PUBLIC REPORTING OF HOSPITAL-ACQUIRED INFECTION RATES: EMPOWERING CONSUMERS, SAVING LIVES

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BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

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PUBLIC REPORTING OF HOSPITAL-ACQUIRED INFECTION RATES: EMPOWERING CONSUMERS, SAVING LIVES

WEDNESDAY, MARCH 29, 2006

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:00 p.m., in Room 2322 of the Rayburn House Office Building, Hon. Ed Whitfield (chairman) presiding.

Members present: Representatives Ferguson, Burgess, Barton (ex officio), Stupak, DeGette, Inslee, Murphy, and Whitfield.

Staff present: Andrew Snowdon, Counsel; Mark Paoletta, Chief Counsel for Oversight and Investigations; Mike Abraham, Legislative Clerk; Edith Holleman, Minority Counsel; and Elizabeth Ertel, Minority Professional Staff Member.

MR. WHITFIELD. Good afternoon, and I am going to call this hearing to order.

As you know, the title of today's hearing is "Public Reporting of Hospital-Acquired Infections Rates: Empowering Consumers and Saving Lives." Hospital-acquired infections are a significant, yet largely unnoticed public health crisis in our country. The costs of hospital-acquired infections are staggering, not just in financial terms, but also in terms of human suffering. Every year, nearly two million people pick up infections in hospitals, and 90,000 of them die from those infections, more than die from breast cancer or automobile accidents.

Numbers that large are almost incomprehensible and they often become just another statistic, but as we will hear from our first witness, Mr. Raymond Wagner, each and every hospital-acquired infection represents a real human being, and I hope that fact will remain front and center as we discuss this important and complex issue.

The question, then, isn't whether something needs to be done about hospital infections, but what should be done? Today's hearing will examine one approach to this oppressing problem. Many States have recently passed laws requiring public reporting of hospital infection rates, believing that public accountability will drive change. To date, 6

States have passed public reporting laws, and some 20 to 30 others have legislation pending.

The public reporting train has left the proverbial station, so collectively, we need to figure out how to make public reporting as effective and fair as possible. A patchwork of State reporting laws presents both a challenge in terms of differing standards and requirements, but also an opportunity. Uniform national standards might ultimately be appropriate, but in the meantime, these State efforts serve as an excellent laboratory to identify the best practices.

On a personal note, I feel strongly that consumers should have the right to know how hospitals measure up on this important issue. Transparency has been a fundamental theme of this committee's healthcare work, and hospital infections are no different.

To steal a line from Dr. Haley, one of the witnesses here today, "What gets measured, gets done." I hope that this hearing will shine a spotlight on hospital-acquired infections and provide an opportunity to obtain diverse perspectives on how best to confront the crisis. This is not a simple issue.

While everyone supports the concept of public reporting, the devil truly is in the details. As States move forward with legislation and the Federal government considers its role in this arena, complexities such as consistency in compliance and variations among patient populations, also known as the "our patients are sicker" defense, will have to be addressed.

We certainly are not going to resolve all of these thorny issues this afternoon, but perhaps we can identify some common ground that will serve as a meaningful starting point. Throughout this process, however, all parties involved, from legislators to hospitals to consumer groups to insurers to standard organizations, must be careful not to allow details to derail the ultimate goal of public reporting and transparency, reducing the number of hospital-acquired infections. There are too many lives at stake to permit the perfect to be the enemy of the good.

I want to thank all of the witnesses who have agreed to participate in today's hearing. As I mentioned earlier, the first witness will be Ray Wagner, whose teenage son got a serious staph infection after undergoing surgery for a broken arm. Determined to prevent other families from going through the same horrible experience, Mr. Wagner was instrumental in the passage of Missouri's public reporting law.

We will also hear from the Centers for Disease Control about what the Federal government has done to track and report hospital infections, and finally, we will hear from the experts on our third panel about the advantages of and concerns about public reporting, as well as the tremendous successes that some of these people have had in reducing hospital-acquired infections.

I am especially interested in hearing from several hospital representatives, since they are on the very front line battling this crisis on a daily basis. I look forward to a lively and informative hearing this afternoon, and once again, I want to thank all of the witnesses. We know it takes a lot of time and effort for you to appear, but we do value your input.

[The prepared statement of Hon. Ed Whitfield follows:]

PREPARED STATEMENT OF THE HON. ED WHITFIELD, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Hospital-acquired infections are a significant, yet largely unnoticed, public health crisis in this country. The costs of hospital-acquired infections are staggering, not just in financial terms, but also in terms of human suffering: every year nearly 2 million people pick up infections in hospitals, and ***90,000 of them die*** -- more than die from breast cancer or automobile accidents. Numbers that large are almost incomprehensible, and they often become just another statistic. But as we will hear from our first witness, Mr. Raymond Wagner, each and every hospital-acquired infection represents a real human being, and I hope that fact will remain front and center as we discuss this important and complex issue.

The question, then, isn't ***whether*** something needs to be done about hospital infections, but ***what***. Today's hearing will examine one approach to this pressing problem. Many states have recently passed laws requiring public reporting of hospital infection rates, believing that public accountability will drive change. To date, six states have passed public reporting laws, and some 20 to 30 others have legislation pending. The public reporting train has left the proverbial station, so, collectively, we need to figure out how to make public reporting as effective and fair as possible. A patchwork of state reporting laws presents both a challenge, in terms of differing standards and requirements, but also an opportunity. Uniform national standards might ***ultimately*** be appropriate, but in the meantime, these state efforts serve as an excellent laboratory to identify the best practices.

On a personal note, I feel strongly that consumers should have the right to know how hospitals measure up on this important issue. Transparency has been a fundamental theme of this Committee's healthcare work, and hospital infections are no different. To steal a line from Dr. Haley, one of the witnesses here today: "What gets measured gets done."

I hope that this hearing will shine a spotlight on hospital-acquired infections and provide an opportunity to get some diverse perspectives on how best to confront this crisis. This is not a simple issue. While almost everyone supports the ***concept*** of public reporting, the devil truly is in the details. As states move forward with legislation -- and the federal government considers its role in this arena -- complexities such as consistency in compliance and variations among patient populations, also known as the "our patients are sicker" defense, will have to be addressed. We certainly aren't going to resolve all of these thorny issues this afternoon, but perhaps we can identify some common ground that will serve as a meaningful ***starting point***.

Throughout this process, however, all parties involved -- from legislatures, to hospitals, to consumer groups, to insurers, to standards organizations -- must be careful not to allow the ***details*** to derail the ***ultimate goal*** of public reporting: reducing the number of hospital-acquired infections. There are too many lives at stake to permit the perfect to be the enemy of the good.

