think, as an industry, we have been talking past each other, and we really need some strategic leadership.

What I would say is, because we viewed getting doctors and nurses to change these things as seen as an AHRQ. Yet, medicine can go around the way it wants to. And what we have learned is that there is as rigorous a science of measuring these things and of implementing change as there is in finding the human genome. It takes different skills, but we have invested in learning how to do that. And I think, with some investments, we can dramatically ratchet up how effective and efficient we are in implementing these programs.

Mr. DAVIS OF VIRGINIA. Behavioral change is one of the most difficult obstacles in a case like this. What are some of the challenges in achieving behavioral change, even when someone isn't watching?

Dr. PRONOVOST. And payment policies have to be part of it, but payment policies that run ahead of science aren't going to get us where we need to be. So even if you prefer, one of the things we are not going to pay for is ventilator-associated pneumonia. With our current ability to diagnose that, ensuring we will have 30 false positives, that is patients who don't really have it, for every one that we diagnose correctly. And certainly we need to allow for policy, but we also need to invest in how to diagnose the darned thing right so that—and how much we can really prevent it, so that we are paving a way to create a wise and just payment system.

The behavioral change has to be multi-factorial. Aligning the payment system is a component. Measurement and giving feedback is another component in making sure that the evidence is sound and is packaged in a way that is practical for busy clinicians, such things as a checklist and not a 200-page guideline, are all things that seem to work.

Chairman WAXMAN. Thank you very much, Mr. Davis.

We are going to have to respond to the vote on the House floor, and it will probably take 20 minutes because there are four separate votes that will be reduced to 5 minutes after the first.

But I do want to recognize Ms. Norton, because while we tried to make it otherwise, she still does not have a vote as a full Member of the House of Representatives. So I want to recognize her for 5 minutes. And when she has completed her 5 minutes, maybe witnesses can take a break themselves and grab a quick bite in a very, very short period of time.

And we will get back hereby 12:30. Thank you.

Ms. NORTON. Thank you very much, Mr. Chairman.

Occasionally you gain something from not having a vote on the House floor. I do get to vote on the Committee of the Whole. This is not a Committee of the Whole vote. And I am pleased that I vote in this committee. It is a very important committee to our country.

I am going to ask you about the rather, for me, frightening notion of infections that appear possible to be spread in hospitals and may be brought into hospitals. It has been brought to my attention, and I am going to try to pronounce this without knowing if it is correct, that a highly resistant bacteria that apparently has ravaged soldiers in Iraq and Afghanistan called Acinetobacter. And, for some, the bacteria can mean the loss of limbs that are otherwise saved, and lives.

The reason I bring this question to you is that, for example, at Bethesda, they said they found hundreds of positive cultures. And I was particularly concerned that, of those who have died, the seven who have died, or that the Defense Department acknowledges have died, from this particular bacteria, five were non-active-duty patients being treated in the same hospitals as infected service patients.

This is an apparently highly resistant bacteria. And according to the experts, the only drugs they found—they don't know—and they believe that this particular bacteria quickly colonizes in such a way to make it resistant to even other pharmaceuticals which are

found, but one was found at Walter Reed here in our District. Some of these have been at Walter Reed here in our District. And one of the doctors said that one of the antibiotics that he has not used in recent years that could be used here is called Colistin. But he hasn't used it because it causes or could cause nerve damage and kidney damage, which is also what this particular bacteria sometimes causes.

Now, they don't know where this came from. I do not believe this originated in hospitals, and they are trying to find out. They don't think it originated in the soil in Iraq. They think, however, that it lies dormant in open wounds. As quick as the paramedics, and they have been miracle workers, have been, that this may be the cause for it.

Well, these soldiers are coming back in large numbers. They are going all over the country. Some of them go to military hospitals, most of them probably would not unless—well, sometimes I suppose if they have a wound. And here we are concerned about kind of low-cost, easy ways to deal with infections that we are well aware of, we know how to combat.

My question really goes to whether hospitals are prepared to deal with the introduction of new infections. People come in the hospital sick. They can be infected with things. And if we can't deal with infections that arise in the hospital, what chance do we have of dealing with what amounts to a global health system as well, where people come with whatever they bring from other countries, including our own American soldiers?

One, do you know anything about this particular bacterium? And, two, what should hospitals do now that soldiers are coming back, and some of them may be treated in ordinary hospitals and by ordinary physicians, about the introduction of bacteria such as this? And is this a rare case? It certainly isn't rare in the Armed Services. Perhaps it hasn't killed large numbers of people. But the possibility of it spreading, and particularly in hospitals, and then being carried heaven knows where exists when people come back.

Quite apart from the important work you have done and commented upon here, are hospitals prepared to deal with the introduction of new kinds of bacteria that they in turn spread to others in the hospital and elsewhere? Don't all of you speak at once.

What would you do if, in fact, maybe as a law school hypothetical, if you knew that there was a patient who had tested positive for this bacteria but was ill of something else? What would you, or what would your hospital do in that case?

Dr. PRONOVOST. These micro-organisms are in some sense the most brilliant scientists, because no matter how clever we think we are with getting drugs, biology or evolution seems to make them resistant to many things. So this Acinetobacter is like a number of other infections, others including pseudomonas that you may have heard. And, by the way, your medical knowledge is impressive. We will give you a degree from Johns Hopkins.

And we struggle with this all the time of having these organisms that are resistant. And, indeed, on many patients, I use Colistin because it is the only drug that works and the risk-benefit ratio is, without a drug, they will most likely die, so we accept some risk of harm.

The strategies that we do are, one would be a surveillance. First, we have to make sure we identify when patients have them. And, if they do, we put that——

Ms. NORTON. Can we test for this? Apparently, we know how to test for it. Will we test for it? Should we be alerting—I guess military hospitals may test for it. But if this bacteria is spread, perhaps it spreads through hospitals. Should we try to get us more tests?

Dr. PRONOVOST. Right now it is probably tested for if someone has some other infections.

Ms. NORTON. If they are tested for some other infections.

Dr. PRONOVOST. It would come up. Right. And typically hospitals, and almost all hospitals, have the ability to say what antibiotics might be effective in treating that infection, and that patient would be isolated. In other words, they would be put in a separate room, and clinicians would have to have what is called contact precautions. So, they would not be allowed to go in the room without having a special gown on to prevent them from spreading it to other patients. There typically would be some environmental surveillance and cleaning, so that we don't have our stethoscopes or the computers or the beds harbor this infection. And maybe we try to treat it with other antibiotics that we could, fully acknowledging that we may induce some harm in trying to save a life or limb.

Ms. NORTON. Ms. Bascetta, do you have a comment?

Ms. BASCETTA. Yes. Your comment brings to light that we are focused on HHS, but as you point out DOD and VA as well have their own Federal hospital system. And I know that the military has a way of tracking global emerging infectious disease, as does CDC. So perhaps Dr. Wright would like to comment on whether HHS, or—I am sure they are—to what extent HHS and DOD and VA are working together on these kinds of issues.

Ms. NORTON. For example, do you think at least the ordinary civilian hospitals ought to be alerted to this infection as something they ought to look for?

Dr. WRIGHT. Yes, Congresswoman.

Acinetobacter really is a problem that has been in intensive care units and has been a problem among soldiers returning from Iraq, as you said. But I think it is important to note that it is not a rare case, and it has actually been a problem in the United States, here locally as well.

As far as the problem with our soldiers, let me assure you that the CDC is working very collaboratively with Walter Reed, looking at that issue, trying to better understand this particular problem and how we can prevent it in the future.

Along that same line, I would like to say that the CDC has done an excellent job in recently releasing guidelines that deal with multi-drug-resistant organisms in hospitals. Certainly MRSA has been an issue that received a great deal of media attention, but it clearly is not the only bacteria that has achieved resistant status. And their approach is to look from a holistic standpoint: What is it that we can do to eliminate these infections from bacteria that have developed resistance?

Ms. NORTON. Thank you.

You are dealing often with infections which do not resist, and yet we still have them. So I am just moving the trajectory up somewhat to say that there is likely to be more and more of these resistant infections that you encounter.

Thank you very much for your testimony. The hearing is recessed. They will return.

[Recess.]

Chairman WAXMAN. Yarmuth.

Mr. YARMUTH. Thank you, Mr. Chairman.

Dr. Wright, in your testimony, you considered that the hospital-associated infections are an important public health challenge. I think that is the way you phrased it. And you also said that more work and leadership is necessary to enhance patient safety. You also detailed various activities that different agencies within the Department are undertaking. That is helpful as far as it goes. But given the stakes involved, it doesn't seem to me that it goes nearly far enough.

We apparently have an epidemic of hospital-associated infections in this country if we are talking about virtually 100,000 people dying a year, resulting in all those deaths and avoidable costs of billions of dollars. And I think every hospital patient and family member has a right to expect more from our government and from the Department. At a minimum, they have a right to expect leadership in this area. And today's GAO report states that no one within the Office of the Secretary is responsible for coordinating infection control activities across HHS. Your testimony does not really address this point, so I would like to have a response to that specific issue.

So, why hasn't there been a coordinated response to this epidemic within the Department?

Dr. WRIGHT. Thank you, Congressman.

The Office of Public Health and Science is in the Office of the Secretary at HHS. I serve as the principal Deputy Assistant Secretary. That particular office is headed by the Assistant Secretary for Health. And the Assistant Secretary for Health is very frequently asked to serve in a coordinating role on issues that involve many of our agencies or operating divisions, and coordinate activities across those.

In the area of healthcare-associated infections, there is a good example of where this office has had a key role in coordination, and it relates to immunizations for seasonal flu for healthcare workers. You are probably well aware that the Center for Disease Control has long stated that healthcare workers are a top priority for receiving this vaccine, and yet the numbers of healthcare workers that actually receive the vaccine is somewhat disappointing. It is only about 40 percent.

Now, this is an issue that has both occupational health concerns as well as patient safety concerns. Certainly a healthcare worker who is exposed on the job by taking care of an influenza patient has a risk of workplace transmission. But, also, there is the concern that a healthcare worker could inadvertently infect patients that they come in contact on a ward. As a result of that, the Assistant Secretary for Health coordinated—led and coordinated an

interagency working group that involved all the major operating divisions of the HHS to address this particular healthcare concern.

The first goal of this particular task force was to see what we could do within the HHS family. There are numerous healthcare workers within HHS and the Indian Health Service and the National Institutes of Health and CDC and Federal Occupational Health. What is it that we can do to set the example? And then, more importantly, what is it that we can do with our other Federal partners and the Veterans Administration and Department of Defense, as well as private sector hospitals, to increase the immunization rate for seasonal influenza. So there is a coordination role. There is a leadership role within the Office of Public Health to work across operating divisions as it relates to issues of healthcare-associated infections.

Mr. YARMUTH. But that doesn't deal specifically with these situations in the hospital. That is a different example. So my question would be, do you think this approach is working? Because apparently, from the data that we have, this type of approach is not working, and there does seem to be a lack of a coordinated effort within the Department.

Dr. WRIGHT. Congressman, there is some good news with healthcare-associated infections. We are seeing improvement in bloodstream infections, partly done by Dr. Pronovost's work and work that was done in Pittsburgh. We are also seeing improvement as it relates to surgical site infections.

That said, clearly there is a great deal of work to be done. And we at the Department do have opportunities to collaborate, and there are examples where we collaborate across operating divisions or agencies in a very effective way. Another great example——

Mr. YARMUTH. I just want to ask Ms. Bascetta whose report this was, if this is the type of cooperation that GAO envisioned when it issued its report and the recommendations that agency made.

Ms. BASCETTA. No, it isn't. And I would like to point out that, and HHS had an opportunity to comment on our report, and they did not bring up that they were in fact coordinating or collaborating at the level that we would have expected. I think they certainly have the potential to do that. And an example of what we would expect to see is some sort of strategy that takes the offense in dealing with HAIs at a much higher level than having their components do their very good but relatively independent activities so far.

Mr. YARMUTH. Thank you for that. I think that is an approach that we all would prefer to see.

Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you, Mr. Yarmuth.

Mr. Burton.

Mr. BURTON. Thank you, Mr. Chairman.

First of all, I want to apologize. I had several other meetings going on, so I haven't been here to hear all of your testimony, but I will read it, and my staff and I will go over it.

I have a couple of questions, and Ms. McCaughey is here, and I appreciate you being here on such short notice. She is the head of the Committee to Reduce Infection Deaths, and she is a former Lieutenant Governor of New York.

And in her article, I would like to read this to you, she says: Restaurants and cruise ships are inspected for cleanliness. Food processing plants are tested for bacterial content on cutting boards and equipment. But hospitals, even operating rooms, are exempt. The Joint Commission which inspects and accredits U.S. hospitals doesn't measure cleanliness, neither do most State Health Departments nor the Federal Centers for Disease Control and Prevention.

Now, I am going to ask her when she gets before the committee if that is true. But if that is true, that is criminal. That is absolutely criminal.

I also found in this little brochure, it says, "things that you should ask a doctor and say to hospitals to reduce your risk of getting an infection." And there are 15 things on here. And it says: Ask the hospital staff to clean their hands before treating you. Before your doctor uses a stethoscope to listen to your chest, ask him to put some alcohol on it to clean it. If you need a central line catheter, ask your doctor about the benefits of one that is antibiotic impregnated or antiseptic coated to reduce infections. If you need surgery, choose a surgeon with a low infection rate. Beginning 3 to 5 days before surgery, shower or bathe daily with chlorhexidine soap.

And it goes on and on and on. And all this ought to be academic to a hospital. The patient should not have to ask these questions.

I mean, when I went into a hospital, I had a shoulder injury, and my doctor was supposed to be the best. I won't go into his name now, but he was pretty negligent. And after about 3 or 4 weeks after the surgery, I had trouble in my shoulder and he said, "well, see how you are working with it." And I raised my arm. He says, "well, you don't have any problem." He says, "you are doing well." And I said, "but I am telling you, something is wrong."

I came back to Washington, and I kept telling myself. I flew back. When I flew back, I said, "I am telling you something is wrong." And he said, "well, you can get an MRI, and it will cost about $1,000, but you don't need it." I went to get the MRI at 8:30 at night. He called me and said, can you be at the hospital tomorrow at 7:00? I was at the hospital at 7 the next morning. He had to operate on me four more times. They had to cut into the bone and the muscle, and he said I might have arthritis and never be able to use the arm again. But we worked real hard, so it is OK.

But the point is, it was an infection that I got either through the surgery or the hospital, and he wouldn't even acknowledge it without testing it. And it was just lucky that I found out about it. And I talked to the surgeon here at the Capitol, our doctor, when he came in, and he said he had a person with a similar problem who had an infection and dropped dead right after he met with him because the infection had spread so much.

I guess the question I would like to ask you generally, and I don't know which one of you to address this to, is, why aren't we, across the country and the States and the HHS and FDA, why aren't we insisting that these 15 steps be implemented in every single hospital across this country? And if what Ms. McCaughey says, that restaurants and cruise ships and food processing plants are tested for bacteria, if they are doing it there, why aren't we doing it in the hospitals? I mean, I just don't understand it. And if they are handing out this brochure for me to ask my doctor of things to do,

and most people aren't going to see this thing. They are never going to see this thing. And so they are going to go in, and they are going to rely on the nurses to wash their hands and do all the things that this thing says. Why isn't that standard operating procedure? And, why isn't there a requirement to make sure these things are done in every hospital in this country? Now, with that, any one of you can answer.

Ms. BINDER. I couldn't agree with you more. As I talked about earlier, the Leapfrog survey last year of covering about 60 percent of the in-patient beds in this country we found that 87 percent of those responding to our voluntary survey did not undertake the required practices for safe practices for a hospital, which was astounding to us, even though we came into this realizing this was a problem.

Fundamentally, I worked in a hospital. I know it is extremely difficult to make the kinds of changes that are needed to have safe practices. You have to educate every staff person, not just the physician and not just the nurses; but the person who admits the patient, the janitor, everybody has to understand and comply completely with safe practices to prevent infection. To get to that point——

Mr. BURTON. I am running out of time, if the chairman will give me one more second here. This is probably the most important thing that people deal with regarding their health, and you just said that it is very difficult. Even if it is difficult, it should be done.

Ms. BINDER. Absolutely.

Mr. BURTON. And there ought to be penalties imposed by FDA, HHS, or State health agencies to make sure that this stuff is done. And if a nurse or a doctor doesn't comply with the requirements, they ought to be penalized severely. Severely. Because people are dying because of that.

With that, Mr. Chairman, I am sorry I took so much time.

Chairman WAXMAN. Thank you, Mr. Burton.

Mr. Hodes.

Mr. HODES. Thank you, Mr. Chairman.

The testimony from Dr. Pronovost and Mr. Labriola is very convincing about the results in Michigan, and I think you have made a convincing case for replicating the Michigan project in every State in the country. Every ICU patient should have the benefit of reductions of risk of infection that come from the application of a checklist regardless of what State they are in. And, frankly, not just in ICUs, but in all other areas of care in the hospitals where there is a risk of infection.

Now, the Michigan project was made possible by $1 million from Merck, and estimates apparently vary as to the benefits. Dr. Pronovost pointed out in his testimony that, for every dollar we spend on biomedical research, we spend only a penny on research. So there we have, I don't know, a 100 to 1 ratio. But it looks like we saved about $200 million for the $1 million investment in Michigan.

Now, the Department's budget for fiscal year 2009 heads in the opposite direction. AHRQ's fiscal year 2008 budget for general patient safety research is $34 million. For the next year, the Department proposes to cut this amount by $2 million. I find it incompre-

hensible. In a New Yorker article, which with the permission of the chair, I will submit for the record.

[The information referred to follows:]

THE NEW YORKER

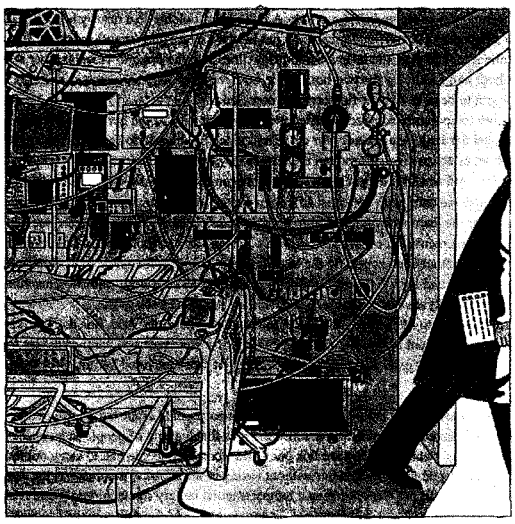
ANNALS OF MEDICINE

THE CHECKLIST

If something so simple can transform intensive care, what else can it do?

by Atul Gawande

DECEMBER 10, 2007



If a new drug were as effective at saving lives as Peter Pronovost's checklist, there would be a nationwide marketing campaign urging doctors to use it.

The damage that the human body can survive these days is as awesome as it is horrible: crushing, burning, bombing, a burst blood vessel in the brain, a ruptured colon, a massive heart attack, rampaging infection. These conditions had once been uniformly fatal. Now survival is commonplace, and a large part of the credit goes to the irreplaceable component of medicine known as intensive care.

It's an opaque term. Specialists in the field prefer to call what they do "critical care," but that doesn't exactly clarify matters. The non-medical term "life support" gets us closer. Intensive-care units take artificial control of

failing bodies. Typically, this involves a panoply of technology—a mechanical ventilator and perhaps a tracheostomy tube if the lungs have failed, an aortic balloon pump if the heart has given out, a dialysis machine if the kidneys don't work. When you are unconscious and can't eat, silicone tubing can be surgically inserted into the stomach or intestines for formula feeding. If the intestines are too damaged, solutions of amino acids, fatty acids, and glucose can be infused directly into the bloodstream.

The difficulties of life support are considerable. Reviving a drowning victim, for example, is rarely as easy as it looks on television, where a few chest compressions and some mouth-to-mouth resuscitation always seem to bring someone with waterlogged lungs and a stilled heart coughing and sputtering back to life. Consider a case report in *The Annals of Thoracic Surgery* of a three-year-old girl who fell into an icy fishpond in a small Austrian town in the Alps. She was lost beneath the surface for thirty minutes before her parents found her on the pond bottom and pulled her up. Following instructions from an emergency physician on the phone, they began cardiopulmonary resuscitation. A rescue team arrived eight minutes later. The girl had a body temperature of sixty-six degrees, and no pulse. Her pupils were dilated and did not react to light, indicating that her brain was no longer working.

But the emergency technicians continued CPR anyway. A helicopter took her to a nearby hospital, where she was wheeled directly to an operating room. A surgical team put her on a heart-lung bypass machine. Between the transport time and the time it took to plug the inflow and outflow lines into the femoral vessels of her right leg, she had been lifeless for an hour and a half. By the two-hour mark, however, her body temperature had risen almost ten degrees, and her heart began to beat. It was her first organ to come back.

After six hours, her core temperature reached 98.6 degrees. The team tried to put her on a breathing machine, but the pond water had damaged her lungs too severely for oxygen to reach her blood. So they switched her to an artificial-lung system known as ECMO—extracorporeal membrane oxygenation. The surgeons opened her chest down the middle with a power saw and sewed lines to and from the ECMO unit into her aorta and her beating heart. The team moved the girl into intensive care, with her chest still open and covered with plastic foil. A day later, her lungs had recovered sufficiently for the team to switch her from ECMO to a mechanical ventilator and close her chest. Over the next two days, all her organs recovered except her brain. A CT scan showed global brain swelling, which is a sign of diffuse damage, but no actual dead zones. So the team drilled a hole into the girl's skull, threaded in a probe to monitor her cerebral pressure, and kept that pressure tightly controlled by constantly adjusting her fluids and medications. For more than a week, she lay comatose. Then, slowly, she came back to life.

First, her pupils started to react to light. Next, she began to breathe on her own. And, one day, she simply awoke. Two weeks after her accident, she went home. Her right leg and left arm were partially paralyzed. Her speech was thick and slurry. But by age five, after extensive outpatient therapy, she had recovered her faculties completely. She was like any little girl again.

What makes her recovery astounding isn't just the idea that someone could come back from two hours in a state that would once have been considered death. It's also the idea that a group of people in an ordinary hospital could do something so enormously complex. To save this one child, scores of people had to carry out thousands of steps correctly: placing the heart-pump tubing into her without letting in air bubbles; maintaining the sterility of her lines, her open chest, the burr hole in her skull; keeping a temperamental battery of machines up and running. The degree of difficulty in any one of these steps is substantial. Then you must add the difficulties of orchestrating them in the right sequence, with nothing dropped, leaving some room for improvisation, but not too much.

For every drowned and pulseless child rescued by intensive care, there are many more who don't make it—and not just because their bodies are too far gone. Machines break down; a team can't get moving fast enough; a simple step is forgotten. Such cases don't get written up in *The Annals of Thoracic Surgery*, but they are the norm. Intensive-care medicine has become the art of managing extreme complexity—and a test of whether such complexity can, in fact, be humanly mastered.

On any given day in the United States, some ninety thousand people are in intensive care. Over a year, an estimated five million Americans will be, and over a normal lifetime nearly all of us will come to know the glassed bay of an I.C.U. from the inside. Wide swaths of medicine now depend on the lifesupport systems that I.C.U.s provide: care for premature infants; victims of trauma, strokes, and heart attacks; patients who have had surgery on their brain, heart, lungs, or major blood vessels. Critical care has become an increasingly large portion of what hospitals do. Fifty years ago, I.C.U.s barely existed. Today, in my hospital, a hundred and fifty-five of our almost

seven hundred patients are, as I write this, in intensive care. The average stay of an I.C.U. patient is four days, and the survival rate is eighty-six per cent. Going into an I.C.U., being put on a mechanical ventilator, having tubes and wires run into and out of you, is not a sentence of death. But the days will be the most precarious of your life.

A decade ago, Israeli scientists published a study in which engineers observed patient care in I.C.U.s for twenty-four-hour stretches. They found that the average patient required a hundred and seventy-eight individual actions per day, ranging from administering a drug to suctioning the lungs, and every one of them posed risks. Remarkably, the nurses and doctors were observed to make an error in just one per cent of these actions—but that still amounted to an average of two errors a day with every patient. Intensive care succeeds only when we hold the odds of doing harm low enough for the odds of doing good to prevail. This is hard. There are dangers simply in lying unconscious in bed for a few days. Muscles atrophy. Bones lose mass. Pressure ulcers form. Veins begin to clot off. You have to stretch and exercise patients' flaccid limbs daily to avoid contractures, give subcutaneous injections of blood thinners at least twice a day, turn patients in bed every few hours, bathe them and change their sheets without knocking out a tube or a line, brush their teeth twice a day to avoid pneumonia from bacterial buildup in their mouths. Add a ventilator, dialysis, and open wounds to care for, and the difficulties only accumulate.

The story of one of my patients makes the point. Anthony DeFilippo was a forty-eight-year-old limousine driver from Everett, Massachusetts, who started to hemorrhage at a community hospital during surgery for a hernia and gallstones. The bleeding was finally stopped but his liver was severely damaged, and over the next few days he became too sick for the hospital's facilities. When he arrived in our I.C.U., at 1:30 A.M. on a Sunday, his ragged black hair was plastered to his sweaty forehead, his body was shaking, and his heart was racing at a hundred and fourteen beats a minute. He was delirious from fever, shock, and low oxygen levels.

"I need to get out!" he cried. "I need to get out!" He clawed at his gown, his oxygen mask, the dressings covering his abdominal wound.

"Tony, it's all right," a nurse said to him. "We're going to help you. You're in a hospital."

He shoved her—he was a big man—and tried to swing his legs out of the bed. We turned up his oxygen flow, put his wrists in cloth restraints, and tried to reason with him. He eventually let us draw blood from him and give him antibiotics.

The laboratory results came back showing liver failure, and a wildly elevated white-blood-cell count indicating infection. It soon became evident from his empty urine bag that his kidneys had failed, too. In the next few hours, his blood pressure fell, his breathing worsened, and he drifted from agitation to near-unconsciousness. Each of his organ systems, including his brain, was shutting down.

I called his sister, who was his next of kin, and told her of the situation. "Do everything you can," she said.

So we did. We gave him a syringeful of anesthetic, and a resident slid a breathing tube into his throat. Another resident "lined him up." She inserted a thin, two-inch-long needle and catheter through his upturned right wrist and into his radial artery, and then sewed the line to his skin with a silk suture. Next, she put in a central line—a twelve-inch catheter pushed into the jugular vein in his left neck. After she sewed that in place, and an X-ray showed its tip floating just where it was supposed to—inside his vena cava at the entrance to his heart—she put a third, slightly thicker line, for dialysis, through his right upper chest and into the subclavian vein, deep under the collarbone.

We hooked a breathing tube up to a hose from a ventilator and set it to give him fourteen forced breaths of a hundred-per-cent oxygen every minute. We dialled the ventilator pressures and gas flow up and down, like engineers at a control panel, until we got the blood levels of oxygen and carbon dioxide where we wanted them. The arterial line gave us continuous arterial blood-pressure measurements, and we tweaked his medications to get the pressures we liked. We regulated his intravenous fluids according to venous-pressure measurements from his jugular line. We plugged his subclavian line into tubing from a dialysis machine, and every few minutes his entire blood volume washed through this artificial kidney and back into his body; a little adjustment here and there, and we could alter the levels of potassium and bicarbonate and salt in his body as well. He was, we liked to imagine, a simple machine in our hands.

But he wasn't, of course. It was as if we had gained a steering wheel and a few gauges and controls, but on a runaway eighteen-wheeler hurtling down a mountain. Keeping his blood pressure normal was requiring gallons of intravenous fluid and a pharmacy shelf of drugs. He was on near-maximal ventilator support. His temperature

climbed to a hundred and four degrees. Less than five per cent of patients with his degree of organ failure make it home. And a single misstep could easily erase those slender chances.

For ten days, though, all went well. His chief problem had been liver damage from the operation he'd had. The main duct from his liver was severed and was leaking bile, which is caustic—it digests the fat in one's diet and was essentially eating him alive from the inside. He had become too sick to survive an operation to repair the leak. So we tried a temporary solution—we had radiologists place a plastic drain, using X-ray guidance, through his abdominal wall and into the severed duct in order to draw the leaking bile out of him. They found so much that they had to place three drains—one inside the duct and two around it. But, as the bile drained out, his fevers subsided. His requirements for oxygen and fluids diminished. His blood pressure returned to normal. He was on the mend. Then, on the eleventh day, just as we were getting ready to take him off the mechanical ventilator, he developed high, spiking fevers, his blood pressure sank, and his blood-oxygen levels plummeted again. His skin became clammy. He got shaking chills.

We didn't understand what had happened. He seemed to have developed an infection, but our X-rays and CT scans failed to turn up a source. Even after we put him on four antibiotics, he continued to spike fevers. During one fever, his heart went into fibrillation. A Code Blue was called. A dozen nurses and doctors raced to his bedside, slapped electric paddles onto his chest, and shocked him. His heart responded, fortunately, and went back into rhythm. It took two more days for us to figure out what had gone wrong. We considered the possibility that one of his lines had become infected, so we put in new lines and sent the old ones to the lab for culturing. Forty-eight hours later, the results returned: *all* of them were infected. The infection had probably started in one line, perhaps contaminated during insertion, and spread through his bloodstream to the others. Then they all began spilling bacteria into him, producing his fevers and steep decline.

This is the reality of intensive care: at any point, we are as apt to harm as we are to heal. Line infections are so common that they are considered a routine complication. I.C.U.s put five million lines into patients each year, and national statistics show that, after ten days, four per cent of those lines become infected. Line infections occur in eighty thousand people a year in the United States, and are fatal between five and twenty-eight per cent of the time, depending on how sick one is at the start. Those who survive line infections spend on average a week longer in intensive care. And this is just one of many risks. After ten days with a urinary catheter, four per cent of American I.C.U. patients develop a bladder infection. After ten days on a ventilator, six per cent develop bacterial pneumonia, resulting in death forty to fifty-five per cent of the time. All in all, about half of I.C.U. patients end up experiencing a serious complication, and, once a complication occurs, the chances of survival drop sharply.

It was a week before DeFilippo recovered sufficiently from his infections to come off the ventilator, and it was two months before he left the hospital. Weak and debilitated, he lost his limousine business and his home, and he had to move in with his sister. The tube draining bile still dangled from his abdomen; when he was stronger, I was going to have to do surgery to reconstruct the main bile duct from his liver. But he survived. Most people in his situation do not.

Here, then, is the puzzle of I.C.U. care: you have a desperately sick patient, and in order to have a chance of saving him you have to make sure that a hundred and seventy-eight daily tasks are done right—despite some monitor's alarm going off for God knows what reason, despite the patient in the next bed crashing, despite a nurse poking his head around the curtain to ask whether someone could help "get this lady's chest open." So how do you actually manage all this complexity? The solution that the medical profession has favored is specialization.

I tell DeFilippo's story, for instance, as if I were the one tending to him hour by hour. But that was actually Max Weinmann, an intensivist (as intensive-care specialists like to be called). I want to think that, as a general surgeon, I can handle most clinical situations. But, as the intricacies involved in intensive care have mounted, responsibility has increasingly shifted to super-specialists like him. In the past decade, training programs focussed on critical care have opened in every major American city, and half of I.C.U.s now rely on super-specialists.

Expertise is the mantra of modern medicine. In the early twentieth century, you needed only a high-school diploma and a one-year medical degree to practice medicine. By the century's end, all doctors had to have a college degree, a four-year medical degree, and an additional three to seven years of residency training in an individual field of practice—pediatrics, surgery, neurology, or the like. Already, though, this level of preparation has seemed inadequate to the new complexity of medicine. After their residencies, most young doctors today are going on to do

fellowships, adding one to three further years of training in, say, laparoscopic surgery, or pediatric metabolic disorders, or breast radiology—or critical care. A young doctor is not so young nowadays; you typically don't start in independent practice until your mid-thirties.

We now live in the era of the super-specialist—of clinicians who have taken the time to practice at one narrow thing until they can do it better than anyone who hasn't. Super-specialists have two advantages over ordinary specialists: greater knowledge of the details that matter and an ability to handle the complexities of the job. There are degrees of complexity, though, and intensive-care medicine has grown so far beyond ordinary complexity that avoiding daily mistakes is proving impossible even for our super-specialists. The I.C.U., with its spectacular successes and frequent failures, therefore poses a distinctive challenge: what do you do when expertise is not enough?

On October 30, 1935, at Wright Air Field in Dayton, Ohio, the U.S. Army Air Corps held a flight competition for airplane manufacturers vying to build its next-generation long-range bomber. It wasn't supposed to be much of a competition. In early evaluations, the Boeing Corporation's gleaming aluminum-alloy Model 299 had trounced the designs of Martin and Douglas. Boeing's plane could carry five times as many bombs as the Army had requested; it could fly faster than previous bombers, and almost twice as far. A Seattle newspaperman who had glimpsed the plane called it the "flying fortress," and the name stuck. The flight "competition," according to the military historian Phillip Meilinger, was regarded as a mere formality. The Army planned to order at least sixty-five of the aircraft.

A small crowd of Army brass and manufacturing executives watched as the Model 299 test plane taxied onto the runway. It was sleek and impressive, with a hundred-and-three-foot wingspan and four engines jutting out from the wings, rather than the usual two. The plane roared down the tarmac, lifted off smoothly, and climbed sharply to three hundred feet. Then it stalled, turned on one wing, and crashed in a fiery explosion. Two of the five crew members died, including the pilot, Major Ployer P. Hill.

An investigation revealed that nothing mechanical had gone wrong. The crash had been due to "pilot error," the report said. Substantially more complex than previous aircraft, the new plane required the pilot to attend to the four engines, a retractable landing gear, new wing flaps, electric trim tabs that needed adjustment to maintain control at different airspeeds, and constant-speed propellers whose pitch had to be regulated with hydraulic controls, among other features. While doing all this, Hill had forgotten to release a new locking mechanism on the elevator and rudder controls. The Boeing model was deemed, as a newspaper put it, "too much airplane for one man to fly." The Army Air Corps declared Douglas's smaller design the winner. Boeing nearly went bankrupt.

Still, the Army purchased a few aircraft from Boeing as test planes, and some insiders remained convinced that the aircraft was flyable. So a group of test pilots got together and considered what to do.

They could have required Model 299 pilots to undergo more training. But it was hard to imagine having more experience and expertise than Major Hill, who had been the U.S. Army Air Corps' chief of flight testing. Instead, they came up with an ingeniously simple approach: they created a pilot's checklist, with step-by-step checks for takeoff, flight, landing, and taxiing. Its mere existence indicated how far aeronautics had advanced. In the early years of flight, getting an aircraft into the air might have been nerve-racking, but it was hardly complex. Using a checklist for takeoff would no more have occurred to a pilot than to a driver backing a car out of the garage. But this new plane was too complicated to be left to the memory of any pilot, however expert.

With the checklist in hand, the pilots went on to fly the Model 299 a total of 1.8 million miles without one accident. The Army ultimately ordered almost thirteen thousand of the aircraft, which it dubbed the B-17. And, because flying the behemoth was now possible, the Army gained a decisive air advantage in the Second World War which enabled its devastating bombing campaign across Nazi Germany.

Medicine today has entered its B-17 phase. Substantial parts of what hospitals do—most notably, intensive care—are now too complex for clinicians to carry them out reliably from memory alone. I.C.U. life support has become too much medicine for one person to fly.

Yet it's far from obvious that something as simple as a checklist could be of much help in medical care. Sick people are phenomenally more various than airplanes. A study of forty-one thousand trauma patients—just trauma patients—found that they had 1,224 different injury-related diagnoses in 32,261 unique combinations for teams to attend to. That's like having 32,261 kinds of airplane to land. Mapping out the proper steps for each is not possible,

and physicians have been skeptical that a piece of paper with a bunch of little boxes would improve matters much.