I want to thank all of the witnesses who have agreed to participate in today's hearing. As I mentioned earlier, the first witness will be Ray Wagner, whose teenage son got a serious staff infection after undergoing surgery for a broken arm. Determined to prevent other families from going through the same terrible experience, Mr. Wagner was instrumental in the passage of Missouri's public reporting law. We will also hear from the CDC about what the federal government has done to track and report hospital infections. Finally, we will hear from the experts on our third panel about the advantages of, and concerns over, public reporting, as well as the tremendous successes that some of these people have had in reducing hospital-acquired infections. I am especially interested in hearing from several hospital representatives, since they are at the front line, battling this crisis on a daily basis.

I look forward to a lively and informative hearing this afternoon. With that, I turn to Mr. Stupak, the Ranking Member of this Subcommittee, for his opening remarks.

MR. WHITFIELD. At this time, I would like to recognize Mr. Stupak, the Ranking Member of this subcommittee for his opening remarks.

MR. STUPAK. Thank you, Mr. Chairman, and thank you for holding this hearing on a topic of immense importance to the American public.

Most of us have either been in a hospital or had family or friends in a hospital. We all know that in recent years, there has been a growing and real sense among the public that you should get out of the hospital as soon as possible to avoid getting a hospital-acquired infection.

The Centers for Disease Control estimates that 90,000 patients die every year from hospital-acquired infections, and that 75 percent of them are preventable deaths. Over 80 percent of these deaths each year could be prevented. The human loss is tragic and unacceptable. The economic loss is staggering. In Pennsylvania alone, the additional costs of treating these infections is $2 billion.

Perceiving a lack of will from the healthcare industry, consumer advocates have launched legislative and public information campaigns to demand that hospitals clean up their acts, so to speak, and publicly report their infection rates. However, reporting is only one of the many tools worthy of examination. Reporting alone will not reduce infections.

Although CDC has been collecting data from a small group of hospitals for over 30 years, it has not been able to stop the epidemic of hospital-acquired infections. Reducing hospital infection rates requires more than agreeing on definitions of what a hospital-acquired infection is. It requires process changes: process changes in hospital cleanliness, in the insertion of central lines, in the operating rooms where surgical site infections occur, and in the treatment of patients on ventilators. More importantly, it requires commitment and enforcement at the top levels of hospital administration: the full cooperation of doctors, nurses, and surgeons; a good hospital training program; and clear action plans that have real results.

Two of our witnesses today are from Michigan, and one is from Pennsylvania. They will demonstrate what can be done when hospitals

decide to act. Lives are saved and healthcare costs are reduced. I am particularly proud of the work done by Michigan hospitals through the Keystone Center for Patient Safety and Quality. Ms. Chris Goeschel is here today representing Michigan's efforts without public reporting and with very little public money. Ms. Goeschel will also point out how much this country spends on developing new healthcare technologies, and how little this country spends on actually improving the delivery of healthcare. Fortunately, many nonprofit groups are working on changing processes in hospitals. Consumers Union provides a checklist for persons undergoing surgery to discuss with their doctors. The Institute for Healthcare Improvement, sponsored by private foundations, set up a project with 14 hospitals that reduce ventilator associated pneumonia, a leading killer in hospital-acquired infections, to zero for an entire year.

The hospitals implemented simple procedures, such as raising the head of patients. The project has now been expanded to 3,000 hospitals as part of their campaign to save 100,000 lives by implementing evidence-based preventative care for not only ventilator associated pneumonia, but also surgical site and central line infections.

At a time when our country is facing a healthcare crisis, we must act now. These infections cost lives and billions of dollars in healthcare costs in untold amounts to the larger economy. There is no more time for excuses. Hospitals, government agencies, and legislators cannot sit back and allow this unacceptable trend of increased hospital infections to continue. I hope this hearing will advance the discussion and shine light on this important consumer and health issue.

With that, Mr. Chairman, I yield back the balance of my time.

MR. WHITFIELD. Thank you, Mr. Stupak.

At this time, I recognize Dr. Burgess of Texas for his five-minute opening statement.

MR. BURGESS. Thank you, Mr. Chairman, and thank you for holding this hearing today. I want to give a special welcome to two North Texans who were gracious enough to travel here to Washington, D.C. to testify with us today, Dr. Jennifer Daley and Dr. Robert Haley. Dr. Jennifer Daley is the Senior Vice President and the Chief Medical Officer at Tenet Healthcare Corporation in Dallas, while Dr. Haley is with the Division of Epidemiology at Southwestern Medical School and the University of Texas Southwestern Medical School in Dallas. Dr. Haley also has the distinction of being the individual who cracked the code and solved the riddle of Gulf War Syndrome as being a pseudo-cholodestrates deficiency, and we were all very grateful for your work in that endeavor, Dr. Haley. Of course, Southwestern Medical School, as everyone in Washington knows, is one of the premier medical institutions in the Nation. I don't need to tell this committee that. I am

proud to have an established healthcare fellowship program in my office, and my healthcare fellow is with us today. Dr. Daley and Dr. Haley, thank you both very much for being here and spending some time with us today.

I was Chief of Staff at Lewisville Medical Center in Lewisville, Texas, back in the '90s, and I understand all too well the dangers of those communal infections. There are many thousands of people each year who suffer and in fact die because of infections they contract while staying in a hospital, but I also understand the difficulties involved with managing these situations. In fact, I remember as in intern at Parkland Hospital we were not allowed to use what were called prophylactic antibiotics, and someone pointed out one day that our C-section infection rate was so high everyone got sick, so it wasn't really prophylactic antibiotics, it was early treatment. Once we switched to early treatment, we were able to save a lot of patients serious morbidity and possibly even mortality.

As Members of Congress, it is our duty to utilize our effective oversight methods to ensure that the healthcare needs are adequately met and that patients have the tools available to them to make informed decisions, and this degree of transparency is something that I think we need to really establish.

But again, Mr. Chairman, I thank you for holding this hearing in which we can address some of these important concerns relating to hospital-acquired infections. It is not an easy subject and there are not any absolutely right or absolutely wrong answers, but it behooves us to direct our time and attention to this matter. And with that, I will yield back the balance of my time.

MR. WHITFIELD. At this time, I recognize the gentleman from Washington, Mr. Inslee, for his opening statement.

MR. INSLEE. Thank you. One of the things that has really impressed me about this subject and others is how often using existing technology can be so supremely effective, you know. I know everybody has been associated with a hospital and knows about all the new technology we have, but using existing technology can be so effective.