In 2001, though, a critical-care specialist at Johns Hopkins Hospital named Peter Pronovost decided to give it a try. He didn't attempt to make the checklist cover everything; he designed it to tackle just one problem, the one that nearly killed Anthony DeFilippo: line infections. On a sheet of plain paper, he plotted out the steps to take in order to avoid infections when putting a line in. Doctors are supposed to (1) wash their hands with soap, (2) clean the patient's skin with chlorhexidine antiseptic, (3) put sterile drapes over the entire patient, (4) wear a sterile mask, hat, gown, and gloves, and (5) put a sterile dressing over the catheter site once the line is in. Check, check, check, check, check. These steps are no-brainers; they have been known and taught for years. So it seemed silly to make a checklist just for them. Still, Pronovost asked the nurses in his I.C.U. to observe the doctors for a month as they put lines into patients, and record how often they completed each step. In more than a third of patients, they skipped at least one.

The next month, he and his team persuaded the hospital administration to authorize nurses to stop doctors if they saw them skipping a step on the checklist; nurses were also to ask them each day whether any lines ought to be removed, so as not to leave them in longer than necessary. This was revolutionary. Nurses have always had their ways of nudging a doctor into doing the right thing, ranging from the gentle reminder ("Um, did you forget to put on your mask, doctor?") to more forceful methods (I've had a nurse bodycheck me when she thought I hadn't put enough drapes on a patient). But many nurses aren't sure whether this is their place, or whether a given step is worth a confrontation. (Does it really matter whether a patient's legs are draped for a line going into the chest?) The new rule made it clear: if doctors didn't follow every step on the checklist, the nurses would have backup from the administration to intervene.

Pronovost and his colleagues monitored what happened for a year afterward. The results were so dramatic that they weren't sure whether to believe them: the ten-day line-infection rate went from eleven per cent to zero. So they followed patients for fifteen more months. Only two line infections occurred during the entire period. They calculated that, in this one hospital, the checklist had prevented forty-three infections and eight deaths, and saved two million dollars in costs.

Pronovost recruited some more colleagues, and they made some more checklists. One aimed to insure that nurses observe patients for pain at least once every four hours and provide timely pain medication. This reduced the likelihood of a patient's experiencing untreated pain from forty-one per cent to three per cent. They tested a checklist for patients on mechanical ventilation, making sure that, for instance, the head of each patient's bed was propped up at least thirty degrees so that oral secretions couldn't go into the windpipe, and antacid medication was given to prevent stomach ulcers. The proportion of patients who didn't receive the recommended care dropped from seventy per cent to four per cent; the occurrence of pneumonias fell by a quarter; and twenty-one fewer patients died than in the previous year. The researchers found that simply having the doctors and nurses in the I.C.U. make their own checklists for what they thought should be done each day improved the consistency of care to the point that, within a few weeks, the average length of patient stay in intensive care dropped by half.

The checklists provided two main benefits, Pronovost observed. First, they helped with memory recall, especially with mundane matters that are easily overlooked in patients undergoing more drastic events. (When you're worrying about what treatment to give a woman who won't stop seizing, it's hard to remember to make sure that the head of her bed is in the right position.) A second effect was to make explicit the minimum, expected steps in complex processes. Pronovost was surprised to discover how often even experienced personnel failed to grasp the importance of certain precautions. In a survey of I.C.U. staff taken before introducing the ventilator checklists, he found that half hadn't realized that there was evidence strongly supporting giving ventilated patients antacid medication. Checklists established a higher standard of baseline performance.

These are, of course, ridiculously primitive insights. Pronovost is routinely described by colleagues as "brilliant," "inspiring," a "genius." He has an M.D. and a Ph.D. in public health from Johns Hopkins, and is trained in emergency medicine, anesthesiology, and critical-care medicine. But, really, does it take all that to figure out what house movers, wedding planners, and tax accountants figured out ages ago?

Pronovost is hardly the first person in medicine to use a checklist. But he is among the first to recognize its power to save lives and take advantage of the breadth of its possibilities. Forty-two years old, with cropped light-brown hair, tenth-grader looks, and a fluttering, finchlike energy, he is an odd mixture of the nerdy and the messianic. He

grew up in Waterbury, Connecticut, the son of an elementary-school teacher and a math professor, went to nearby Fairfield University, and, like many good students, decided that he would go into medicine. Unlike many students, though, he found that he actually liked caring for sick people. He hated the laboratory—with all those micropipettes and cell cultures, and no patients around—but he had that scientific "How can I solve this unsolved problem?" turn of mind. So after his residency in anesthesiology and his fellowship in critical care, he studied clinical-research methods.

For his doctoral thesis, he examined intensive-care units in Maryland, and he discovered that putting an intensivist on staff reduced death rates by a third. It was the first time that someone had demonstrated the public-health value of using intensivists. He wasn't satisfied with having proved his case, though; he wanted hospitals to change accordingly. After his study was published, in 1999, he met with a coalition of large employers known as the Leapfrog Group. It included companies like General Motors and Verizon, which were seeking to improve the standards of hospitals where their employees obtain care. Within weeks, the coalition announced that its members expected the hospitals they contracted with to staff their I.C.U.s with intensivists. These employers pay for health care for thirty-seven million employees, retirees, and dependents nationwide. So although hospitals protested that there weren't enough intensivists to go around, and that the cost could be prohibitive, Pronovost's idea effectively became an instant national standard.

The scientist in him has always made room for the campaigner. People say he is the kind of guy who, even as a trainee, could make you feel you'd saved the world every time you washed your hands properly. "I've never seen anybody inspire as he does," Marty Makary, a Johns Hopkins surgeon, told me. "Partly, he has this contagious, excitable nature. He has a smile that's tough to match. But he also has a way of making people feel heard. People will come to him with the dumbest ideas, and he'll endorse them anyway. 'Oh, I like that, I like that, I like that!' he'll say. I've watched him, and I still have no idea how deliberate this is. Maybe he really does like every idea. But wait, and you realize: he only acts on the ones he truly believes in."

After the checklist results, the idea Pronovost truly believed in was that checklists could save enormous numbers of lives. He took his findings on the road, showing his checklists to doctors, nurses, insurers, employers—anyone who would listen. He spoke in an average of seven cities a month while continuing to work full time in Johns Hopkins's I.C.U.s. But this time he found few takers.

There were various reasons. Some physicians were offended by the suggestion that they needed checklists. Others had legitimate doubts about Pronovost's evidence. So far, he'd shown only that checklists worked in one hospital, Johns Hopkins, where the I.C.U.s have money, plenty of staff, and Peter Pronovost walking the hallways to make sure that the checklists are being used properly. How about in the real world—where I.C.U. nurses and doctors are in short supply, pressed for time, overwhelmed with patients, and hardly receptive to the idea of filling out yet another piece of paper?

In 2003, however, the Michigan Health and Hospital Association asked Pronovost to try out three of his checklists in Michigan's I.C.U.s. It would be a huge undertaking. Not only would he have to get the state's hospitals to use the checklists; he would also have to measure whether doing so made a genuine difference. But at last Pronovost had a chance to establish whether his checklist idea really worked.

This past summer, I visited Sinai-Grace Hospital, in inner-city Detroit, and saw what Pronovost was up against. Occupying a campus of red brick buildings amid abandoned houses, check-cashing stores, and wig shops on the city's West Side, just south of 8 Mile Road, Sinai-Grace is a classic urban hospital. It has eight hundred physicians, seven hundred nurses, and two thousand other medical personnel to care for a population with the lowest median income of any city in the country. More than a quarter of a million residents are uninsured; three hundred thousand are on state assistance. That has meant chronic financial problems. Sinai-Grace is not the most cash-strapped hospital in the city—that would be Detroit Receiving Hospital, where a fifth of the patients have no means of payment. But between 2000 and 2003 Sinai-Grace and eight other Detroit hospitals were forced to cut a third of their staff, and the state had to come forward with a fifty-million-dollar bailout to avert their bankruptcy.

Sinai-Grace has five I.C.U.s for adult patients and one for infants. Hassan Makki, the director of intensive care, told me what it was like there in 2004, when Pronovost and the hospital association started a series of mailings and conference calls with hospitals to introduce checklists for central lines and ventilator patients. "Morale was low," he said. "We had lost lots of staff, and the nurses who remained weren't sure if they were staying." Many doctors were

thinking about leaving, too. Meanwhile, the teams faced an even heavier workload because of new rules limiting how long the residents could work at a stretch. Now Pronovost was telling them to find the time to fill out some daily checklists?

Tom Piskorowski, one of the I.C.U. physicians, told me his reaction: "Forget the paperwork. Take care of the patient."

I accompanied a team on 7 A.M. rounds through one of the surgical I.C.U.s. It had eleven patients. Four had gunshot wounds (one had been shot in the chest; one had been shot through the bowel, kidney, and liver; two had been shot through the neck, and left quadriplegic). Five patients had cerebral hemorrhaging (three were seventy-nine years and older and had been injured falling down stairs; one was a middle-aged man whose skull and left temporal lobe had been damaged by an assault with a blunt weapon; and one was a worker who had become paralyzed from the neck down after falling twenty-five feet off a ladder onto his head). There was a cancer patient recovering from surgery to remove part of his lung, and a patient who had had surgery to repair a cerebral aneurysm.

The doctors and nurses on rounds tried to proceed methodically from one room to the next but were constantly interrupted: a patient they thought they'd stabilized began hemorrhaging again; another who had been taken off the ventilator developed trouble breathing and had to be put back on the machine. It was hard to imagine that they could get their heads far enough above the daily tide of disasters to worry about the minutiae on some checklist.

Yet there they were, I discovered, filling out those pages. Mostly, it was the nurses who kept things in order. Each morning, a senior nurse walked through the unit, clipboard in hand, making sure that every patient on a ventilator had the bed propped at the right angle, and had been given the right medicines and the right tests. Whenever doctors put in a central line, a nurse made sure that the central-line checklist had been filled out and placed in the patient's chart. Looking back through their files, I found that they had been doing this faithfully for more than three years.

Pronovost had been canny when he started. In his first conversations with hospital administrators, he didn't order them to use the checklists. Instead, he asked them simply to gather data on their own infection rates. In early 2004, they found, the infection rates for I.C.U. patients in Michigan hospitals were higher than the national average, and in some hospitals dramatically so. Sinai-Grace experienced more line infections than seventy-five per cent of American hospitals. Meanwhile, Blue Cross Blue Shield of Michigan agreed to give hospitals small bonus payments for participating in Pronovost's program. A checklist suddenly seemed an easy and logical thing to try.

In what became known as the Keystone Initiative, each hospital assigned a project manager to roll out the checklists and participate in a twice-monthly conference call with Pronovost for trouble-shooting. Pronovost also insisted that each participating hospital assign to each unit a senior hospital executive, who would visit the unit at least once a month, hear people's complaints, and help them solve problems.

The executives were reluctant. They normally lived in meetings worrying about strategy and budgets. They weren't used to venturing into patient territory and didn't feel that they belonged there. In some places, they encountered hostility. But their involvement proved crucial. In the first month, according to Christine Goeschel, at the time the Keystone Initiative's director, the executives discovered that the chlorhexidine soap, shown to reduce line infections, was available in fewer than a third of the I.C.U.s. This was a problem only an executive could solve. Within weeks, every I.C.U. in Michigan had a supply of the soap. Teams also complained to the hospital officials that the checklist required that patients be fully covered with a sterile drape when lines were being put in, but full-size barrier drapes were often unavailable. So the officials made sure that the drapes were stocked. Then they persuaded Arrow International, one of the largest manufacturers of central lines, to produce a new central-line kit that had both the drape and chlorhexidine in it.

In December, 2006, the Keystone Initiative published its findings in a landmark article in *The New England Journal of Medicine*. Within the first three months of the project, the infection rate in Michigan's I.C.U.s decreased by sixty-six per cent. The typical I.C.U.—including the ones at Sinai-Grace Hospital—cut its quarterly infection rate to zero. Michigan's infection rates fell so low that its average I.C.U. outperformed ninety per cent of I.C.U.s nationwide. In the Keystone Initiative's first eighteen months, the hospitals saved an estimated hundred and seventy-five million dollars in costs and more than fifteen hundred lives. The successes have been sustained for almost four years—all because of a stupid little checklist.

Pronovost's results have not been ignored. He has since had requests to help Rhode Island, New Jersey, and the

country of Spain do what Michigan did. Back in the Wolverine State, he and the Keystone Initiative have begun testing half a dozen additional checklists to improve care for I.C.U. patients. He has also been asked to develop a program for surgery patients. It has all become more than he and his small group of researchers can keep up with.

But consider: there are hundreds, perhaps thousands, of things doctors do that are at least as dangerous and prone to human failure as putting central lines into I.C.U. patients. It's true of cardiac care, stroke treatment, H.I.V. treatment, and surgery of all kinds. It's also true of diagnosis, whether one is trying to identify cancer or infection or a heart attack. All have steps that are worth putting on a checklist and testing in routine care. The question—still unanswered—is whether medical culture will embrace the opportunity.

Tom Wolfe's "The Right Stuff" tells the story of our first astronauts, and charts the demise of the maverick, Chuck Yeager test-pilot culture of the nineteen-fifties. It was a culture defined by how unbelievably dangerous the job was. Test pilots strapped themselves into machines of barely controlled power and complexity, and a quarter of them were killed on the job. The pilots had to have focus, daring, wits, and an ability to improvise—the right stuff. But as knowledge of how to control the risks of flying accumulated—as checklists and flight simulators became more prevalent and sophisticated—the danger diminished, values of safety and conscientiousness prevailed, and the rock-star status of the test pilots was gone.

Something like this is going on in medicine. We have the means to make some of the most complex and dangerous work we do—in surgery, emergency care, and I.C.U. medicine—more effective than we ever thought possible. But the prospect pushes against the traditional culture of medicine, with its central belief that in situations of high risk and complexity what you want is a kind of expert audacity—the right stuff, again. Checklists and standard operating procedures feel like exactly the opposite, and that's what rankles many people.

It's ludicrous, though, to suppose that checklists are going to do away with the need for courage, wits, and improvisation. The body is too intricate and individual for that: good medicine will not be able to dispense with expert audacity. Yet it should also be ready to accept the virtues of regimentation.

The still limited response to Pronovost's work may be easy to explain, but it is hard to justify. If someone found a new drug that could wipe out infections with anything remotely like the effectiveness of Pronovost's lists, there would be television ads with Robert Jarvik extolling its virtues, detail men offering free lunches to get doctors to make it part of their practice, government programs to research it, and competitors jumping in to make a newer, better version. That's what happened when manufacturers marketed central-line catheters coated with silver or other antimicrobials; they cost a third more, and reduced infections only slightly—and hospitals have spent tens of millions of dollars on them. But, with the checklist, what we have is Peter Pronovost trying to see if maybe, in the next year or two, hospitals in Rhode Island and New Jersey will give his idea a try.

Pronovost remains, in a way, an odd bird in medical research. He does not have the multimillion-dollar grants that his colleagues in bench science have. He has no swarm of doctoral students and lab animals. He's focussed on work that is not normally considered a significant contribution in academic medicine. As a result, few other researchers are venturing to extend his achievements. Yet his work has already saved more lives than that of any laboratory scientist in the past decade.

I called Pronovost recently at Johns Hopkins, where he was on duty in an I.C.U. I asked him how long it would be before the average doctor or nurse is as apt to have a checklist in hand as a stethoscope (which, unlike checklists, has never been proved to make a difference to patient care).

"At the current rate, it will never happen," he said, as monitors beeped in the background. "The fundamental problem with the quality of American medicine is that we've failed to view delivery of health care as a science. The tasks of medical science fall into three buckets. One is understanding disease biology. One is finding effective therapies. And one is insuring those therapies are delivered effectively. That third bucket has been almost totally ignored by research funders, government, and academia. It's viewed as the art of medicine. That's a mistake, a huge mistake. And from a taxpayer's perspective it's outrageous." We have a thirty-billion-dollar-a-year National Institutes of Health, he pointed out, which has been a remarkable powerhouse of discovery. But we have no billion-dollar National Institute of Health Care Delivery studying how best to incorporate those discoveries into daily practice.

I asked him how much it would cost for him to do for the whole country what he did for Michigan. About two million dollars, he said, maybe three, mostly for the technical work of signing up hospitals to participate state by

state and coördinating a database to track the results. He's already devised a plan to do it in all of Spain for less.

"We could get I.C.U. checklists in use throughout the United States within two years, if the country wanted it," he said.

So far, it seems, we don't. The United States could have been the first to adopt medical checklists nationwide, but, instead, Spain will beat us. "I at least hope we're not the last," Pronovost said.

Recently, I spoke to Markus Thalmann, the cardiac surgeon on the team that saved the little Austrian girl who had drowned, and learned that a checklist had been crucial to her survival. Thalmann had worked for six years at the city hospital in Klagenfurt, the small provincial capital in south Austria where the girl was resuscitated. She was not the first person whom he and his colleagues had tried to revive from cardiac arrest after hypothermia and suffocation. They received between three and five such patients a year, he estimated, mostly avalanche victims (Klagenfurt is surrounded by the Alps), some of them drowning victims, and a few of them people attempting suicide by taking a drug overdose and then wandering out into the snowy forests to fall unconscious.

For a long time, he said, no matter how hard the medical team tried, it had no survivors. Most of the victims had gone without a pulse and oxygen for too long by the time they were found. But some, he felt, still had a flicker of viability in them, and each time the team failed to sustain it.

Speed was the chief difficulty. Success required having an array of equipment and people at the ready—helicopter-rescue personnel, trauma surgeons, an experienced cardiac anesthesiologist and surgeon, bioengineering support staff, operating and critical-care nurses, intensivists. Too often, someone or something was missing. So he and a couple of colleagues made and distributed a checklist. In cases like these, the checklist said, rescue teams were to tell the hospital to prepare for possible cardiac bypass and rewarming. They were to call, when possible, even before they arrived on the scene, as the preparation time could be significant. The hospital would then work down a list of people to be notified. They would have an operating room set up and standing by.

The team had its first success with the checklist in place—the rescue of the three-year-old girl. Not long afterward, Thalmann left to take a job at a hospital in Vienna. The team, however, was able to make at least two other such rescues, he said. In one case, a man was found frozen and pulseless after a suicide attempt. In another, a mother and her sixteen-year-old daughter were in an accident that sent them and their car through a guardrail, over a cliff, and into a mountain river. The mother died on impact; the daughter was trapped as the car rapidly filled with icy water. She had been in cardiac and respiratory arrest for a prolonged period of time when the rescue team arrived.

From that point onward, though, the system went like clockwork. By the time the rescue team got to her and began CPR, the hospital had been notified. The transport team got her there in minutes. The surgical team took her straight to the operating room and crashed her onto heart-lung bypass. One step went right after another. And, because of the speed with which they did, she had a chance.

As the girl's body slowly rewarmed, her heart came back. In the I.C.U., a mechanical ventilator, fluids, and intravenous drugs kept her going while the rest of her body recovered. The next day, the doctors were able to remove her lines and tubes. The day after that, she was sitting up in bed, ready to go home. ♦

ILLUSTRATION: YAN NASCIMBENE

Chairman WAXMAN. Without objection, we will make it part of the record.

Mr. HODES. Thank you, Mr. Chairman.

The interviewer asked Mr. Pronovost how much it would cost him to do for the whole country what he did for Michigan. About $2 million, he said, maybe $3 million, mostly for the technical work of signing up hospitals to participate State By State and coordinating a data base to track the results. He has already devised a plan to do it in all of Spain for less. "We could get ICU checklists in use throughout the United States within 2 years, if the country wanted it," he said. Well, I think the country wants it. I think the country needs it.

So, Dr. Pronovost, how are we able to fund the replication of what you did in Michigan if it cuts its budget by the $2 million that you say we need to spend to move this nationwide?

Dr. PRONOVOST. Congressman, I completely agree with the sentiment that I don't understand the logic of saying these are national problems while we need to make wise investments, because the return on them in lives saved and in dollars to the health care system are real. For example, yesterday I was in Pennsylvania. Tonight I am flying to California to try to get them to sign up for that, for this program. But what that screams to me is, where is the leadership? Because I am happy to do it, but it certainly should be a much more integrated program with AHRQ, with CDC, perhaps with NIH of saying, what don't we know that we need to also learn for CMS with payment policy, with consumer groups and this public-private partnership to work together to do this.

Infections needs the equivalent of what we did in Polio. Polio used to kill 350,000 people a year in the 1980's. We collaborated and worked together, and now it is less than a thousand—none in the United States—and in one small part of Africa. And we need that collaborative effort.

Mr. HODES. It strikes me that dealing with infections with the simple use of a checklist is really pretty low-hanging fruit in terms of expenditures of health care dollars in terms of the savings of lives and money. Is that correct?

Dr. PRONOVOST. Absolutely.

Mr. HODES. Let me ask the panel. Would any of you fly in an airplane today if you knew that the pilot was not completing a preflight checklist? Would any of you fly? The answer is, no, of course not. So why should anybody go into a hospital in the United States, given what we now know about what checklists do, and go into an ICU or other area of the hospital where infections are possible and be subject to care without having a checklist there? I can't understand why we are not making that investment.

And Dr. Wright, I just ask you this. You have heard Ms. Bascetta's testimony. Have you not?

Dr. WRIGHT. Yes.

Mr. HODES. Did you read the GAO report?

Dr. WRIGHT. I did.

Mr. HODES. Are you willing to go back to HHS and produce the synergy, which frankly seems pretty simple given all the good work you are doing, the synergy among the different silos in HHS to create the momentum that we need to follow the GAO recommenda-

tions and get on this in a very coordinated way? Because you are doing lots of work, but it sounds like there are some simple things the GAO has pointed out your agency needs to do to get it better. Are you willing to do it?

Dr. WRIGHT. As I said in my initial testimony, we think that there are great opportunities for enhanced collaboration and cooperation at HHS and will make efforts to carry that out, and in the area of healthcare-associated infections and in other areas as well.

Mr. HODES. I appreciate the opportunities, and I don't want to belabor the point. My question is, will you follow the recommendations that the GAO has set out as a path for you to collaborate in the area of reducing infections?

Dr. WRIGHT. This is a top priority for HHS, to lower healthcare-associated infections. And certainly we need to collaborate. We must collaborate. We must do better working across the very important operating divisions, from NIH to CDC to AHRQ, etc.

Mr. HODES. Thank you for that answer. I understand it is a priority. My question was, will you follow the GAO recommendations, yes or no?

Dr. WRIGHT. We will make every effort to move forward with the recommendations as made by the GAO.

Mr. HODES. I will take that as a yes. Thank you.

Chairman WAXMAN. Thank you, Mr. Hodes.

Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chairman. I am going to read from something, and then, Mr. Chairman, I have two articles I would like to submit for the record.

[The information referred to follows:]

FACT SHEET

Patient Safety & Quality

Minnesota Hospital Association

Every hospital's top priority is the quality and safety of the care it provides. Minnesota hospitals are consistently recognized as national leaders on this critical front.

For example, in 2006 the Agency for Health Care Research and Quality ranked Minnesota the second in the nation in overall health-care quality performance. Additionally, ten Minnesota hospitals were recognized by *HealthGrades* to an elite list of 2007 Distinguished Hospitals for Patient Safety. Hospitals scoring in the top 15 percent on national patient-safety indicators earned this designation. The Centers for Medicare and Medicaid Services also recognizes Minnesota as a high-quality, low-cost state.

Today several initiatives continue to build on Minnesota's advancements in keeping patients safe.

Federal actions requested:

Congress should ensure that any final PSO rules utilize current reporting systems and allow hospital associations and related organizations to serve as PSOs.

PSO = Patient Safety Org.

Congress should ensure that any new patient safety standards or reporting requirements incorporate existing national standards, such as the National Quality Forum's requirements.

Minnesota's Adverse Health Events Reporting System

Minnesota's groundbreaking adverse-health event (AHE) reporting law continues to improve safety: Last year, 29 fewer AHEs were reported than the year before that. In total, the AHEs decreased from 154 events to 125 events.

Minnesota's system is successful largely because it focuses on sharing information across facilities through Minnesota Hospital Association's (MHA's) Web-based patient safety registry. Under the initiative, hospitals not only report events, but they also openly exchange key lessons learned through root-cause analysis and corrective action plans.

The reporting system has helped pinpoint the most prevalent types of AHEs statewide: pressure ulcers, retained foreign objects, falls and wrong-site surgeries. In response, MHA has developed tailored call-to-action prevention initiatives.

For example, under the SAFE SITE call-to-action, surgeons must mark the surgical site with their initials. As part of a safety effort, this step has been shown to prevent wrong-site procedures.

Last year, building upon Minnesota's history of leadership in this area, Minnesota hospitals became the first in the country to formally announce what had been their practice for years — not billing patients for care made necessary by adverse health events.

Numerous states are looking to Minnesota's AHE reporting system, billing policy and call-to-action initiatives as they seek to improve patient safety and quality.

Preventing and Reporting Hospital-Acquired Infections

Also in 2007, Minnesota hospitals continued their tradition of proactively addressing patient safety issues. For instance, members of the hospital community collaborated with numerous organizations to design a campaign to combat methicillin-resistant *Staphylococcus aureus*, or MRSA. A new state law requires hospitals to implement recommendations from this group by January 2009.

In a similar effort, Minnesota hospitals will begin reporting in 2009 information about hospital-acquired infections based on National Quality Forum care standards. This information will be available to consumers through the Minnesota Hospital Quality Report Web site.

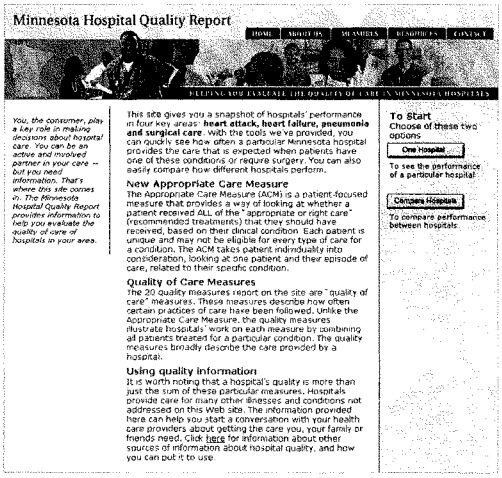
The Minnesota Hospital Quality Partnership

MHA and Stratis Health, Minnesota's Quality Improvement Organization, created the Minnesota Hospital Quality Partnership in 2005. The partnership publishes a Web site (www.mnhospitalquality.org) that lists hospital-specific performance information on four common categories of care: heart attack, heart failure, pneumonia, and surgery. The report tells consumers how frequently hospitals used best practices, such as whether a heart attack patient was given aspirin upon arrival at the hospital or if a blood test was taken for a patient with pneumonia. In 2006, the partnership added a new overall care measurement, unavailable anywhere else. The "appropriate care measure" indicates the percentage of patients who received optimal care for their condition.

Patient Safety Organizations

The 2005 Patient Safety and Quality Improvement law provides for voluntary data reporting to Patient Safety Organizations, or PSOs. The federally certified organizations will collect and analyze patient safety data. Proposed rules implementing standards for PSOs were published in February.

www.mnhospitalquality.org



Minnesota Hospital Quality Report

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HELPING YOU EVALUATE THE QUALITY OF CARE IN MINNESOTA HOSPITALS

You, the consumer, play a key role in making decisions about hospital care. You can be an active and involved partner in your care -- but you need information. That's where this site comes in. The Minnesota Hospital Quality Report provides information to help you evaluate the quality of care of hospitals in your area.

This site gives you a snapshot of hospitals' performance in four key areas: **heart attack, heart failure, pneumonia and surgical care**. With the tools we've provided, you can quickly see how often a particular Minnesota hospital provides the care that is expected when patients have one of these conditions or require surgery. You can also easily compare how different hospitals perform.

New Appropriate Care Measure

The Appropriate Care Measure (ACM) is a patient-focused measure that provides a way of looking at whether a patient received ALL of the "appropriate or right care" (recommended treatments) that they should have received, based on their clinical condition. Each patient is unique and may not be eligible for every type of care for a condition. The ACM takes patient individuality into consideration, looking at one patient and their episode of care, related to their specific condition.

Quality of Care Measures

The 20 quality measures report on the site are "quality of care" measures. These measures describe how often certain practices of care have been followed. Unlike the Appropriate Care Measure, the quality measures illustrate hospitals' work on each measure by combining all patients treated for a particular condition. The quality measures broadly describe the care provided by a hospital.

Using quality information

It is worth noting that a hospital's quality is more than just the sum of these particular measures. Hospitals provide care for many other illnesses and conditions not addressed on this Web site. The information provided here can help you start a conversation with your health care providers about getting the care you, your family or friends need. Click here for information about other sources of information about hospital quality, and how you can put it to use.

To Start
Choose of these two options

One Hospital

To see the performance of a particular hospital

Compare Hospitals

To compare performance between hospitals

Minnesota Hospital Transparency Initiatives

QUALITY

Quality information is just a click away on the Minnesota Hospital Quality Report Web site. Information on the site shows each Minnesota hospital's performance in the following areas:

- Clinical quality measures for heart attack, heart failure and pneumonia;
- Best practice measures for preventing surgical infections; and
- "appropriate care measures," which show what percentage of patients got all the appropriate care they should have had.

www.mnhospitalquality.org

Coming this spring, the site will add patients' experience of care information. Using data from a national survey, the site will give consumers hospital-by-hospital information on patients' experience with communication, pain management, cleanliness and their overall satisfaction. Currently, Minnesota hospitals' results exceed the national average.

By next January, the site will add hospital infection reporting. Minnesota will follow the standards soon-to-be announced by the National Quality Forum as the basis of infection reporting for hospitals.

The Minnesota Hospital Quality Report (www.mnhospitalquality.org) is a partnership between the Minnesota Hospital Association and Stratis Health, Minnesota's quality improvement organization.

PATIENT SAFETY

In 2003, Minnesota passed groundbreaking legislation, the Adverse Health Events Reporting law. Minnesota hospitals report adverse health events — 28 types of events defined by the National Quality Forum. The Minnesota Department of Health publishes an annual report of these events, which includes the number and type of events at each hospital in the state. To see the report, visit www.health.state.mn.us/patientsafety.

Patient Safety | Call to Action

The main purpose of the law is to learn from the events and prevent them from occurring in the future. Minnesota hospitals have learned invaluable lessons because of the reporting of events and their root causes. Since the law's inception, many other states have followed Minnesota's lead by adopting some form of adverse health-event reporting.

PRICE

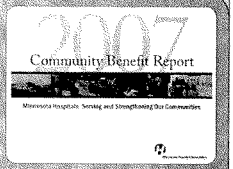
In 2006, MHA launched Minnesota Hospital Price Check (www.mnhospitalpricecheck.org). The site includes the price of the 50 most common inpatient hospitalizations and the 25 most common same-day procedures at Minnesota hospitals.

www.mnhospitalpricecheck.org

Currently, Minnesota providers and health plans are required to provide individuals with a good-faith estimate of charges. Momentum exists, however, to take price transparency to the next level. Proposed change to the payment system includes more transparency and new pricing structures.

COMMUNITY BENEFIT

For the past two years, Minnesota hospitals have voluntarily reported community benefit activities to MHA. In November 2007, the second annual report was released. It represented the vast majority of hospitals and included impressive numbers: $1.4 billion of community benefits in 2006, based on CHA/VHA standards. When other factors like Medicare underfunding and bad debt were accounted for, the total rose to $2.7 billion. To see the full report on Minnesota hospitals' community benefits, visit www.mnhospitals.org.



Minnesota legislation, passed in 2007 and taking effect in 2008, established mandatory community benefit reporting. On the federal level, a new effort to collect community benefit information resulted in the creation of Schedule H, part of the IRS Form 990. Starting in 2010, non-profit hospitals across the country will report community benefit activities for fiscal year 2009.

Ms. MCCOLLUM. Patient Safety: In 2003, Minnesota passed groundbreaking legislation, the Adverse Health Events Reporting Law. Minnesota hospitals report adverse health events, 28 types of events defined by the National Quality Forum. The Minnesota Department of Health publishes an annual report of these events which includes the number and types of events of each hospital in the State. And you can go on a Web site to see the report. And our hospitals are complying with this. Minnesota in fact has been consistently recognized for overall health quality performance. In 2006, it was ranked No. 2 by the Agency for Health Care Research and Quality for Overall Health Care, Quality Performance, and was recognized by the Center for Medicaid and Medicare as a high-quality, low-cost State. Also, 10 hospitals were recognized by Health Grades to an elite list of 2007 distinguished hospitals for patient safety, a designation which goes to hospitals scoring in the top 15 percent of national patient safety indicators.

Minnesota hospitals credit their success to their ability to share information across facilities through the Minnesota Hospital Association's Web-based information Patient Registry. Under this initiative, hospitals not only report events, but they also openly—openly—exchange lessons learned.

GAO has reported the need for improvement and coordination for sharing. The three agencies, CDC, CMS, and the Agency for Health Care Quality Research, need to be sharing.

Are there any plans underway at HHS to improve the sharing about best practices? That is one question I have.

And, how will this information get to hospitals and providers?

So, for three of you, I have three specific questions.

Ms. Bascetta, what level of cooperation did GAO really find using these different data bases? And, is there any meaningful effort at the Department level to coordinate the data collection among different agencies?

Dr. Pronovost, is there research physicians working on quality improvement? And, does it make sense to you that the Department data bases are not linked?

And then, finally, Mr. Wright, President Bush has talked about the four cornerstones of the better health care system. The first is information and technology interoperability. How is it even possible then that your own internal data bases aren't linked? And, can you show us the plan, show this committee the plan that you just alluded to, to Mr. Hodes, that you have to make this a reality? Where is the plan? And is that plan 2011? And if it is 2011, how do we make that plan 2009, 2010? Thank you.

Ms. BASCETTA. You asked about the level of cooperation that we have seen, and whether there is evidence of a meaningful effort to coordinate. And we would have to say that, so far, we have not seen a meaningful effort to coordinate or collaborate at the level that is necessary to really make headway on this problem.

HHS has 60 days from the release of the report to respond in writing to our recommendations as to how they plan to implement them, and we will be looking very closely at what they tell us.

Ms. MCCOLLUM. And what is 60 days?

Ms. BASCETTA. Sixty days from today.

Dr. PRONOVOST. Congresswoman McCollum, the need to improve quality and safety is going to require skilled workers who know how to measure, how to do improvement and how to lead these efforts. And there are virtually no programs in this country to train doctors or nurses in public health to get these degrees. We have quite robust training if you want as to basic research. Now we have programs if you want to do clinical trials and find drug therapies. And I think this is a glaring oversight. We need to do improve those programs so that people can do scholarly work like that has been going on in Minnesota or our Michigan project.

From a research perspective or just from a public perspective, I think it is completely unacceptable that we can't link these data bases, because at the end of the day, the public, like Mr. Lawton, want to know, am I safer? And I think we deserve to give them a credible answer, and it is only going to happen with data.

Dr. WRIGHT. First of all, let me say that we at HHS fully realize that health information technology is a crucial link moving forward in all areas of patient safety, not only in the area of reducing healthcare-acquired infections. And we are making efforts to move along that, in that direction.

Secretary Leavitt has asked AHRQ to provide common formats for new patient safety organizations. CMS and CDC are working very closely toward a common set of data requirements. As far as our surveillance system, we certainly believe that what gets measured gets improved. In the National Health Care Safety Network, which is the CDC surveillance tool, I think was reported in the GAO report only had 500 participants. That has grown exponentially. We are now up to 1,400 less than a year later, and we expect that to be 2,000 by the end of next year.

Ms. MCCOLLUM. Mr. Wright, I asked you the plan. And your time is up, and I would like to hear where the plan is.

Dr. WRIGHT. Our efforts to work with software vendors to make sure that, for hospitals, that they will be able to—that the systems are interoperable and can be released into the National Health Care Safety Network, which will provide us additional information in a more timely fashion.