I was just reading in the Washington Post this morning about Allegheny General Hospital found that they had this problem with intravenous infections, or at least they perceived improvements could be made, and they standardized procedures, investigated every single infection in 24 hours. They cut their annual infections from 49 to three. They reduced their deaths from 19 to one. They slashed their infections from ventilators from 45 to eight, just by using standardized procedures of well-known techniques, not inventing a new gizmo or a new medical device, just by using what is known. It is so impressive of the results

that can be attained, so I hope out of this hearing we have some ways to help hospitals and consumers spare this, because I think consumers can be a pretty effective incentive for all of us to continue to improve.

Thanks for holding this hearing, Mr. Chairman.

MR. WHITFIELD. Thank you, Mr. Inslee. At this time, the Chairman of the Committee of Energy and Commerce is here, and we will recognize Chairman Joe Barton of Texas for his opening statement.

CHAIRMAN BARTON. Thank you, Mr. Chairman, and I want to thank you for holding this hearing. There is so much going on today that it is probably not going to get the attention it deserves, but there is no more important hearing in the Congress today than this one that we are about to undertake.

When people check into the hospital, they hope and expect to leave better off than when they checked in, but unfortunately, some of the people that check in pick up an infection and they are lucky to check out, or very unfortunately, some never do. Hospital-acquired infections are a serious and growing problem, and I want to thank you for agreeing to hold a hearing to shine the spotlight on this problem.

Two weeks ago, the Health Subcommittee heard about pricing transparency in the health market. During that hearing, I said that the term "healthcare market" is an oxymoron because the current system prevents consumers from making informed choices by denying them access to relevant information. I want to add today that the quality of healthcare is at least as murky as its cost. We don't know which hospitals are safe and successful anymore than we know how much they charge. I believe consumers should have the right to find out just how well their hospitals perform. We demand safety information when we buy a car or a child safety seat. It is baffling that we would accept less when it comes to something as important as our health in our hospitals.

I hope that this is beginning to change. A half dozen States have passed laws requiring hospitals to publicly report their infection rates, and more than 20 others, including my State of Texas, are considering similar legislation. I applaud these efforts, but it seems likely that a patchwork of 50 different State reporting laws might confuse consumers and burden hospital systems operating in more than one State. I am also mindful of the fact that this is not a simple issue, and I expect that we are going to hear this afternoon some of the concerns and complexities associated with public reporting.

I do believe, though, that transparency and public scrutiny create pressure to improve. Pressure comes from a variety of sources: it comes from the peers in the medical community, of course, but it also comes from the employers, the Federal government, and private insurers who don't want to pay top dollar for substandard care. To some extent, it

comes from the individual patients like me. Back in December I had a heart attack. I was taken to the emergency here in Washington, D.C., at a local hospital. I can promise you that at that time, the specific topic of infection rates was not at the top of my mind, but I was never more interested in the general topic of quality.

I will give an example. The doctor here in the Capitol, when he told me that I was having a heart attack, he asked if I had a cardiologist. Well, obviously, I didn't have a cardiologist, so as we were speeding in the ambulance, my Chief of Staff, Bud Albright, and my personal assistant, Ryan Thompson, they actually got to the hospital a little bit before the ambulance did, which was amazing. They go into the emergency room and they start asking about cardiologists. Mr. Albright said "do you all recommend a cardiologist?" And the emergency room doctor said "we can't recommend anybody." And Bud said, "isn't this where Vice President Cheney had his heart operation?" And the emergency room doctor said "yes." Bud said "we want his doctor." And that's who we got.

MR. BURGESS. That's why they sedated you during your procedure, by the way.

CHAIRMAN BARTON. So I was very interested in the quality when I went into the emergency room with my heart attack.

My presence here today at this hearing is evidence that I found a lot of quality in the staff at the hospital here in Washington, D.C., and in their practice of medicine, and I am very thankful to those people for all that they did for me and they have done for hundreds, if not thousands, of others. I didn't really have a choice. I had to see a doctor and I had to have an operation. If I were choosing today to submit to elective surgery, I think I would want to know a little bit more about the hospital, and I would want to know a little bit more about the infection rates and things like that. It seems to me that there is no better indicator of poor quality than hospitals which in and of themselves might make people sick.

I want to express my thanks to the witnesses for being here this afternoon. I am especially anxious to hear from Dr. Haley about the status of the Texas reporting law. I look forward to learning from these distinguished experts how we can stem the tide of hospital-acquired infections and make sure the consumers get the information that they need to make informed healthcare decisions.

Again, Mr. Chairman, thank you for holding this hearing.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

When people check into the hospital, they hope and expect to leave better off than they arrived. But some of the millions of Americans who pick up infections in hospitals each year are lucky to check out, and a few never do. Hospital-acquired infections are a serious and growing problem in this country, and I want to thank Chairman Whitfield for shining a spotlight on them.

Two weeks ago, the Health Subcommittee heard about pricing transparency in the health care market. During that hearing, I said that the term "health care market" is an oxymoron in this country because the current system prevents consumers from making informed choices by denying them access to relevant information. I want add today that the ***quality*** of health care is at least as murky as its cost. We don't know which hospitals are safe and successful any more than we know how much they charge. I believe consumers should have the right to find out just how well their hospitals perform. We demand safety information when we buy a car or child safety seat, so it is baffling that we would accept less when it comes to something as important as our health.

I hope that this is starting to change. A half-dozen states have passed laws requiring hospitals to publicly report their infection rates, and more than 20 others, including Texas, are considering similar legislation. While I applaud these efforts, it seems likely that a patchwork of 50 different state reporting laws might confuse consumers and burden hospital systems operating in more than one state. I am also mindful of the fact that this is not a simple issue, and I expect that we will hear this afternoon some of the concerns and complexities associated with public reporting.

Having said that, I firmly believe that transparency and public scrutiny create pressure to improve. This pressure comes from a variety of sources. It comes from peers in the medical community, of course, but it also comes from large employers, the federal government, and private insurers who don't want to pay top dollar for substandard care. And, to some extent, it comes from individual patients, like me.

Back in December, I had a heart attack and was taken to the emergency room at a local hospital. I can promise you that at that time, the specific topic of infection rates was not in the front of my mind, but I've never been more interested in the general topic of quality. My presence here today is evidence that I found a lot of it in the staff and practices at George Washington Hospital that night. That's good, because I had no choice. If I were choosing today to submit to elective surgery, however, I'd want to know a lot about a hospital's infection rate. It seems to me that there is no better indicator of poor quality than hospitals which make people sick.