Ms. MCCOLLUM. Mr. Chair, I asked where the plan was. I heard goals. I heard dreams. I didn't hear clear sets of objectives. Is the committee planning on being able to resubmit a question to ask for a definite plan in a timeline?

Chairman WAXMAN. We will certainly have the record open if a Member wishes to ask a question and get a written response. But I think the purpose of this hearing is to make sure that something gets done. And it doesn't have to be this second, but we want to impress on HHS that we want them to act. And I think Mr. Hodes' question was very, very targeted. I don't think Dr. Wright is in a position to tell us his plan at this moment. But we will check with him next week.

Ms. MCCOLLUM. Thank you, Mr. Chairman.

Chairman WAXMAN. Thank you very much.

We are pleased to have Congressman Murphy with us today, and I want to recognize him for 5 minutes to ask questions.

Mr. MURPHY. Thank you, Mr. Chairman. It is good to be back. I used to be a member of this committee. And also I have a bill

sitting out there for a couple of years, called The Healthy Hospitals Act, which would require hospitals to report infection rates; and ask HHS to devise a system to do that; and also, recognizing a lot of savings comes from that, establish a grant program for those hospital that dramatically lower their rate or maintain a very low level of infections.

A couple things first, and then I am going to ask you all one question, if you can answer that.

It amazes me that I can go online and find out if any airline I want to take is going to depart on time. I cannot go online and find out if I am going to depart from a hospital. Many States have laws on this. Pennsylvania has a law of things that require reporting; you are able to go and compare and find out different infection rates for different hospitals. And I also know that when hospitals, such as the VA system in Pittsburgh, worked toward identification and eradication as much as possible of nosocomial infections, they were able to drop the rate by some 60 percent of one type. And actually paying attention to one type helped them reduce all others.

I also note the number of people per day that die from healthcare-acquired infections, 270 or so, give or take, roughly the population you would see on an airplane. And if an airplane went down today and 270 people were killed, it would be a huge national tragedy. If tomorrow a plane crashed where 270 people were killed, you would have lots of questions being asked, lots of Federal agencies would begin to investigate. If, on the third day, a plane went down, crashed, killed 270 people, my guess is every airline in America would stop flying. But we have been putting up with this for years.

A few years ago, when I first introduced my bill, it still has been part of this every day; even while this committee has been holding hearings, people have died.

Given that scenario, I would like to ask each one of you, just answer yes or no, do you believe the Federal Government should mandate a uniform reporting system for healthcare-acquired infections with the results available to the public online?

Mr. Lawton.

Mr. LAWTON. Yes, sir.

Mr. MURPHY. Ms. Bascetta.

Ms. BASCETTA. Yes.

Mr. MURPHY. Dr. Pronovost.

Dr. PRONOVOST. Yes. And I would like to see it coupled with efforts to reduce those infections.

Mr. MURPHY. Mr. Labriola.

Mr. LABRIOLA. Yes, sir.

Mr. MURPHY. Ms. Binder.

Ms. BINDER. Yes.

Mr. MURPHY. Dr. Wright.

Dr. WRIGHT. Certainly we support transparency in health care. It is one of the Secretary's top priorities, and States are really taking the lead in this area. There are 25 States now that mandate reporting back to State agencies of healthcare-associated infections on a hospital basis. Two States in particular, Vermont and North or South Carolina, are now making that information available. Certainly we in the Federal system will be looking to those States as

a laboratory to see what next steps the Federal Government should do.

Mr. MURPHY. I appreciate that. And many States have made some changes. One of my points was, if you got sick today in Washington, DC, and you needed to choose a hospital, would you know which one to choose? I think the answer is no. And if you weren't in Vermont or Pennsylvania, where the information is available online, the answer is no. And given 100,000 deaths a year, I agree—and I certainly commend Secretary Leavitt. He has been a champ in pushing for transparency, and he and I have had many conversations. I appreciate that.

But this is my final question to the panel: Should we move quickly in terms of a Federal standard to move forward in reporting that is available to the public? Go down the line again. Mr. Lawton.

Mr. LAWTON. Absolutely. Yes.

Mr. MURPHY. Ms. Bascetta.

Ms. BASCETTA. Yes, urgency is very important.

Mr. MURPHY. Dr. Pronovost.

Dr. PRONOVOST. My mother is having an operation in a week from now. I sure hope she would have some of these tools available.

Mr. MURPHY. Mr. Labriola.

Mr. LABRIOLA. Clearly the magnitude of the problem requires urgency. I would just ask, from the other side of it, that it be very, very thoughtful in terms of what and how and the method in which it is done. More requirements may not necessarily just make it better for the patients. It has to be thoughtfully done.

Mr. MURPHY. I appreciate that.

Ms. Binder.

Ms. BINDER. We 100 percent agree there needs to be much more urgency. And I will point out that the Leapfrog Group does publish some of the results on infections for various hospitals that respond to our survey. And we stand ready to help in any way in working Federal agencies to do similar work.

Mr. MURPHY. Dr. Wright.

Dr. WRIGHT. Yes, we need to move.

Mr. MURPHY. I appreciate that. Because I also think that if we move quickly and called upon HHS to at least have some standards—and I recognize we don't want to burden hospitals with paperwork. But I also know, when I have spoken to hospitals, they do pay attention. They do reduce infection rates, and they find they save a lot of money for each patient.

Mr. Chairman, I thank you for indulging me and allowing me to sit on this committee hearing. I appreciate that.

Chairman WAXMAN. Thank you very much, Mr. Murphy, for being here. I wish you were back on our committee. I appreciate the leadership you have given to this and other health issues. I know, at this time, the Energy and Commerce Committee is considering a bill that you have co-sponsored that I have joined you on to make sure that we have the adequate funds for the most vulnerable in our population for healthcare services. So I very much appreciate your being here. Thank you.

Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman.

I apologize for not being here for the whole hearing, and welcome the witnesses.

I am intrigued by the sort of payment dimension of this, how you used payment as a carrot and stick. And there was a comment that we are all familiar with this adage, that what gets measured gets done. But in health care, what gets paid for often is what gets done.

So, Dr. Pronovost, I would be interested in, I was reading your testimony, maybe you speaking a little bit more directly with respect to the reimbursement regime. What particular things do you see us using increased reimbursement for, new reimbursement for to enhance; and then I know you also talked about in effect penalties where people don't take steps to address complications that could be avoided. Although you did point out that there is not sufficient research yet, maybe to put that kind of approach into play. So if you could just kind of talk about the carrot and stick from the funding and reimbursement side.

Dr. PRONOVOST. Sure. Congressman Sarbanes, for far too long, the healthcare community has labeled all these complications in the inevitable bucket. And we know that was a mistake, and patients like Mr. Lawton suffered for that. What we have done now is labeled them at the other extreme, all in the preventable bucket, and are trying to align payment policies with that. And we certainly need to align payment with high quality. The problem is they are not all preventable. And truth is, probably somewhere in the middle, and so we have to do things wisely.

What I believe we should do is those where CMS's complications that they are not going to pay for, I quite frankly think the only two that the science is robust enough—and what I mean by that is that we know how to measure them and we have good evidence that most, not all, but the majority are preventable are catheter-related bloodstream infections and retained foreign bodies after surgery; we leave things in that we shouldn't.

The others, we are not even clear how to measure accurately let alone to have any idea how many are preventable. We need to. And so I think the leadership ought to be, let's learn how to tackle, let's make a national goal to eliminated these catheter-related bloodstream infections, and find out what does it take to get all the different agencies CMF with policy, CDC with measurement, AHRQ implementing these programs, to really lick a problem well and, in the meantime, support efforts so we do learn how to measure more outcomes and estimate that they are preventable, we can have more Michigan projects so the public has a group of outcome measures that they could believe that hospitals aren't paying for things but that we are not holding them liable for things that really aren't preventable, because that is going to be gamesmanship, and we are going to be in the same place 10 years from now where we have data but harm continues unabated.

Mr. SARBANES. What about on the sort of front-end side of it? Should there be more funding in the form of reimbursement targeted to training and other things that are going on in hospital settings or other provider settings?

Dr. PRONOVOST. Absolutely. Right now, there are two medical schools, maybe three, one including Johns Hopkins, that has a re-

quired course for patient safety for medical students. And you say, well, why aren't there teachers? Because most don't have people who know this stuff well enough to teach it. They have geneticists and physiologists, but they don't have safety experts. And we need absolutely to invest in training that we are producing doctors and nurses who, at a minimum, are skilled in the basics of this, and that we have populated it with people who have formal training like myself who know how to measure it in a scholarly way, who know how to lead health systems and do the quality improvement efforts that can really realize the benefits that the public so dramatically wants.

Mr. SARBANES. One last question, which is a completely different question. To what degree have we seen, or do you predict we will see going forward, actual implications for the design of—physical design and layout and so forth of hospitals and different provider venues in response to this healthcare-acquired infection issue?

Dr. PRONOVOST. I think the science of how do you design a safe hospital is immature, but we are doing that. And I have worked with five different hospitals, including my own, who, for the first time, built mock shelves of what they are doing to simulate how easy it is to do hand hygiene? How easy it is to prevent these infections? What the physical layout should be? And I think those requirements ought to be built into the design as they are planning new hospitals. I think a big limitation of that is most hospitals don't have people with those skills, and so what we need to continue to do—we set up a program for the World Health Organization to train leaders in patient safety, and several countries around the world are supporting those people to get public health degrees at the Johns Hopkins School of Public Health. And they work with us to be trained and go back to their country. There is no support for a U.S. person on there, and I think there needs to be.

Mr. SARBANES. Thank you.

Chairman WAXMAN. Thank you, Mr. Sarbanes.

You have been a terrific panel. We raised this question with the GAO, and we asked them to give us a report, because we are aware of the work that Dr. Pronovost and many others have been doing. We have heard about the successes in Michigan and elsewhere. We asked the Secretary to come in, and the Secretary wasn't able to make it. The first suggestion of the Department was have the Centers for Disease Control come in. Well, Centers for Disease Controls are one of three agencies that have been mentioned that deal in this area. What the GAO report has told us is that we need stronger leadership and coordination at the Departmental level, and that is why I am glad Dr. Wright is here representing the full Department.

This is a classic example of a national problem, and we ought to find an easy way to use techniques that are available and have been successful. I know that no hospital, and I am sure that Mr. Labriola will tell me this, wants to be inundated with all sorts of checklists of this and that and the other. Let's coordinate what is essential, what is successful, and what is doable, and make sure the job gets done. We can criticize each other. We can say things haven't been successful, and there is a lot of justification for it. But what we wanted from this hearing is not just to criticize but to

urge that the Department take the leadership. And we are willing to work with the Department to give them any assistance that they need, but we are going to have a period of time, a short period of time in which we want to make sure something gets done.

So we will be checking in with the Secretary and Dr. Wright. And in the meantime, if we don't see aggressive action from HHS, this committee is going to ask each of the State hospitals associations what their plans are to adopt these proven measures we discussed today. I would prefer that we use all the tools that we have at the Federal level, because all hospitals take patients for which the taxpayers in this country pay them compensation for, at least the Medicare and the Medicaid population, and through that, we want to make sure that the hospitals are doing what they need.

But this is not to be punitive. This is to be constructive. And we all need to work together to use our best guidance as to how we can accomplish those goals.

I want to thank GAO for the report that you have done and all of the witnesses for your presentations.

Mr. Lawton, I am sorry you had to go through what you did, but at least you are here to tell us that we don't want others, to happen to them what happened to you. And it is preventable.

Mr. BURTON. Mr. Chairman, if I may make one comment.

Chairman WAXMAN. Yes, Mr. Burton.

Mr. BURTON. I agree with you that we shouldn't be overly critical of many of the people who are trying to do the right thing, but I do think that punitive action sometimes is necessary. If we have a food processing plant that is letting salmonella come out of their plants on a regular basis, we would close it down or we would penalize them severely. And I think if hospitals across this country are letting 100,000 people a year die a because of bacterial infections, then there ought to be penalties involved. And those who are responsible should have punitive action taken against them. We are talking about American lives here, and I think there ought to be penalties for people who don't do the job properly.

With that, thank you very much, Mr. Chairman.

Chairman WAXMAN. I appreciate that. And we want to use all the tools that we have available to us. Penalties is obviously one tool, but guidance and coordination and successfully setting out what needs to be done along with recommendations of the GAO I think will get us there. We want to prevent the infections, and we want to prevent the penalties, because we want to make sure that not each individual has to check just the hospital but that the hospital systems are working so that each individual who goes to a hospital is going to get the best possible care.

I want to thank you very much for your presentation. We have one other witness, and I want to ask her to come forward as this panel leaves. Thank you.

Our last witness is Dr. Betsy McCaughey, who is the former Lieutenant Governor of New York. She is testifying today as the founder and chair of the Committee to Reduce Infection Deaths, a nonprofit group dedicated to reducing deaths from hospital infections. We are pleased to welcome you to our hearing today.

It is the committee's policy to swear in all witnesses before they testify, so I would like to ask you, if you would, to rise and raise your hand.

[Witness sworn.]

Ms. MCCAUGHEY. The question is, is the Federal Government——

Chairman WAXMAN. Just a minute. If you have a prepared statement, we are going to put it in the record. So I am going to——

Ms. MCCAUGHEY. I am just going to tell you what I think.

Chairman WAXMAN. We are going to give you 5 minutes to say what you are going to say. Since you were here for the first panel, you can give us your comments on what they had to say and your thoughts on how to get this job done.

There is a button on the base of the mic. Is it on?

STATEMENT OF BETSEY MCCAUGHEY, PH.D., FOUNDER AND CHAIRMAN, COMMITTEE TO REDUCE INFECTION DEATHS

Ms. MCCAUGHEY. Is the Federal Government doing everything it should to prevent hospital infections? The answer is "no." And actually, the Centers for Disease Control and Prevention is largely to blame. The CDC has consistently understated the size of this problem and the cost of the problem. And their lax guidelines give hospitals an excuse to do too little.

So I am going to provide you with four kinds of information in these 5 minutes: the size of the problem, the cost of the problem, and the CDC's two most serious or deadly mistakes.

First, the size of the problem. The CDC claims that 1.7 million people contract infections in the hospital each year, but the truth is several times that number. And the data prove it.

I am going to hold up this chart to show you. Methicillin-resistant staphylococcus aureus [MRSA], is one of the fast-growing hospital infection problems in the United States. In 1993, there were 2,000 hospital-acquired MRSA infections, according to the AHRQ. Last year 880,000—the largest-ever survey of hospital infections in U.S. hospitals, published in December in the American Journal of Infection Control, showed that 2.4 percent of all hospital patients acquired healthcare-related MRSA infections—880,000 during the course of a year. That is from one bacterium. Imagine how many infections there are from Acinetobacter, Pseudomonas, klebsiellas, vancomycin-resistant enterococcus, Clostridium difficile, and the other bacteria contained within the hospital.

Dr. Julie Gerberding testified to this committee in November that MRSA hospital-acquired infections are only 8 percent of the total. All right. So clearly these facts discredit the CDC estimate of 1.7 million infections. That guesstimate, that irresponsible guesstimate is based on a sliver of evidence that is 6 years old, from 2002.

The Centers for Disease Control and Prevention also understates the cost of this problem. The average hospital infection adds $15,275 to the medical costs of caring for a patient in the hospital. That means that 2 million hospital infections a year would add 30.5 billion a year to the Nation's health tab. So you do the arithmetic. What that really means is that the United States is spending as much treating hospital infections as the entire Medicare

Part D drug benefit. We could be paying for drugs for all seniors for what we are spending on treating these hospital infections.

But the problem doesn't end there. What causes these infections? Unclean hands, inadequately cleaned equipment and rooms, and lax procedures in the hospital. The Centers for Disease Control and Prevention has for many years now advocated rigorous hand hygiene. That is a start, but it is not enough, because as long as hospitals are heavily contaminated with these bacteria on all the surfaces, doctors' and nurses' hands are going to be recontaminated seconds after they wash and glove, when they touch a computer keyboard, a bed rail, a privacy curtain, any surface or tool within the hospital.

How dirty are hospitals? Research shows that three-quarters of surfaces in hospitals are contaminated with vancomycin-resistant enterococcus and methicillin-resistant staphylococcus and other bacteria. A recent study done by Boston University of 49 operating rooms in four New England hospitals found that over half the surfaces in the operating room that are supposed to be disinfected were left untouched by the cleaners. And a followup study of over 1,100 patient rooms, all the way from Washington, DC, to Boston, found that over half the surfaces in patient rooms were also overlooked by the cleaners. Numerous studies link contaminated blood pressure cuffs, unclean EKG wires, and other equipment with hospital infections.

A recent study done right down the street at the University of Maryland showed that 65 percent of doctors and other medical professionals admit they change their white lab coat less than once a week, even though they know it is contaminated; 15 percent admitted they changed it less than once a month.

The Centers for Disease Control and Prevention's standards of hospital hygiene are so vague as to be meaningless. They are mind-numbing. And as you pointed out, Congressman Burton, restaurants are inspected for cleanliness in this country but not hospitals.

An accreditation by the Joint Commission is no guarantee that a hospital is clean. In fact, last year a study done showed that 25 percent of hospitals deemed unsanitary in the State of California by State health department inspectors responding to complaints had been accredited within the previous 12 months.

Hospitals in the United States used to inspect surfaces, test surfaces for bacteria levels. In 1970, the CDC and the American Hospital Association jointly announced that hospitals should stop doing that testing because they considered it a waste of money. And since that time, as late as this year right now, the Centers for Disease Control and Prevention adheres to that position against bacterial testing of surfaces in hospitals.

Bacterial testing of surfaces is so simple and so inexpensive that it is routine in the food processing industry. And I would like to ask you, Congressman Burton, whether you think that it is more necessary to test for bacteria at a hot dog factory than in an operating room.

Finally, the Centers for Disease Control and Prevention has also failed to call for screening for MRSA. You cannot control the spread of this deadly bacteria in hospitals if you don't know the source.

People are carrying this bacteria on their skin and enter the hospital shed it everywhere, on wheelchairs, on bed rails, on stethoscopes, on the floor, on literally every surface. It doesn't make them sick until it gets inside their body via a ventilator, an IV, a urinary tract catheter, or a surgical incision.

But testing, which is a simple noninvasive nasal swab or skin swab, enables the hospital to take the precautions to prevent that bacteria from spreading to all the other patients in the hospital.

A new study just out from Case Western Reserve 2 weeks ago, shows that people who are unknowing carriers of MRSA are just as contagious as those who are infected and currently isolated in hospitals. Denmark, Holland, and Finland virtually eradicated these bugs in their hospitals through screening and cleaning, and the British National Health Service is now making screening universal. Some 50 studies in the United States prove that it is effective and that it has reduced MRSA infections, where it has been tried here, by 60 to 90 percent. And yet—and the entire Veterans Administration is now launching universal screening.

The CDC continues to delay recommending universal screening. And every year of delay is costing millions—billions of dollars and thousands of lives. And that is my statement. Thank you.

Chairman WAXMAN. Thank you very much.

[The prepared statement of Ms. McCaughey follows:]

Testimony of Betsy McCaughey, Ph.D., Chairman of the Committee to Reduce Infection Deaths to the House Committee on Government Oversight and Reform

April 15, 2008
by Betsy McCaughey

I am Dr. Betsy McCaughey, the founder and Chairman of the Committee to Reduce Infection Deaths (RID). RID is a national not-for-profit that educates hospital executives, doctors and nurses, patients, and lawmakers about how to prevent hospital infections.

Is the federal government doing enough to stop hospital infections? The answer is no, and the biggest culprit is the CDC. The CDC consistently understates the size and cost of this problem, and its lax guidelines give hospitals an excuse to do too little.

I am going to provide you with four pieces of information:

The size of the problem, the cost of the problem, and the two deadly mistakes of the CDC.

SIZE OF THE PROBLEM

The CDC claims that 1.7 million people contract infections in the hospital each year. The truth is several times that number. The proof is in the data.

One of the fastest growing infections is MRSA or "Mersah," which stands for methicillin resistant Staphylococcus aureus, a superbug that isn't treatable with commonly used antibiotics.

In 1993 there were fewer than 2000 MRSA infections in U.S. hospitals. In 2007, the largest ever survey of hospitals in the U.S. conducted by the Association of Professionals in Infection Control and published in the *American Journal of Infection Control*, found that 2.4% of patients had MRSA infections they contracted *in* the hospital. That's 880,000 thousand patients.

That's from one superbug. Imagine the number of infections from bacteria of all sorts, including killers such as VRE (Vancomycin resistant Enterococcus), pseudomonas, and C. diff (Clostridium difficile.)

Dr. Julie Gerberding testified to this committee in November that MRSA hospital infections account for only 8% of total hospital infections.

The conclusion is obvious. Many millions of patients are affected by hospital infections each year. These facts discredit the CDC's official estimate of 1.7 million. The CDC's number is an irresponsible guesstimate based on a sliver of data from way back in 2002.

How can the CDC deal responsibly deal with a health threat if the agency relies on six year old data?

The problem doesn't stop there.

COST OF THE PROBLEM:

The CDC also consistently understates the cost of the problem.

When a patient contracts an infection, it adds on average $15,275 in direct additional medical costs.

Every two million hospital infections add about $30.5 billion dollars to the nation's health tab in treatment costs alone.

In view of the numbers you just heard, these infections are costing the nation at least as much as the entire Medicare Part D drug benefit, enough to pay for medications for all seniors.

What causes these infections: unclean hands, inadequately cleaned equipment and rooms, and lax procedures. The CDC is responsible for providing guidelines to hospitals to prevent infections, but their lax guidelines actually give hospitals an excuse to do too little.

WHAT IS NEEDED TO PREVENT THESE INFECTIONS: CLEANING AND SCREENING:

Cleaning:

For several years the CDC has emphasized the importance of doctors and nurses cleaning their hands. Cleaning hands is essential. But it's only the first step.

As long as hospitals are inadequately cleaned, doctors' and nurses' hands will become recontaminated seconds after they wash and glove, as soon as they touch a keyboard, or a privacy curtain, or a bedrail. How dirty are hospitals? A recent survey of 49 operating rooms in 4 New England hospitals found that over half the surfaces in the operating room that were supposed to be disinfected by hospital cleaners were left uncleaned. A follow-up survey of over 1100 patients' rooms found that over half the surfaces that are supposed to be cleaned when one patient is discharged – and before another patient is admitted to the room – were left uncleaned.

Research shows that nearly 3/.4 of surfaces in hospitals are contaminated with bacteria such as MRSA and VRE, which can survive for 96 hours on surfaces. Numerous studies link hospital infections to these bacteria on unclean EKG wires, unclean blood pressure cuffs, and other equipment. The blood pressure cuffs that are rolled from room to room and wrapped around each patient's bare arm are heavily contaminated with these superbugs. In a recent study, 65% of doctors and other medical professionals admit they change their white lab coat less than once a week, even though they know it's contaminated. 15% admit they change it less than once a month.

The CDC's guidelines for hospital cleanliness are so vague as to be meaningless.

In this country, restaurants are inspected for cleanliness. But not hospitals, not even operating rooms.

Hospitals used to routinely test surfaces for bacterial levels, but in 1970 the CDC and the American Hospital Association held a joint press conference and advised hospitals to stop testing for bacterial levels. Even now, when MRSA infections have increased 32 fold, the CDC continues to adhere to that position.

Testing surfaces for bacteria is so simple and inexpensive that it is done routinely in the food processing industry. But not in hospitals. How can it be more important to test for bacteria in a hot dog factory than an operating room?

Screening:

The CDC has also failed to call on all hospitals to screen for MRSA. The test is a simple, noninvasive nasal or skin swab. Screening is necessary because patients who unknowingly carry the germ on their body shed it in particles on every surface. With screening, hospitals can identify the MRSA positive patients and take steps to prevent the germ from spreading. Countries such as Holland, Denmark, Finland, and Western Australia, that have virtually eradicated MRSA infections, did it by screening and cleaning. The British National Health Service is making screening routine. And some fifty studies show that screening works in the U.S. too, reducing MRSA infections by 67 to 90%. And actually making hospitals more profitable, even in the short run.

About 30% of hospitals in the U.S. are leading the way and screening, including the entire Veterans Administration. But most hospitals are not screening, largely because the CDC has not called on all hospitals to screen. Every year that the CDC delays costs thousands of lives and billions of dollars.

Betsy McCaughey *is the founder and Chairman of The Committee to Reduce Infection Deaths and former Lt. Governor of New York State.*

Chairman WAXMAN. I am going to recognize Mr. Burton to ask questions.

Mr. BURTON. First of all, I want to thank you for coming on such short notice. And I want to thank you for your dedication to investigating all these things. What do you think ought to be done? I mean you have expressed very clearly the problem.

Ms. MCCAUGHEY. First of all, let me say what ought to be done.

Mr. BURTON. And the chairman has indicated you have had a GAO study that is being conducted right now on the hospitals. What do you think should be done by the FDA and CDC and HHS to correct these problems? And is there a timeframe within which you think it can be done?

Ms. MCCAUGHEY. No. 1, American people deserve clean hospitals. Clean them or close them. That is what they are doing in Britain now. Now, they don't have a better healthcare system than we do, but there the political leaders are very, very engaged in affording the public clean hospitals. And that is the least we can do.

We cannot cure every major illness in the United States, but we can guarantee that patients have a clean hospital. And it is not rocket science to inspect a hospital for cleanliness. Yet when I called the Joint Commission and asked them if they inspect for cleanliness when they go to accredit a hospital, they say no.

The CDC has reams of paper, hundreds of pages devoted to the issue of hospital hygiene. It is mumbo-jumbo. You can say in two or three pages how to inspect a hospital for cleanliness, how to test the surfaces for bacteria, as was done routinely before 1970. You can say that doctors should change their lab coat every day to avoid their own clothing becoming vectors for disease. So the least we can expect is rigorous hygiene in our hospitals. And it is highly cost-effective.

Mr. BURTON. You think that within a relatively short period of time, with the proper instructions, that they could clean up most of the hospitals?

Ms. MCCAUGHEY. Yes. Let me give you an example. In Los Angeles, restaurants are inspected three times a year for cleanliness and the results are posted in the restaurant window. But not hospitals. You don't have to go to a restaurant. You can go home and make your own lunch.

Mr. BURTON. Yeah. What kind of penalties do you think should be imposed if hospitals would not adhere to the requirements of keeping the place clean?

Ms. MCCAUGHEY. You are the lawmakers, but it seems to me there should be substantial penalties. The greatest, of course, is adverse publicity. Hospitals are advertising for our business. You hear their ads on the radio, Come to our hospital. We have the best doctors, the latest technology. They are not telling you how many patients get an infection under their care.

But now in Britain and Ireland and Scotland, hospitals are routinely inspected every year for cleanliness. And the red, yellow or green ratings are posted and publicized. And you can bet that the newspapers in the United States would carry those results as well.

Mr. BURTON. I can't understand why—I mean, Health and Human Services and the FDA are charged with the responsibility of making sure that we have the best healthcare in the world. And

I can't understand why they would not take the kind of advice you are giving to heart and actually do this. Can you give me a reason why you think this isn't happening? Because, I mean——

Ms. MCCAUGHEY. I can.

Mr. BURTON. We have had these people before the committee many times, the chairman—and when I was chairman—and they seem like they are dedicated. And I can't figure out why they wouldn't do this.

Ms. MCCAUGHEY. Yes. I must say I am amazed. When I spoke with the Joint Commission about it, the Vice President for Quality said, we can only ask hospitals to do so much. But is asking for a clean room too much? So much of this is about hygiene.

Mr. BURTON. Well, I appreciate your being here. I think this is something, Mr. Chairman, we ought to pursue as diligently as possible. I know you feel the same way. And if there is any way we can urge or force the health agencies to be more diligent in this regard, I would really appreciate it.

And as a person who suffered infections that darn near cost me mobility in my left arm, and possibly my life, and I had to spend 6 or 7 weeks with a bag full of antibiotics hanging from a stand to keep me from having an infection that would kill me, I can attest to the fact that I know this stuff goes on.

And there ought to be some way that the hospitals and FDA and CDC and HHS can implement a program that will make sure—that will minimize the possibility of these infections. And I would like to have your statistical data.

Ms. MCCAUGHEY. Of course. With all the footnotes, I am submitting the entire thing in evidence. Let me just add this. I am not asking the hospitals to do something they cannot afford to do. Numerous studies illustrate that the more rigorous cleaning that I have discussed actually yields a very handsome financial return without a capital outlay. It can be done in the first year.

In Rush Medical College in Chicago, the researchers who identified the frequently overlooked areas of the operating rooms and patients' rooms that were not cleaned worked with the cleaning staff, showed them how to clean properly, drench and wait, not just a quick spray and wipe, and how important it was to get certain surfaces that were always overlooked. They reduced the spread of another nasty bug, VRE, vancomycin-resistant enterococcus by two-thirds simply working with the cleaning staff.

Another hospital experienced a 350 percent return the first year by adding cleaning staff and working with them to identify the often overlooked areas. So cleaning is a highly effective strategy to reduce the spread of most bacteria.

Chairman WAXMAN. Thank you very much. Did you read the GAO report?

Ms. MCCAUGHEY. I haven't gotten it yet. I requested it, but I am looking forward to reading it very soon.

Chairman WAXMAN. I would be interested in your response to it. What GAO had to say was that they are not as harsh on CDC as you seem to be. They point out that the CDC and the other agencies within Department of Health and Human Services—and there is no one giving guidance when you have three different agencies promoting different data base, different rules, and so on and so

forth. But we need rules and we need to approach this as a Federal responsibility.

Ms. MCCAUGHEY. I would like to add one other thing.

Chairman WAXMAN. Let me finish.

What was recommended to us in that first panel were some things that I think are doable. And when they are done, they have been very successful. What you are advocating goes beyond that. And I think you are—from what I understand your analysis of the possibility of infection from a lot of the cleaning problems is accurate, but there seems to be some controversy as to whether all of that is necessary.

I don't know the accuracy of it, but that is what we have been told by some of the scientists. What we want to have done is, first of all, what can be done now to reduce infections get done; get the best science on what else needs to be done; and then make sure that the best science is implemented.

And you have come before us and given us a broader perspective. And you are right in pointing out that it is not just a hospital infection. MRSA is a problem beyond the hospitals themselves. And we want to recognize that fact and make sure we get strategies in place to approach that.

So I appreciate your passion on this issue and the work you have done. And I want you to give us your comments on that GAO report. Because what we want to do is make sure that we do what can be done, do what must be done, and prevent these diseases. And I thank you very much for being here.

I am going to have to end the hearing because there is another group that is going to be coming into the meeting room. But thank you so much. And this committee hearing stands adjourned.

[Whereupon, at 1:44 p.m., the committee was adjourned.]

[The prepared statement of Hon. Elijah E. Cummings and additional information submitted for the hearing record follow:]

CONGRESSMAN ELIJAH E. CUMMINGS OF MARYLAND
OPENING STATEMENT
FOR THE RECORD

"HOSPITAL ASSOCIATED INFECTIONS:
A PREVENTABLE EPIDEMIC"

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

WEDNESDAY, APRIL 16, 2008

Mr. Chairman,

Thank you for holding this vitally important hearing to examine what steps the Department of Health and Human Services and its agencies are taking to combat hospital associated infections (HAIs).

As you know, the Centers for Disease Control and Prevention (CDC) estimated that in 2002 there were approximately 1.7 million hospital-acquired infections which caused approximately 98,987 deaths.

But HAIs are expensive as well as dangerous.

According to GAO, the average payment for Pennsylvania hospital patients who contracted an HAI in 2005 was over six times higher than for patients who did not acquire infections.

Most of the costs of HAIs are borne by insurers including Medicare, and the hospitals.

Shockingly, these diseases are as preventable as they are harmful.

Dr. Peter Pronovost, a researcher at Johns Hopkins, identified five simple practices that when fully implemented, reduce catheter infections.

These steps include:

(1) handwashing;
(2) full draping of the patient;
(3) cleaning the skin with proven cleansers;
(4) avoiding catheters in the groin if possible; and
(5) removing catheters as soon as possible.

I am aware that our federal agencies are making progress in the effort to reduce hospital associated infections that affect both the bottom line and patients' quality of life—but we must do more.

For this reason, I have introduced the "Community and Healthcare Associated Infections Reduction (CHAIR) Act of 2007," H.R. 4214.

Many of the issues that we will discuss in this hearing today are addressed in my legislation.

Specifically, the GAO report released today entitled, "Health-Care Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections," indicates that the Department of Health

and Human Services must do more to coordinate efforts among agencies.

The legislation I have introduced does just that by establishing an interagency working group.

In addition, the CHAIR Act will reduce HAIs by:

- Developing best practices guidelines for infection control plans in hospitals through the Agency for Healthcare Research and Quality (AHRQ) and CDC;

- Updating current surveying of infection control plans by the Centers for Medicare and Medicaid Services (CMS) to incorporate these best practices;

- Requiring hospitals to report infection data to CDC;

- Making this data available to researchers, states, healthcare providers, and the public;

- Requiring a feasibility study on the use of quality improvement payments to reward hospitals for reducing hospital-acquired infection rates;

- Creating a grant program through CDC for states to carry out public awareness campaigns, especially in schools; and

- Expanding research into community and healthcare associated infections at the National Institutes of Health (NIH).

The CHAIR Act is endorsed by the Consumers Union, the Committee to Reduce Infection Deaths, the MRSA Survivors Network, and the Association for Professionals in Infection Control and Epidemiology.

I look forward to the opportunity to learn from today's witnesses what we must do to address this critical issue now.

Thank you and I yield back the remainder of my time.

ELIJAH E. CUMMINGS
Member of Congress

Statement of Lisa McGiffert
Director, Consumers Union's Stop Hospital Infections Campaign
House Oversight and Government Reform Committee
On Healthcare -Acquired Infections
April 16, 2008

Consumers Union, nonprofit publisher of *Consumer Reports*, appreciates the opportunity to comment to the Committee about the serious problem of health care-acquired infections.

Five years ago, Consumers Union launched a national campaign, www.StopHospitalInfections.org, advocating for public disclosure of hospital-acquired infection rates to inform people about the safety of their hospitals and to mobilize hospitals to do more to prevent infections occurring in their facilities. We also advocate for screening hospital patients for methicillin-resistant *Staphylococcus aureus* (MRSA) as a means to prevent its spread to other vulnerable hospital patients.

Twenty-two states now have laws requiring reporting of hospital infection rates, an "outcome measure" that we believe is the best measure of the overall effectiveness of a hospital's infection control program. Also, three states (IL, PA, NJ) require hospitals to use life-saving protocols to prevent the spread of MRSA, including screening incoming patients who are at high risk for carrying MRSA.

CONGRESSIONAL/FEDERAL RESPONSE TO HEALTH CARE-ACQUIRED INFECTIONS

Currently, five bills have been introduced to establish a national infection reporting law and more aggressive MRSA infection prevention, including some patient screening and well researched and tested protocols. A listing of the bills is attached to this testimony. We are encouraged with this interest by Congress and strongly support a national law requiring all US hospitals to report their infection rates and to require hospitals to screen patients for MRSA and follow protocols to prevent its spread. The states have proven to be good laboratories in which many issues have been debated such as which infections hospitals should initially report, how the data is analyzed and when the reports should be published. The groundwork done in the states will help to guide a national reporting system.

Another federal activity that has stimulated activity around the country is the Centers for Medicare and Medicaid Services (CMS) "no-payment" rules which go into effect in October 2008. This rule halts hospital payments for patient care required due to harm the hospital caused, or hospital-acquired conditions. It also prohibits billing patients for these services. Several hospital-acquired infections are on the list: catheter-associated urinary tract infections, vascular catheter associated infections, and mediastinitis, a type of infection from Coronary Artery Bypass Graft (CABG) Surgery.

However, now, almost a year after adopting the rule, several states have adopted similar policies for their Medicaid programs, numerous private insurers have announced they will no longer pay for these hospital-acquired conditions, and some hospitals are no longer charging for the services associated with them. This demonstrates the incredible power that CMS has to change the behavior of hospitals and the way our health care system responds to these preventable infections, but rarely has used in the last 30 years.