I want to express my thanks to the witnesses for being here this afternoon. I am particularly anxious to hear from Dr. Haley about the status of the Texas reporting law, and I look forward to learning from these distinguished experts how we can stem the tide of hospital-acquired infections and make sure that consumers get the information that they need to make informed health care decisions.

MR. WHITFIELD. Thank you, Chairman Barton.

At this time, I recognize the gentlelady from Colorado, Ms. DeGette.

MS. DEGETTE. Thank you very much, Mr. Chairman.

Mr. Chairman, every year, thousands of people are injured or die unnecessarily because of infections that they contract as patients in a hospital. Too often, these are infections that could be easily prevented and in many cases, just making one small change is all it would take to save a life.

Hospitals that have made a commitment to reducing infections have seen substantial benefits, both to patient care and to their bottom line. As this morning's Washington Post noted, though, while the medical community is well aware of the risks of contracting an infection during a hospital stay, we do not have enough quantifiable data to support making necessary changes. The CDC has maintained a database of hospital-acquired infections since the 1970s, but this database only includes data from 300 hospitals. The CDC has recently expanded data collection on hospital-acquired infections through its new National Healthcare Safety Network, but the data remains insufficient to truly understand the problem.

Mr. Chairman, I would suggest that we need to do more to support increased reporting of hospital-acquired infection data, but we also have to ensure that the process by which we collect this data and the method used to disseminate the information are effective. We need to have a standards-based approach to see how hospitals collect data on infections that will enable apples to apples comparisons. If we are going to have an accurate picture of infections throughout the country, the data cannot be ambiguous.

As part of this, we must not forget to include qualifying information on infection data. As some of the witnesses will address in their testimony today, some hospitals may indeed have patients who are unhealthier than on average, and so have greater numbers of co-morbidities. We need to have an infection reporting system that includes collection of this qualifying information so that all hospitals will be judged fairly, and using this qualifying data will also prevent hospitals, in the other direction, hiding behind excuses.

How we report this data is just as important as how the data is collected. Some have suggested that we should aggregate infection data into one collective grade for each hospital. Consumers would compare hospitals in their area then based on overall infection rates. This type of reporting concerns me in that all hospitals provide different services, and aggregation can often be misleading. I believe we need a more sophisticated method of comparing data from hospitals, examining types of infections, so we can get a more complete picture. Having more nuanced reporting will also help Federal agencies to provide needed assistance to hospitals looking to improve infection rates.

At the same time that I support increased data collection of hospital-acquired infections and improved reporting systems, I think this is merely the first step. We need to look at better ways to use this data. Maybe some patients will go online to verify the infection grade when deciding which hospital to select for surgery, although I suspect the Chairman probably didn't have time to go online before he ran over to

the hospital when he had his heart attack. In most cases, patients don't even have a choice when it is non-emergency where they obtain their care. So I don't think that we can rely solely on market forces to improve infection rates. Reducing infection rates must be addressed in a much more comprehensive way.

Correctly reporting and analyzing data is just the first step we need to take before tackling the bigger problem of reducing these infections. And as I am sure we are going to hear from Dr. Shannon later, Allegheny General Hospital was able to reduce bloodstream infections by standardizing procedures and reviewing each case of infection within 24 hours. We need to figure out how to replicate the response to infections that places like Allegheny had. We also need to develop evidence-based best practices that can be utilized by all hospitals to reduce infection rates.

Mr. Chairman, lowering infection rates in hospitals is about a continuum of care. Our system must collect infection data in a standardized format. The data then must be reported to various stakeholders, including patients, in the most effective way possible. We need programs in place to help hospitals employ best practices to lower their infection rates, and finally, we need to examine data over time to verify improvement so that we can make changes where necessary. This is how we will make lasting change. Yes, we need to examine how we report data, but what we really need to do, Mr. Chairman, is to talk about how we can use that data to reduce infections in hospitals.

Thank you.

MR. WHITFIELD. Thank you, Ms. DeGette.

At this time, I recognize Mr. Ferguson of New Jersey for his opening statement.

MR. FERGUSON. Thank you, Mr. Chairman. Thank you for holding this important hearing.

Today is my mom's birthday. She would have been 62 years old today. She died 2 1/2 years ago at 59. She fought bone marrow cancer for six years, and she was in and out of hospitals all the time. For six years, she and our family spent an enormous amount of time--and any one of you who knows has been through that, either yourself or with someone you love--know how much time you spend in a hospital. She had a bone marrow transplant, she had a compromised immune system for better part of five years, and we were constantly in fear that she would contract some sort of illness, an infection of some sort, that would literally kill her. Fortunately, she had great medical care. She was in wonderful hospitals and had professionals who helped her, and she lived 6 years with this disease and got to meet three of her grandkids. It is a great story. She would have been 62 today, so I think about her a lot,

particularly today. But it highlights a very, very important issue, which many, many, many Americans face, sometimes without very good results, and that is why I am very pleased, Mr. Chairman, that you are holding this hearing.

The CDC estimates that two million Americans contract infections during the course of a hospital stay, and 90,000 of them die from the infection that they acquired. In our hospitals today, physicians and nurses are fighting what seems like a never-ending battle against an invisible enemy, and today we are fighting new germs that are resistant to some antibiotics. At the same time, hospitals see the sickest patients, the elderly and the young, whose immune systems, like my mom's, have been compromised and may be more susceptible than yours or mine to germs.

To win this battle, infection control has to be everybody's job. And I remember every time we went into the room to see my mom, we would have to get our anti-bacterial gel and wipe our hands down, and anything else that may have been carrying germs. Hospitals have a long track record of working at preventing infections, and are already reporting infection prevention measures. I believe the information has to be meaningful and has to be comparable. The information shared should focus on infections that have the potential for the greatest consequences to patients, areas where clinically proven prevention efforts exist and areas where good solid data exists.

Today, more than 1,300 hospitals are sharing information about infection prevention on a public website, and in the coming year additional information will be shared specific to surgical infections. Through the Institute for Healthcare Improvements 100,000 Lives Campaign, more than 3,000 hospitals are implementing one or more evidence-based interventions and establishing new standards of care. For example, in my home State of New Jersey, a consortium of 23 teaching hospitals has reduced their bloodstream infection rates by 50 percent, and in their intensive care units, the rate of ventilator-associated pneumonia has been reduced by 75 percent over a 9-month period. This is definitely a step in the right direction, but maybe more can be done, and that is what we have to figure out.

I look forward to hearing from our panels today. Thanks very much to our witnesses all for being here today to help us gain new insights into the best ways that we can track this phenomenon and work in ways to curb its danger.

Thank you, Mr. Chairman. I yield back.

MR. WHITFIELD. Thank you, Mr. Ferguson.

Dr. Tim Murphy is a member of the full Energy and Commerce Committee. He is not a member of the Oversight and Investigations

Subcommittee, but he has had a special interest in hospital infection rates, and I would ask unanimous consent that he be allowed three minutes to give an opening statement, if there is no objection.

Mr. Murphy, you have three minutes.

MR. MURPHY. Thank you, Mr. Chairman. I appreciate the special privilege of being allowed to speak.

You know, if an airplane went down in America today, we would send every Federal agency around to investigate it. If another plane went down tomorrow, we would be alarmed at this. And if a plane went down the next day, we would shut down the airline industry. Curiously enough, more people die in America every day from an infection they may pick up while seeking medical care.

Now, the thing about this is we are facing some 90,000 deaths a year according to the CDC, far more than died in Vietnam. We are facing an enemy that is microscopic, and yet one that we can kill off before it kills us by things as simple as taking some gel and wiping your hands off before you see a patient, making sure supplies and other instruments are cleaned up before we see patients. But oftentimes, that doesn't happen.

When I was visiting a relative in a hospital, I watched someone come in who had gloved and scrubbed before they came in and began to handle this patient's IV line, until I stopped them and asked them to fix it up and to say wash their hands again. It is a concern that happens, and yet despite the deaths, despite the problems, we continue this on too long. Medicare and Medicaid pay billions of dollars a year in this care that we could be preventing, and the loss of life goes on. However, a number of hospitals have done some remarkable things to turn this around. We are going to hear today from Dr. Richard Shannon, the Chair of the Department of Medicine at Allegheny General Hospital, who I greeted over there today as a hero in what he has done to really actively save lives and turn a hospital around.

We will also hear from Mr. Mark Volavka of the Pennsylvania Healthcare Cost Containment Council, who will talk about some research that they have found in Pennsylvania among hospitals that are reported with some of their data to tell us what is going on.

It is a serious concern, and I believe as we look at things that Congress talks about and argues about in the area of healthcare, oftentimes we are talking about who is going to pay for the expensive costs of healthcare. We may argue about health savings accounts or association health plans or single payer having the Government to take over. None of those will work to drive costs down in healthcare like taking care of infection rates. In fact, the issue is so staggering, I wonder why we have not taken action before. I think the action of this committee is courageous in what it is doing. We could actually find all

the savings we are looking for in Medicare and Medicaid if this was the only thing that Congress did for the rest of year. It could actually do a whole lot towards balancing the whole budget and taking care of these issues. That is why I am introducing legislation to establish pay for performance incentives through Medicare to greatly incentivize providers to continue their efforts to reduce infections and save thousands of lives.

So amidst the horror stories that may be out there--we may hear some today--the shining light is that it can be done. I know in hospitals that I worked at, I have seen them turn this system around, and we have a lot to be proud of from what hospitals have done, and we need to find ways of continuing to encourage hospitals around the Nation to do this. I know that some of the VA hospitals have taken the lead on these issues, and you can't go by a room or a hall without finding some sort of dispenser of some sort of alcohol or other gel to make sure you wash and clean up. We also need to be telling patients' families the same thing when they come in to visit.

So, Mr. Chairman, thank you so much for doing this. As we approach this, I hope we are all careful at looking at the methodology of these studies and being able to apply them in a cost-effective and efficient way as we tackle this terrible enemy of infections.

Thank you, Mr. Chairman.

MR. WHITFIELD. Thank you very much.

Today, we have three panels of witnesses, and on the first panel we have Dr.--not doctor, but you probably feel like a doctor by now.

MR. WAGNER. I have begun to.

MR. WHITFIELD. Mr. Raymond Wagner, Jr., who is a Legislative Vice President and Legal Vice President of Enterprise Rent-a-Car, and he is going to relate to us a personal experience that he had with his son, Raymond, and also, we are going to hear from him about his involvement in passing legislation in the State of Missouri on this very topic.

So before we begin, Mr. Wagner, you are aware that the committee is holding an investigative hearing, and when doing so, we have the practice of taking testimony under oath. Do you have any objection to testifying under oath today?

MR. WAGNER. No, Mr. Chairman.

MR. WHITFIELD. And I am assuming that you do not have any legal counsel, so if you would stand I would like to swear you in.

[Witness sworn.]

MR. WHITFIELD. Thank you. You are now sworn in, Mr. Wagner, so if you would turn on your microphone, we look forward to your opening statement.

STATEMENT OF RAYMOND T. WAGNER, JR., LEGAL AND LEGISLATIVE VICE PRESIDENT, ENTERPRISE RENT-A-CAR

MR. WAGNER. Mr. Chairman, members of the committee, thank you for the opportunity to appear before you today. My name is Ray Wagner. I am from St. Louis where I am employed by Enterprise Rent-a-Car, as you stated. I do not appear today as a representative from my company; I appear today as a father.

You heard the statistics in the opening statements, and yet there seems to be a quiet paralysis in the medical and hospital community about what to do about these infections. I appear today before you because my son is one of those nameless, faceless statistics you heard about and you read about all too often today.

On Christmas Eve, 2002, my son Raymond went out to ride his sled and he suffered a break to his left elbow from falling from his sled. He needed surgery. The surgery appeared to go well and Raymond was discharged on Christmas Day, 2002, his 14th birthday. A fever developed and persisted. To make a year-long story very short, Raymond had acquired a staph infection, which developed into osteomyelitis. In total, he endured six additional surgeries and surgical procedures. Raymond spent several weeks in the hospital. He endured bone scans, CAT scans, ultrasounds, countless x-rays, aspirations, hearing tests, kidney tests, just to name a few. He can tell you about one surgery where he was awake with his eyes closed because he was not given enough anesthesia for a boy his size. He remembers every detail of that surgery. Raymond spent many months on a PIC line--with a PIC line threaded up his arm into his chest muscles to inject antibiotics. When his veins collapsed and he could no longer sustain the PIC line, he received a Broviac catheter pump, which was surgically embedded into his chest, again for several months. There were regular visits from the home health professionals for wound cleanings, broken equipment, pulled catheter lines, and concerns of new infections. He managed a very structured antibiotic pill regimen for many months thereafter as well. He spent countless hours in physical therapy to stretch his arm, which had frozen into a right angle.