Unfortunately, there has been a consistent lack of strong leadership in the federal government to fight hospital-acquired infections. The work that has been done rarely focuses on the public interest or demonstrates sensitivity to the years of horrific and painful recovery an infected patient must endure. Rather, it has focused more on the need of the health care providers than the threat to the public – with voluntary reporting and {limited visible enforcement of Medicare requirement that hospitals implement infection prevention policies. The Hospital Compare site now publishes how often hospitals use proven surgical infection prevention techniques – but the public needs to see outcome measures, such as infection rates, to get a real sense of the effectiveness of their hospitals' infection control programs.

The Centers for Disease Control and Prevention leaps into action when cases of other infectious diseases – TB, measles – affect significantly fewer people. CDC does respond at times to hospital outbreaks, but not in the highly visible way they respond to other infectious disease cases. Further, most infections are not identified in an outbreak situation, rather they have become routine in our nation's hospitals. This is where CDC could use its power to affect change – by strongly coming out with a zero tolerance campaign against hospital-acquired infections. The agency has significantly increased the amount of information available to the public in the last few years and has developed an updated system for collecting information about infections occurring across the country. Another major responsibility of CDC is to develop infection prevention guidelines – yet these often take years to develop and fail to establish a clear gold standard of policies for hospitals to follow. There is a great need for translation of these often incomprehensible policies to the front line workers who must implement them. Numerous definitions that are used to identify when an infection is hospital-acquired are outdated or lead to inaccuracies in identifying hospital-acquired infections. For example, the definition of ventilator associated pneumonia, among the most common and deadly infections, is pages long and, if followed, over reports the problem. Most hospitals find the definition unusable and infection control professionals have been pushing for the definition to change for years.

There have been many missteps and lost opportunities in the past, but it is important to seize the opportunity for change now that public attention and policymakers' interest in this problem is high. It is essential for federal agencies to make it a priority to stop the millions of injuries and deaths that these infections cause. In addition, CU is concerned about evidence indicating that African Americans suffer two times the rate of MRSA infection as whites. We urge this committee to investigate the reasons for these disparities, and seek ways to reduce and eliminate risks of infection.

THE IMPORTANCE OF PUBLIC REPORTING

Public Reporting stimulates change and brings attention to issues that were previously hidden. When state legislators began responding to our activists' requests to

take action against hospital-acquired infections, it stimulated a public discourse on the subject throughout the country and put this problem front and center where it should be.

An effective tool in creating change, public reporting serves many purposes. It satisfies patients' right to know about the safety of their local hospital and helps them have more informed conversations with their physicians and make more informed health care choices. It informs hospitals and other providers about how they compare to their competitors. Public reporting laws standardize definitions and collection techniques so that the information presented to consumers allows for fair comparisons. It educates about evidence-based medicine and the importance of understanding that health care outcomes matter and can be improved. Disclosure stimulates change within hospitals because it requires them to identify the problems as they are occurring. This is perhaps the most important result of public reporting, since most hospitals do the bare minimum of tracking infections. Monitoring selected infections in the ICU and selected surgeries is the standard in most American hospitals. But that is now changing because of reporting laws and other complementary initiatives, such as the Institute for Healthcare Improvement's campaigns to help hospitals implement life-saving protocols that prevent infections and other unwanted outcomes.

Finally, public awareness of performance can stimulate community pressure for change. So, even a town with only one hospital can see how its hospital is performing compared to other similar hospitals in the state or nation. This happens through the public forum of local media, conversations among providers, and citizen activism.

THE COST OF HOSPITAL-ACQUIRED INFECTIONS

The cost of hospital-acquired infections can be assessed at numerous levels. The **human cost** is by far the greatest: each year nearly two million patients get an infection while being treated in our nation's hospitals, and almost 100,000 of them die.[i]

Cost to the health care system:

John Jernigan, Chief of Interventions and Evaluations at the Centers for Disease Control and Prevention (CDC), estimates the hospital costs for these infections to be as high as $27.5 billion each year. The cost of an infection depends on the type and how long it takes for a patient to recover, and it is difficult to pin down the actual costs because most estimates are based on "charges." Generally, the cost-charge ratio is estimated at 0.5 (so cost is about half of the charges); of course, this ratio can vary by hospital.[ii]

Most estimates only look at hospital costs, but the cost for each patient goes far beyond hospital care to include medications, home health care, doctors' services, physical therapy, wound care, etc.

The best public estimates we have to date are from Pennsylvania which reports rates on all four of the major types of infections (surgical site infections, blood-stream infections, ventilator associated pneumonia, and urinary tract infections) and reports on infections occurring throughout the hospital. The state also collected information directly from private insurers to get a more accurate picture of the actual costs to the health care system.[iii] The private insurance payments ranged from $27,000 for urinary tract

infections to $80,000 for blood stream infections.[iv] In 2005, Pennsylvania estimated the total charges for the state's infections at $1.4 billion.

Governor Schwarzenegger's office estimates the cost of hospital-acquired infections in California to be $3 billion. And, a Massachusetts Panel estimated the total cost of hospital-acquired infections in that state to be $200 million to $473 million.

Cost to Government.

The cost of hospital-acquired infections to state and federally funded health care programs is substantial and must be considered when looking at the investment needed for a public reporting system. The increased public and hospital awareness that comes with such a system will reduce infections and has the potential for saving significant taxpayer dollars.

While there are no comprehensive estimates to data on the Medicare costs associated with hospital-acquired infections, the recent "no-payment" proposal contained some statistics estimating the number of certain infections and their costs. The law required CMS to identify conditions that were of high cost and high volume to the Medicare program. In FY 2006 they identified the following Medicare incidences and costs:

- Catheter associated urinary tract infections: 11,780 cases at an average charge for the entire hospital stay of $40,347.
- Serious staph aureus infections: 29,500 cases at an average charge of $82,678.
- Clostridium difficile-associated disease (CDAD): 110,761 Medicare patients at an average charge of $52,464.
- Ventilator Associated Pneumonia (VAP) and Other Types of Pneumonia: 92,586 cases, average charge of $88,781.
- Methicillin-Resistant Staphylococcus Aureus (MRSA): 95,103 cases at average charge of $31,088.
- Surgical Site Infections: 38,763 with any type of postoperative infection at an average charge of$79,504.

Pennsylvania estimated that 68 percent of that state's hospital-acquired infections were paid for by Medicare and Medicaid.

State costs. A 2007 study by the Association of Professionals in Infection Control and Epidemiology (APIC), found that Medicaid was the payer for 11.4% of hospital-acquired infection cases nationwide. A 2005 Pennsylvania report analyzing who was paying for hospital-acquired infections in that state found that Medicaid paid for 9% of all hospital-acquired infections, accounting for 18% of the hospital charges for that state's infected patients. Pennsylvania estimated that the average charges for Medicaid patients with an infection were more than $391,000, while the average charges for Medicaid patients without an infection were just under $30,000. Oregon estimated that the excess Medicaid costs for hospital-acquired infections in that state exceeded $2.4 million in 2005.

INFORMATION ABOUT MRSA

In June 2007, the Association for Professionals in Infection Control and Epidemiology (APIC) released the first-ever nationwide analysis on the prevalence of

MRSA in U.S. healthcare facilities based on data collected from more than 1,200 hospitals in all 50 states. The APIC report found that MRSA hospital-acquired infections are 8.6 times more prevalent than previous estimates and those MRSA infections are found in all wards throughout most hospitals. This is significant as APIC found that less than half (45 percent) of hospitals are tracking infections throughout the hospital – the rest are focusing only on intensive care, surgical, or high risk nursery patients.[v]

An estimated 95,000 people developed MRSA infections in 2005, according to CDC researchers.[vi] Hospitalizations due to MRSA infections have doubled in recent years. Between 1999 and 2005, the number of patients hospitalized with MRSA infections went from 127,000 to almost 280,000.[vii]

While MRSA once affected primarily the sick and elderly in hospitals, according to many published reports it has now spread outside of these facilities. The bugs, typically different strains than the types found in hospitals, are striking young, healthy people through contact with infected skin mainly by sharing towels or other personal items. However, the community strain is now being spread in hospitals when patients unknowingly carry it in and it is then carried to other patients by health care workers.

Though reports of community-acquired MRSA infections are increasing, recent CDC sponsored research shows that 85 percent of such infections are picked up in the hospital or some other health care setting.[viii]

Patients who develop MRSA infections end up staying longer in the hospital, have higher medical care bills, and are more likely to die from their infection. A study by the Pennsylvania Health Care Cost Containment Council found that hospital patients with MRSA infections are four times as likely to die, will stay in the hospital two and a half times as long, and are charged three times as much compared to patients without MRSA.[ix]

As MRSA infection rates have climbed, more and more attention has focused on preventing the spread of these superbugs. In addition to strict hand hygiene, successful strategies for controlling MRSA include screening patients using active surveillance cultures (quick turn around cultures from nasal swabs), isolating patients colonized with MRSA, observing strict hand hygiene compliance, using gowns, gloves, and in some cases masks when treating them, and routine decontamination of patient rooms and operating rooms.[x]

Many hospitals in northern Europe have used these strategies to successfully control MRSA infections for decades. MRSA made up 33 percent of all staph infections in Denmark in the 1960s, but has declined steadily after aggressive control practices were instituted and has hovered around 1 percent for the past 25 years.[xi] Likewise, the prevalence of MRSA has been kept under .5 percent in both Finland and the Netherlands.[xii]

APIC found that only 29 percent of infection control professionals it surveyed for its 2007 MRSA prevalence study reported that their hospitals used active surveillance cultures to identify patients who are colonized with MRSA. Fifty percent of the infection control professionals surveyed said their hospital "was not doing as much as it could or should to stop the transmission of MRSA."[xiii]

A number of hospitals in the U.S. following this "bundle" of MRSA infection control strategies have documented impressive results. A pilot program at the Veterans Health Administration's (VHA) Pittsburgh Healthcare System in Pennsylvania in 2001 has reduced infections in the hospital's surgical unit by 70 percent.[xiv]

All patients admitted to the hospital underwent a nasal swab upon admission to screen for MRSA. Patients who tested positive were isolated from other patients and were treated by health care workers who wore disposable gowns, masks, and gloves. Medical equipment – like stethoscopes and blood pressure cuffs – was disinfected after each use. Patients received another nasal swab right before discharge to see if they developed a MRSA infection during treatment.[xv]

This pilot was so successful that the VHA issued a directive in January 2007 "to interrupt the chain of transmission of MRSA" by requiring all of its 150 hospitals to follow this MRSA protocol. Initially, the directive required screening patients in intensive care units, then in other high risk units such as transplant units and general surgical wards, and continuing to phase in other units of the hospitals "until all inpatient areas (with the exception of inpatient psychiatry) are incorporated in the initiative."[xvi]

The University of Pittsburgh Medical Center has reduced MRSA in its intensive care units by 90 percent using this approach[xvii] and significant results have been documented at the University of Virginia Health System[xviii] and Evanston Northwestern Healthcare in Illinois.[xix]

The effectiveness of MRSA screening efforts at three hospitals in the Evanston Northwestern Healthcare system were documented in a study published on March 18, 2008 in *Annals of Internal Medicine*. Researchers studied MRSA interventions and found that universal screening of all patients upon admission resulted in an over 50 percent reduction in hospital-acquired MRSA infections.[xx]

Another study published recently in the *Journal of the American Medical Association* concluded that MRSA screening of surgical patients was not effective for preventing surgical infections. However, this study did not measure the impact on the spread of infections throughout the hospital, rather it only measured infections among the surgical patients screened. The study revealed that the results of 31 percent of the patients' tests were not received prior to their surgery, thus negating the benefit of screening. Further, the study actually found those patients who were pre-screened and who got results prior to surgery, were able to receive the appropriate preventive antibiotics for MRSA and to "decolonize" prior to surgery. In this group, no infections occurred.[xxi]

Critics argue that this bundled approach for controlling MRSA is too expensive. But numerous studies have shown that screening and isolating patients who test positive for MRSA ends up saving money by preventing infections that would result in even higher costs for patients and hospitals.[xxii] For example, the infection control program at Evanston Northwestern saves the hospital $25,000 in uncovered medical costs per patient every time a MRSA infection is prevented.[xxiii]

Similarly, a recent analysis found that hospitals nationwide would save over $231 million annually if all elective surgery patients were screened for MRSA upon admission and proper precautions were taken with those found colonized with MRSA.[xxiv]

HOSPITAL-ACQUIRED INFECTION REPORTING IN THE STATES

Twenty-two state laws require reporting of the rate of various types of infections: CO, CT, DE, FL, IL, MD, MN, MO, NH, NY, NJ , OH, OK, OR, PA, SC, TN, TX, VA, VT, WA, and WVA. Several other states do not report rates but have various other requirements: CA & RI report information about the processes hospitals use to prevent infections; AR reporting is voluntary with aggregated public reports (not hospital-

specific); NV, NE hospitals send confidential reports to a state agency. So far five states have issued reports (FL, PA, MO, SC, VT) which can be viewed at http://www.consumersunion.org/campaigns/stophospitalinfections/learn.html.

Most of the states are planning to use the CDC National Healthcare Safety Network (NHSN) as the data collector (including CO, CT, NJ, NY, OR, PA, SC, TN, VA, VT, WA). While NHSN is a voluntary, confidential reporting system, the laws in these states establish the requirement to report infection rates. The hospitals send data to NHSN and then provide the analyzed information from NHSN to the state agency responsible for the public reports. NHSN has developed with these emerging state laws in mind and facilitates the process of sharing of data between state agencies and hospitals. This is an update of a system that was in place at CDC for more than 30 years. That prior system had limited capacity (315 hospitals) while NHSN states that it will be able to handle every hospital in the country. However, reports from participating hospitals around the country indicate that the data input is slow and highlights the importance of sufficiently funding this resource at CDC.

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[i] "Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002," R. Monina Klevens, DDS, MPH, Jonathan R. Edwards, MS, Chesley L. Richards, Jr., MD, MPH, Teresa C. Horan, MPH, Robert P. Gaynes, MD, Daniel A. Pollock, MD, Denise M. Cardo, MD, Public Health Reports, March–April 2007, Volume 122, pp. 160-166.

[ii] Friedman, B, LaMare, J, Andrews, R, McKenzie, D, "Practical options for estimating cost of hospital stays," J Health care Finance, 2002:29(1); (1-13)

[iii] "PHC4 • Hospital-acquired Infections in Pennsylvania, January 1, 2005 – December 31, 2005," November 2006, page 2.

[iv] The average "costs" in Pennsylvania: SSI: $27,470; UTI: $43,932; VAP: $62,509; BSI: $80,233; Multiple infections: $91,898

[v] Executive Summary: National Prevalence Study of MRSA in U.S. Healthcare Facilities (Washington, D.C.: Association for Professionals in Infection Control and Epidemiology, 2007), p. 4.

[vi] Klevens, p. 1769

[vii] Klein, p. 1840.

[viii] Klevens, p. 1763.

[ix] MRSA in Pennsylvania Hospitals (Harrisburg, Pennsylvania, Pennsylvania Health Care Containment Council, August 2006), p. 2.

[x] Muto, Carlene A., et al, "SHEA Guideline for Preventing Nosocomial Transmission of Multidrug-Resistant Strains of Staphylococcus aureua and Enterococcus," Infection Control and Hospital Epidemiology, 24 (May 2003) 5, p. 368.

[xi] Bager, F DANMAP 98: "Consumption of Microbial Agents and Occurrence of Antimicrobials in Bacteria from Food Animals, Food and Humans in Denmark," Copenhagen: Statens Serum Institute, Danish Vetinary and Food Administration, Danish Medicines Agency, Danish Veterinary Laboratory; 1998.

[xii] Verhoef, J., et al, "A Dutch Approach to Methicillin-Resistant *Staphylococcus Aureus*," European Journal of Microbiologyand Infectious Diseases, 1999; 18: 461-466.

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Penn Center for Evidence-based Practice Advisory

MORTALITY FROM REASONABLY-PREVENTABLE HOSPITAL-ACQUIRED INFECTIONS

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Summary

- Survey data from the National Nosocomial Infections Surveillance (NNIS) system, National Hospital Discharge Summary, and American Hospital Association report the incidence of hospital-acquired infections (HAIs) and the mortality resulting from them.
    - In 2002, there were 1.74 million HAIs and 99 thousand attributable deaths.
    - Two-thirds of those deaths are the result of bloodstream infections and ventilator-associated pneumonia.
    - There was a decreasing trend in HAI incidence from 1975 to 2002.
- An Agency for Healthcare Research and Quality (AHRQ) report published in 2007 surveyed the evidence on various interventions to reduce HAIs.
    - The AHRQ reviewers found that the quality of evidence was low, and that there was little consistency in patient populations and interventions examined. Therefore, they did not combine the results of the studies into a single numeric result estimating the ability of interventions to reduce HAIs.
- We used the 2002 estimate of HAIs and resulting deaths from the NNIS survey and the range of HAI reductions observed in the AHRQ report to calculate the number of preventable HAIs and HAI deaths per year:
    - Bloodstream infections: 18%–82% of infections preventable, 5,520–25,145 preventable deaths per year
    - Ventilator-associated pneumonia: 46%–55% of infections preventable, 13,667–25,537 preventable deaths per year
    - Urinary tract infections: 17%–69% of infections preventable, 2,225–9,031 preventable deaths per year
    - Surgical site infections: 26%–54% of infections preventable, 2,133–4,431 preventable deaths per year
- There is considerable uncertainty in these figures because of the numerous assumptions going into them. One should not base policy decisions on these figures without understanding the sources of uncertainty.

Background

To inform policy discussions regarding the reduction of infections in hospitals, the Center for Evidence-based Practice at the University of Pennsylvania Health System was asked to estimate the number of annual deaths in U.S. hospitals from reasonably-preventable cases of hospital-associated infections (HAIs), particularly bloodstream infections (BSI) and ventilator-associated pneumonia (VAP).