Of course, Raymond missed school. He missed baseball, swimming, football his freshman year, and lifeguarding that summer. We were devastated each time we learned that the infection had returned and he needed one more surgery. One very poignant moment came as we were talking to the team of doctors over his bed one evening, and one doctor looked at our little boy in his bed and asked if he had any questions. He replied "Yes. Am I going to die from this?" We assured him that he would not die. We would not let that happen. His mother and I looked

at each other; we were not so sure. Raymond next asked "Am I going to lose my arm over this?" And let me show you a brief clip. We will come back to that, but that was Raymond in the hospitals after one of his surgeries.

Today, we believe Raymond's infection is cleared up. We thank God and we consider ourselves to be among the lucky ones. Our son is alive. We spent several thousand dollars in miscellaneous expenses as well associated with Raymond's treatments, including co-pays, deductibles, out-of-pocket, network expenses, un-reimbursed expenses, et cetera. The overall costs to the health system must be staggering, as was alluded to in the opening statements. And of course, we had ongoing battles with certain providers about expenses and coverage which took over two years to resolve. There were also the lost days of work for Raymond's mother and me.

The question which haunted me as a parent was how could this have happened to us? We live in a community with more than a dozen excellent, highly regarded hospitals. How could we have known that the hospital we chose might be more likely to threaten his life? The answer was that we simply could not have known. There was no form of public or non-public reporting of hospital-acquired infections. So Raymond and I started an effort to require public reporting in Missouri. We worked to develop a model bill with the Consumers Union, which had then just undertaken a major initiative to address this subject. We joined forces with a State representative who is also a practicing medical physician. We enlisted the support of the State Hospital Association.

In short, Missouri Senate Bill 1279 requires the Department of Health to make available on their website risk-adjusted infections for certain types of infections, after consulting with an advisory committee and the CDC.

1279 passed the legislature in a single session nearly unanimously. Raymond spent time before the legislature. His story received considerable attention. The bill widely became known as "Raymond's Bill." Lobbyists, legislators, and staff all freely and willingly joined in the effort because of their own experiences. While the effort was predominantly consumer and patient driven, business groups and hospital medical groups ultimately embraced the topic.

I know that it is not as easy as simply reporting raw data on hospital-acquired infections, but to let these doubts and issues overcome any solution or serious effort to address the problem would do a grave injustice to the victims of hospital-acquired infections. The Missouri Department of Health and its advisory committee are addressing the concerns that often are raised. My written statement addresses these in more detail as well. All of these challenges can be overcome by proper

guidance and instruction at the State and Federal level, experience in gathering statistics, and developing reports. I think much can be learned from the growing volume of State experiences.

It has been important for me to underscore that our involvement has never been about assigning any blame or embarrassment to any hospitals. We certainly never considered any legal recourse as a result of Raymond's surgeries. I have never publicly named any of the hospitals or the doctors involved in our case. Our simple goal was to put a spotlight on the growing issue of hospital infections. In my opinion, hospitals were not leading the discussion as they should. This, I believe, is why you see consumers and patients across the country demanding attention on this issue.

I hope and look forward to this committee and Congress studying all approaches under consideration. I urge you, the medical community, and the hospital community to embrace the issue and to earnestly look for solutions with a level of commitment that they have not shown to date. This effort needs their expertise. Please include individual consumers in the process, people such as myself who have been touched by hospital-acquired infections. This effort needs their motivation. Together, I believe we can make huge advances so that other hospital patients do not have to become a statistic like my son Raymond.

Mr. Chairman, thank you, and with the Chairman's permission, I would like to attach to my statement a statement from my son who could not be with us today, and he has a brief video which, with your permission, I could show right now.

[The prepared statement of Raymond T. Wagner, Jr. follows:]

PREPARED STATEMENT OF RAYMOND T. WAGNER, JR., LEGAL AND LEGISLATIVE VICE PRESIDENT, ENTERPRISE RENT-A-CAR

Chairman Barton, Chairman Whitfield, Members of the Committee,

Thank you for the opportunity to appear before you today to speak about this very serious issue of hospital-acquired infections.

My name is Ray Wagner. I am from St. Louis, Missouri. I am employed by Enterprise Rent-A-Car where I serve as the Government Relations and Legislative Vice-President. However, I do not appear before you today as a representative from my company. I appear before you today as a father.

I thank this Committee for involving itself in this issue. As you will undoubtedly learn, this growing phenomenon of hospital-acquired infections is reaching epidemic proportions. It is time that state and Federal policy makers undertake a comprehensive, and even coordinated, look at these infections. The Center for Disease Control has estimated that 90,000 deaths per year are caused from hospital infections. Nearly 3/4 of the deadly infections or about 75,000 were preventable according to the CDC, the result of unsanitary facilities, germ-laden instruments, unwashed hands, and other lapses in hospital practices. Astoundingly, deaths linked to hospital germs represent the fourth leading cause of mortality among Americans, behind major heart disease, cancer and lung ailments according to recent studies. These infections kill more people each year than

motor vehicle accidents, fires and drownings combined. In addition, according to Consumers Union, one in 20 hospital patients will get an infection while being treated for an unrelated health care problem, thus translating to almost two million patients each year. And yet, it seems there has been a quiet paralysis in the medical and hospital community about what to do about this problem.

I appear before you because my family is one of these statistics. My son is one of those nameless, faceless statistics which we read about all too often with increasing frequency on an almost daily basis.

I will begin by telling you a bit about the nosocomial infection or staphylococcus aureus infection which infected my son, Raymond Wagner III. Today, Raymond is a healthy junior in high school. He is an honor student, currently studying in Europe at the International School of Luxembourg while my wife is working in Luxembourg for the time being. Raymond wishes he could be here, but that is not possible under the circumstances. On his behalf, I have submitted his brief statement for the record. And, with the Chairman's permission I have a brief video which I would like to show at the end of my remarks.

On Christmas Eve, December 24, 2002, the day before Raymond's 14th birthday, we had a beautiful snow fall in St. Louis. That afternoon, Raymond, then 13, went out to ride his sled behind our house with some friends. While he was playing, he suffered a serious break to his left humorous bone from falling off his sled as he was coming down the hill. When his brother raced in to tell us about the accident and I saw Raymond moments later, I knew instantly that we had a problem. We put him in the car. I drove him on the snow-covered roads to a local hospital. Once in the hospital, pain medication was administered and X-rays were taken. As was immediately clear from the X-rays, the orthopedic surgeon on call explained that he would need surgery on his left arm due to the seriousness of the break.

After consulting with his pediatrician, we calmly and coolly determined to move him in an ambulance to a <u>different hospital</u> where he would be attended to by a more experienced surgeon specializing in pediatric, orthopedic surgeries. His surgery appeared to go well, although he received a screw and two pins in the area of his elbow. Raymond was discharged the next morning, on Christmas day, also his 14th birthday.