Methods

An accurate estimation of this figure requires accurate estimates of two underlying figures: the current total of annual deaths from HAIs and the proportion of these deaths that are "reasonably preventable." Uncertainty in either of these components will necessarily lead to uncertainty in the final estimate.

A best-evidence approach was used to obtain the source data for this calculation. To estimate the number of HAIs and resulting mortality, we used estimates from the National Nosocomial Infections Surveillance (NNIS) system, National Hospital Discharge Summary, and American Hospital Association as reported by Klevens and colleagues.(1) To estimate the proportion of HAIs that could be prevented, we used the estimates of HAI risk reductions resulting from quality improvement strategies as reported in an Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) report.(2) Given the limited quality of the studies reviewed by the AHRQ report, we only used HAI risk reductions reported from US studies that were graded as good quality by AHRQ, and that examined risk reductions in BSI, VAP, urinary tract infections (UTI) and surgical site infections (SSI). When there were fewer than three studies that met these criteria, we also included studies graded as moderate quality.

Because the patient populations and interventions tested in the published studies of HAI prevention varied from study to study, it was not appropriate to combine the risk reductions into a single summary estimate. Thus, to calculate a range of possible risk reductions for each HAI, we simply used the highest and lowest infection reductions for each HAI as listed in the AHRQ report. We then multiplied this range of risk reduction for each HAI by the frequency of that HAI as reported by the NNIS survey to calculate a range for the number of preventable infections for each HAI. To estimate a range for the number of preventable deaths for each HAI, we multiplied the risk reduction for each HAI by the reported frequency of deaths for that HAI.

Number of Annual Deaths

A comprehensive estimate of annual incidence of and mortality from hospital-acquired infections was reported by Klevens and colleagues of the Centers for Disease Control and Prevention (CDC) in 2007.(1) (Table 1) This estimate was based on broad surveys of U.S. hospitals so the risk of uncertainty from measuring an unrepresentative sample is low. However, the survey data is from 2002, so changes in infection rates and mortality resulting from improved care practices implemented between 2002 and today are not captured in these figures. If care has improved since that time, the current number of infections and deaths will be lower than observed in 2002. That would continue the trend observed since 1975-76, when the total number of hospital-associated infections estimated by the CDC's SENIC project was 2.15 million. (3) Infection-related deaths were not estimated in that project.

The survey data show that BSI and VAP cause more than two-thirds of the deaths resulting from HAIs, and that they are five times more deadly than the other infections. Thus it may make sense to target these two types of infections first for reduction measures.

Table 1. Hospital-acquired infections in 2002

Type of infection	Number of infections (2002)	Deaths from infections (2002)	% Fatal infections
BSI	248,678	30,665	12.3%
VAP	250,205	35,967	14.4%
UTI	561,667	13,088	2.3%
SSI	290,485	8,205	2.8%
Other	386,090	11,062	2.9%
Total	1,737,125	98,987	5.7%

Data from Klevens (1)

Proportion of Deaths that are Preventable

We based our estimates of the preventability of infection-related deaths on the evidence tables of the AHRQ EPC report. (2) An earlier review by Harbarth and colleagues (4), done in much less detail, has similar findings.

Description of Studies Included in the AHRQ Report

The quality of the evidence base reviewed in the AHRQ report was poor. For example, half of the BSI studies met none or one of the reviewers' three internal validity standards. The AHRQ report divided the before-after studies into "good", "moderate", and "poor" quality categories (Table 2) but did not explain how the categories were defined. They did not grade the quality of controlled and interrupted time series trials.

The AHRQ investigators reported that there was little consistency among patient groups studied or among interventions tested. Therefore they could not perform any quantitative synthesis of the data, and they did not attempt to make a summary estimate of the proportion of infections or deaths that could be considered preventable.

The highest quality studies in the AHRQ report examined interventions to reduce BSI, VAP, UTI and SSI. For prevention of other HAIs, the evidence bases were even weaker and any numeric conclusions are even more speculative.

Table 2. Description of infection prevention studies examined in AHRQ report

Infection type	N	Controlled trials	Time series	Simple before-after studies		
				Good	Moderate	Poor
BSI	19	2	1	6	2	8
VAP	12	0	0	3	4	5
UTI	10	3	0	0	6	1
SSI	28	4	2	1	6	15

Not all studies in this table were used to calculate results, since they did not all report infection results.
Data from AHRQ EPC report (2)

Estimates of Preventable Deaths

Our estimates for the ranges of potential reductions in HAIs are found in the fifth column of Table 3 and the resulting estimates of preventable infections and deaths are found in the seventh and last columns of Table 3 respectively.

There is nothing novel about trying to estimate the number of infections that could be prevented or lives that could be saved if hospitals followed best practices in infection control. The SENIC project made such an estimate in 1975. They considered 30 to 35 percent of most HAIs preventable with effective surveillance and control programs, and 22 percent of pneumonia cases preventable. In a 1985 follow-up survey, they found that only a fraction of those infections were actually being prevented, because many hospitals still had not implemented recommended infection control measures.(5) This was still the case in the present decade.(6) Our estimated ranges of potential reductions in HAIs is in line with the estimates in Kaye's review.(7)

Table 3. Estimates of preventable infections and deaths

Infection type	Number of HAIs*	Number of deaths*	Case fatality rate	Reduction in infection risk with QI programs†	Projected number of infections with institution of QI programs	Estimated number of preventable infections	Projected number of deaths with institution of QI programs	Estimated number of preventable deaths
BSI	248,678	30,665	12.3%	18%–82%	44,762-203,916	44,762–203,916	5,520–25,145	5,520–25,145
VAP	250,205	35,967	14.4%	38%–71%	72,559–155,127	95,078–177,646	10,430–22,300	13,667–25,537
UTI	561,667	13,088	2.3%	17%–69%	174,117–466,184	95,483–387,550	4,057–10,863	2,225–9,031
SSI	290,485	8,205	2.8%	26%–54%	133,623-204,959	75,526–156,862	3,774–6,072	2,133–4,431

HAI–hospital-acquired infection

QI–quality improvement

*–NNIS 2002 estimates

†–Range from US based QI studies of good or moderate quality in AHRQ report

Limitations

There is considerable uncertainty in our estimate of preventable HAI-related deaths. Uncertainty stems from both the component numbers and the calculation itself. Here we discuss some of those sources of uncertainty.

Number of deaths caused by HAIs

While our estimate of the number of annual deaths caused by HAIs is based on a broad national survey, that survey data is more than five years old. It does not reflect improvements in infection control practice that hospitals have implemented since the time of the survey. The true number of annual HAI deaths at present may be lower. The estimate of HAI-related deaths is also uncertain because there is no definite way to attribute a death to HAI. Patient deaths frequently have multiple causes, and there exists a blurred line between a patient whose death was caused by an HAI and a patient with an HAI whose death was due to another cause.

Proportion of HAIs that are preventable

The key uncertainty in the estimate of preventable HAIs is the limited quality of the HAI reduction studies. In particular, none of the studies are randomized, and few of the studies are controlled, so the validity of the risk reductions reported are limited, and may be exaggerated. For example, most of the studies are of a simple before-after study design, comparing outcomes after the HAI intervention was implemented in a patient population with results from the same population during a time period prior to the HAI intervention. This study design cannot control for other changes in patient care that took place between the control period and the experimental period, making it difficult to attribute the results reported in the study to the study intervention rather than to random variation, patient selection, or other uncontrolled variables, like changes in staffing structures or the implementation of other quality/safety initiatives.

In addition, some of the published studies date back a decade or more, so the infection control practices used in them may have already been implemented at some hospitals, making large HAI reductions less likely in today's hospitals. Another source of uncertainty is generalizing from the results of specialized study populations like the ICU population to more general populations like a general hospital ward.

Number of HAI-caused deaths that are preventable

The key uncertainty here is the fact that we are not estimating preventable deaths from studies that have directly measured death as an outcome. Instead, we are extrapolating reductions in death from the above estimates of reductions in HAIs, and these above estimates have their own limitations. In addition, in multiplying the estimated fraction of HAIs that are preventable by the fatality rate for a given HAI, we assume that the fatality rate for preventable infections is the same as the rate for those infections that weren't prevented. The true effect on deaths could be larger or smaller, depending on the extent to which preventive measures affect the severity of HAIs and the extent to which preventive measures work for the kinds of patients who are more susceptible to fatal HAIs.

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Evidence Tables

Table 4. BSI prevention studies reviewed by AHRQ suggest an 18 to 82% reduction in BSIs depending on the intervention and population examined

Author, Year	Study Design	Setting	Intervention	Comparison	Risk before intervention	Risk after intervention	Risk Reduction
Provonost, 2006	Interrupted time series	ICU patients (United States)	***Preventive:*** Hand hygiene; maximum sterile barrier; insertion site selection; chlorhexidine disinfection; removal of unnecessary catheters ***QI:*** Clinician education, audit and feedback, clinician reminder, organizational change	Previous care	7.7 per 1,000 catheter days	1.4 per 1,000 catheter days	82%
Higuera, 2005	Before-after study	ICU patients (Mexico)	***Preventive:*** Hand hygiene ***QI:*** Clinician education, audit and feedback, organizational change	Previous care	46.3 per 1,000 catheter days	19.5 per 1,000 catheter days	58%
Berenholtz, 2004	Controlled before-after study	ICU patients (United States)	***Intervention:*** ***Preventive:*** Hand hygiene; maximum sterile barrier; insertion site selection; chlorhexidine disinfection; removal of unnecessary catheters ***QI:*** Clinician education, audit and feedback ***Control:*** Clinician education only	Previous care	Intervention 11.3 per 1,000 catheter days	Intervention 0 per 1,000 catheter days	100%
					Control 5.7 per 1,000 catheter days	Control 1.6 per 1,000 catheter days	82%
Coopersmith, 2004	Before-after study	ICU patients (United States)	***Preventive:*** Hand hygiene; maximum sterile barrier; insertion site selection ***QI:*** Clinician education	Previous care	3.4 per 1,000 catheter days	2.8 per 1,000 catheter days	18%
Warren, 2004	Before-after study	ICU patients (United States)	***Preventive:*** Hand hygiene; maximum sterile barrier; insertion site selection ***QI:*** Clinician education, audit and feedback	Previous care	9.4 per 1,000 catheter days	5.5 per 1,000 catheter days	42%
Warren, 2003	Before-after study	ICU patients (United States)	***Preventive:*** Maximum sterile barrier; insertion site selection ***QI:*** Clinician education, audit and feedback	Previous care	4.9 per 1,000 catheter days	2.1 per 1,000 catheter days	57%
Coopersmith, 2002	Before-after study	ICU patients (United States)	***Preventive:*** Hand hygiene ***QI:*** Clinician education, audit and feedback	Previous care	10.8 per 1,000 catheter days	3.7 per 1,000 catheter days	66%
Eggimann, 2000	Controlled before-after study	ICU patients (Switzerland)	***Intervention:*** ***Preventive:*** Hand hygiene; maximum sterile barrier; chlorhexidine disinfection; removal of unnecessary catheters ***QI:*** Clinician education ***Control:*** No additional measures	Previous care	Intervention (MICU) 11.3 per 1,000 catheter days	Intervention 3.8 per 1,000 catheter days	67%
					Control (SICU) 10.3 per 1,000 catheter days	Control 11.6 per 1,000 catheter days	–13% (increase)
Sherertz, 2000	Before-after study	ICU patients (United States)	***Preventive:*** Hand hygiene; maximum sterile barrier ***QI:*** Clinician education	Previous care	4.51 per 1,000 catheter days	2.92 per 1,000 catheter days	35%

Table 5. VAP prevention studies reviewed by AHRQ suggest a 38 to 71% reduction in VAPs depending on the intervention and population examined

Author, Year Quality	Study Design	Setting	Intervention	Comparison	Risk before intervention	Risk after intervention	Risk reduction
Good quality							
Babcock, 2004	Before-after study	ICU patients (United States)	***Preventive:*** Hand hygiene; HOB>30°; daily interruption of sedation ***QI:*** Clinician education	Previous care	8.75 per 1,000 ventilator days	4.74 per 1,000 ventilator days	46%
Zack, 2002	Before-after study	ICU patients (United States)	***Preventive:*** HOB>30° ***QI:*** Clinician education	Previous care	12.6 per 1,000 ventilator days	12.6 per 1,000 ventilator days	55%
Moderate quality							
Rosenthall, 2006	Before-after study	ICU patients (Argentina)	***Preventive:*** Hand hygiene ***QI:*** Clinician education, audit & feedback	Previous care	51.3 per 1,000 ventilator days	35.5 per 1,000 ventilator days	31%
Salahuddin, 2004	Before-after study	ICU patients (Pakistan)	***Preventive:*** Hand hygiene, HOB>30° ***QI:*** Clinician education, audit & feedback	Previous care	13.2 per 1,000 ventilator days	6.5 per 1,000 ventilator days	51%
Lai, 2003	Before-after study	ICU patients (United States)	***Preventive:*** HOB>30° ***QI:*** Clinician education, audit & feedback	Previous care	SICU: 45.1 per 1,000 ventilator days	SICU: 27.9 per 1,000 ventilator days	38%
					MICU: 22.4 per 1,000 ventilator days	MICU: 11.6 per 1,000 ventilator days	48%
Kelleghan, 1993	Before-after study	Not reported (United States)	***Preventive:*** Hand hygiene, HOB>30° ***QI:*** Clinician education, audit & feedback	Previous care	17 per 1,000 ventilator days	5 per 1,000 ventilator days	71%

Table 6. UTI prevention studies reviewed by AHRQ suggest a 17 to 69% reduction in UTIs depending on the intervention and population examined

Author, Year	Study Design	Setting	Intervention	Comparison	Risk before intervention	Risk after intervention	Risk reduction
Good quality							
Huang, 2004	Before-after study	ICU patients (Taiwan)	***Preventive:*** Removal of unnecessary urinary catheters ***QI:*** Clinician reminder	Previous care	11.5 per 1,000 catheter days	8.3 per 1,000 catheter days	29%
Greco, 1991	Before-after study	ICU patients (Italy)	***Preventive:*** Aseptic insertion and catheter care ***QI:*** Audit and feedback, clinician education, clinician reminder	Previous care	12.9 per 100 catheters	11.9 per 100 catheters	8%
Moderate quality							
Topal, 2005	Before-after study	Ward patients (United States)	***Preventive:*** Reduction in placement of catheters, removal of unnecessary catheters ***QI:*** Clinician education, clinician reminder, organizational change	Previous care	36 per 1,000 catheter days	11 per 1,000 catheter days	69%
Rosenthal, 2004	Before-after study	ICU patients (Argentina)	***Preventive:*** Hand hygiene, aseptic catheter care ***QI:*** Audit and feedback, clinician education	Previous care	21.3 per 1,000 catheter days	12.4 per 1,000 catheter days	42%
Dumigan, 1998	Before-after study	ICU patients (United States)	***Preventive:*** Aseptic insertion and catheter care, removal of unnecessary catheters ***QI:*** Clinician education, organizational change	Previous care	SICU: 10.3 per 1,000 catheter days	8.6 per 1,000 catheter days	17%
					MICU: 15.8 per 1,000 catheter days	11.2 per 1,000 catheter days	29%
					CICU: 15.1 per 1,000 catheter days	8.3 per 1,000 catheter days	45%

Table 7. SSI prevention studies reviewed by AHRQ suggest a 26 to 54% reduction in SSIs depending on the intervention and population examined

Author, Year	Study Design	Setting	Intervention	Comparison	Risk before intervention	Risk after intervention	Risk reduction
Good quality							
Van Kasteren, 2005	Interrupted time series	Not reported (Netherlands)	***Preventive:*** Appropriate use of perioperative antibiotics ***QI:*** Audit and feedback, clinician education, clinician reminder	Previous care	5.4%	4.6%	15%
Gastmeier, 2002	Controlled study	ICU (Germany)	***Preventive:*** Hand hygiene, appropriate use of perioperative antibiotics, decreasing use of preoperative shaving, improving perioperative glucose control ***QI:*** Audit and feedback, clinician education	Previous care	2.2%	1.6%	26%
Weinberg, 2001	Interrupted time series	Not reported (Columbia)	***Preventive:*** Appropriate use of perioperative antibiotics ***QI:*** Audit and feedback, organizational change	Previous care	Hospital A: 10.5%	0%	100%
					Hospital B: 6.1%	4.4%	28%
Greco, 1991	Before-after study	ICU (Italy)	***Preventive:*** Appropriate use of perioperative antibiotics, decreasing use of preoperative shaving ***QI:*** Audit and feedback, clinician education, clinician reminder	Previous care	7.8%	6.2%	21%
Moderate quality							
Dellinger, 2005	Before-after study	Not reported (United States)	***Preventive:*** Appropriate use of perioperative antibiotics, decreasing use of preoperative shaving, improving perioperative glucose control ***QI:*** Audit and feedback, clinician education, clinician reminder	Previous care	2.3%	1.7%	26%
Borer, 2004	Before-after study	Operating room (Israel)	***Preventive:*** Hand hygiene, appropriate use of perioperative antibiotics, decreasing use of preoperative shaving, improving perioperative glucose control ***QI:*** Clinician education	Previous care	4.2%	0%	100%
Lutarewych, 2004	Before-after study	Not reported (United States)	***Preventive:*** Improving perioperative glucose control ***QI:*** Audit and feedback, clinician education, patient education	Previous care	7.58%	3.47%	54%
Rao, 2004	Before-after study	Not reported (United States)	***Preventive:*** Appropriate use of perioperative antibiotics, decreasing use of preoperative shaving, improving perioperative glucose control ***QI:*** Clinician education, clinician reminder	Previous care	2.1%	1.5%	29%
Won, 2004	Before-after study	Not reported (Taiwan)	***Preventive:*** Hand hygiene ***QI:*** Clinician education, audit and feedback	Previous care	0.33 per 1000 patient days	0.84 per 1000 patient days	−154% (increase)
Larsen, 1989	Before-after study	Operating room (United States)	***Preventive:*** Appropriate use of perioperative antibiotics ***QI:*** Audit and feedback, clinician reminder	Previous care	1.1%	0.7%	36%