In the following days, a fever developed and persisted. There were several immediate trips to the hospital where we were told that such a fever was normal following such a traumatic break. To make a nearly year long story very short, Raymond had acquired staph infection which also developed into osteomyelitis, meaning the infection had burrowed into his bones. In total, he endured six additional surgeries and surgical procedures following the initial surgery. All of this, we firmly believe resulted from his broken arm. It was a serious break, but one without a cut or tear to the skin when he arrived in the hospitals.

Cumulatively, Raymond spent several weeks in the hospital. It seemed all too often we were meeting with his medical team of orthopedic surgeons, infectious disease doctors, pediatricians and nurses only to learn that we had not yet rid his body of this invader, and that we needed one more surgery. We were devastated each time we were informed that the infection had returned. He endured bone scans, CAT scans, ultra-sound scans, X-Rays, aspirations, hearing tests and kidney tests due to the strong medicine, all to name just a few procedures. He can even tell you about one surgery he well remembers where he was awake with his eyes closed during the surgery because he was not given enough anesthesia for a boy his size; he remembers every detail of that surgery.

During the ordeal, Raymond spent many months with a "PIC line" inserted into his arm. In this procedure, a plastic catheter tube was inserted through his veins in the area of his wrist where it was threaded up his arm and into his chest muscle to inject antibiotics into his upper body. The line originated from a pump strapped around Raymond's waist for several months, 24 hours per day. When the veins in Raymond's

arm failed and he could no longer sustain the PIC line, he received something known as a "Broviac catheter pump." This was surgically imbedded into his chest cavity right above his heart, again connected to a strapped pump for several months. And, there were regular visits from the home health professionals for wound cleanings, broken equipment, pulled catheter lines, and concerns of further infections. Fourteen year old Raymond became extremely adept at changing his dressings and antibiotic packets.

Once the Broviac pump was removed from his chest, Raymond underwent a very structured antibiotic pill regiment for many months. He consumed two large pills at exactly 6:00am, noon, 6:00pm and midnight. He spent countless hours in physical therapy to stretch his arm, which had frozen into a right angle during the course of his surgeries and subsequent casts and braces. He dutifully engaged in many months of early morning and evening stretching exercises to regain the full use of his arm.

Needless to say, Raymond missed many days of school. He was, however, able to perform the role of the Cowardly Lion in his 8th grade school play, the Wizard of Oz; he was escorted from the hospital by a nurse and he was returned to the hospital right after the play that evening where he was reconnected to his lines and monitoring devices. Raymond missed baseball that spring, swimming that summer, and most unfortunately - in his mind - football that fall, his freshman year in high school. He was also scheduled to be a junior lifeguard during that following summer. He had competed for one of these few positions and he was excited for the opportunity. He was able to remain working for the pool, although he was forbidden from getting wet. Raymond spent that summer monitoring the pool deck for running children.

My family and our relatives, friends and colleagues endured many days of anxious agony. One very poignant moment captures the essence of the agony of this whole experience. As Raymond's mother and I were talking to the team of infectious disease doctors and other doctors over his bed one evening, one doctor looked at our boy in his bed and asked if he had any questions. He replied, "Yes. Am I going to die from this?" We assured him that he would not die; we would not let that happen to him. His mom and I looked at each other. We were not so sure. Raymond next asked, "Am I going to lose my arm?" Again, we assured him that would not happen. We told him we would go anywhere and do anything we needed to ensure that he would not loose his arm. (Then he pushed the envelope too far and asked if he would be able to play football at St. Louis University High School in the upcoming fall of his freshman year in school. He served as the team manager that freshman season and waited until his sophomore year to play.)

Today we believe Raymond's infection is cleared up. Although, one cannot be certain for sure; the staph infection may spring back to life someday with a slight trauma of some sort. In addition, Raymond is unable to fully extend or flex his arm, even though it is fully functional. We want to believe we are through the most difficult stages. We thank God and we consider ourselves to be among the lucky ones in light of what these infections are doing to thousands of families across the country each year.

Aside from the very real human emotional costs, another dimension to this problem is the financial costs to victims of hospital-acquired staph infections. We spent several thousand dollars in miscellaneous expenses associated with Raymond's treatments, including co-pays, deductibles, out of network expenditures, unreimbursed expenses etc. And, of course, as is probably all too common, we had ongoing battles with certain providers about expenses and coverages which took over two years to resolve. From my conversations with many others who have endured hospital-acquired infections, they have suffered similar financial experiences and strains. And, of course, there were the lost days of work for Raymond's mother and me.

We were not content to simply thank our lucky stars. Raymond had suffered too much and the family had made too great a sacrifice to not see something positive come out of this ordeal. We kept telling Raymond throughout his treatments that something good would come from this. Yet, the question which haunted me, as a parent, throughout

all of this was: How could this have happened to us? We live in a community with more than a dozen excellent, highly-regarded hospitals. I had even transferred my son on the evening of his accident from one hospital to another where I thought he might receive better care from the specialist on call that evening. How could we have known that the hospital we chose might be more likely to cause our son a hospital staph infection which threatened his life? The answer at that moment was that we simply could not have known whether one hospital was more prone to cause infections over another hospital in our community. There was no form of public or non-public reporting or comparisons of hospital-acquired infection rates.[1]

Standing in line at the pharmacy to refill a prescription for Raymond, I saw the February 2003 publication of Readers Digest. The cover read "FATAL HOSPITAL MISTAKES How to Avoid Them." I found myself reading the entire related article entitled "Death Beds. Dirty hospitals kill 75,000 patients a year. Unnecessarily." before I left the pharmacy. The basic premise of the article was that hospitals do have the capacity to take steps to minimize staph infections; the article underscored that there is little government regulation to force hospitals to step up infection control. About the same time, I learned that Pennsylvania and Illinois had passed laws to require public reporting.

Inspired by this article and the actions in Pennsylvania and Illinois, Raymond and I discussed the idea of starting an effort to require public reporting in Missouri. It was too late at that point for the 2003 session, so we focused on the next 2004 legislative session. I wrote a draft, starting with the Illinois and Pennsylvania reporting laws, as well as concepts from other Missouri reporting laws. I contacted the Consumers Union which had just undertaken a major initiative to address the subject of hospital-acquired infections. I am very grateful to the Consumers Union for its tenacious efforts which can be reviewed at www.stophospitalinfections.org, and in particular Lisa McGiffert who is here today. Together, we prepared a model bill which we would introduce in Missouri and hopefully other states around the country. (Legislation has been introduced in 30 states this year and six states have passed reporting bills: Illinois, Pennsylvania, Missouri, Florida, Virginia and New York.)

With this first draft of a public reporting type bill in Missouri, we joined forces with a then-freshman State Representative who is also a practicing medical physician. Dr. Robert Schaaf had a very keen interest in hospital-acquired infections. We approached the Missouri Hospital Association and ultimately enlisted their help and support in refining a bill that would be workable and acceptable to the hospitals. From this effort, Senate Bill 1279 was introduced.

In short, SB1279 requires the department of health to make available on their website risk-adjusted infection rates for certain types of infections such as class I surgical site infections, ventilator-associated pneumonia, central line-related bloodstream infections, and other infections defined by rule by the department. The bill also requires hospitals to monitor for compliance with infection control regulations. The bill required the department of health and an advisory committee of mostly medical experts to work out the technical, finer details of the reporting system. This bill provided effective dates well off into the future in order to allow the department, the advisory committee and the

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[1] Missouri statutes and regulations are replete with reporting requirements for other issues. For example, genetic and metabolic diseases in newborns are reportable to the department of health. Animal bites are to be reported to the department of health. Hospitals are to report AIDS, arsenic poisoning, carbon monoxide poisoning, different venereal diseases, mercury poisonings, hepatitis, lime disease, mumps, pesticide poisoning, respiratory diseases triggered by environmental contaminants, rocky mountain spotted fever, salmonellas, tetanus, toxic shock syndrome, West Nile fever and even leprosy, only to name a few. Yet staph infections were not reportable and the information was not collected by the department of health in any fashion. Any yet staph infections are the fourth leading cause of death in this country behind heart disease, cancer and lung ailments.

medical community sufficient opportunity to develop specific guidelines to deal with these important matters. In addition, this bill directed the advisory committee to draw upon the considerable body of expertise and methodology established by the Federal Centers for Disease Control and Prevention National Nosocomial Infection Surveillance System.

The simple philosophy behind this bill is that a certain level of public reporting on hospital-acquired infections will serve the public in two ways. One, patients will be given an opportunity to evaluate their health care facility choice and therefore make more informed decisions. More importantly, hospitals will work diligently to improve their outcomes on publicly reported indicators which will help facilitate the adoption of best practices of patient care (hand washing, surgery prep, cleanliness, etc) thus minimizing such infection rates in hospitals.

Prompt passage of SB 1279 proved very successful. The effort had enthusiastic sponsors in both Chambers of the legislature. The process was transparent and inclusive of all concerned. SB 1279 passed the legislature in a single session. It passed unanimously in the Missouri Senate and with all but one vote in the House of Representatives. The Governor signed the bill in a large signing ceremony.

My son Raymond and I testified before the Missouri legislature. We together visited and called legislators about the bill. His story received considerable attention. The bill became widely known as "Raymond's Bill". During that process, it became apparent about how many people are affected by hospital-acquired staph infections. Lobbyists, legislators and their staffs all freely and willingly joined in the effort because of their own experiences. The various business groups and consumer groups all saw the benefits to be derived from SB1279. While the cause was predominantly consumer and patient driven, the hospital association and other medical groups ultimately embraced this issue in an effort to do something constructive to address these staph infections.

Notwithstanding the benefits of disclosure and public reporting, I have come to recognize that it is not as easy as simply reporting raw incidences of hospital-acquired infections to a department of health for a public report. A system must address issues relating to the patient-base or type of the hospital, the types of infection, the disparate statistic gathering practices within those hospitals, and so on. Each of these must be taken seriously. But, to let these doubts and issues overcome any solution or serious effort to address the problem would be a grave injustice to the victims of hospital-acquired infections.

Some critics of public reporting have said a reporting law can not be consistently applied from hospital to hospital. They contend it would cause hospitals with scrupulous reporting practices to look unfavorable as compared to hospitals with less- meticulous practices. While I recognize the complexity of the task, I don't accept this premise. As a society, we are able to apply health codes to rate all kinds of restaurant establishments. We are able to apply a complex set of state and Federal tax codes to every type of business, as well as individuals. We have building codes, traffic codes, uniform labor codes, all to name just a few. I believe these challenges can be overcome with proper guidance and instruction at the state and Federal level, experience in gathering statistics, potential adverse licensure consequences for intentional under-reporting, etc.

Some say that public reporting will be flawed due to differences in the types of hospitals and the practices and services they offer. A rural hospital and an urban hospital will have different reportable experiences; a teaching hospital and non-teaching hospital will have different reportable experiences; a critical-care hospital will have different experiences; and so on. I believe states are developing valuable experiences to address these issues. Missouri, for example, has developed categories for hospitals and surgical procedures. The Missouri statute also calls for risk-adjusted assessments. I think much can be learned from the growing volume of state experiences.

Some raise the difficulty in distinguishing between hospital-acquired infections and community-based staph infections which also are reportedly on the rise. There is concern that any hospital reporting system may falsely include staph and other serious infections acquired outside of the hospital. Reporting systems will have to be sensitive to this. In Missouri, the law focuses primarily on Class I surgeries i.e., surgeries where the patient does not have an open wound upon arrival in the hospital. In my son's case, he arrived at the hospital with no broken skin. Surgery was performed on his left elbow. The infection and osteomyelitis was located at the surgery site. It was clear to me that this was likely a hospital-acquired infection, not a community-based staph infection. On the other hand, patients arriving in the hospital burn unit should not be placed in the same category as Class I surgery patients.

I spoke earlier of the financial cost to my family. I would venture to say that the overall cost on the national health system for hospital acquired infections is staggering. And so much of it can be avoided. I mentioned the costs to my family and the several thousand dollars this cost us. The balance of most of those costs was covered by my health insurance carrier. Ultimately, in theory, employers absorb these costs the following year through increased co-pays, higher deductibles, etc. And for those victims of staph infection who have no insurance, the system as a whole absorbs those expenses. At that point, all consumers and taxpayers pay. I can not begin to quantify what must be a very large amount, but it becomes easy to see that all of us are absorbing a tremendous cost, much of which might be avoidable if hospitals reduced the incidences of these infections.

During the course of our work on Missouri SB1279, it was important for me personally to underscore that our involvement in this cause, like our involvement here today, was never about assigning any blame or embarrassment to any hospitals for my son's staph infection. Nor is it about in any way disparaging hospitals or the important work they do. We certainly never considered any sort of legal recourse. I personally, have nothing but gratitude and respect for the doctors, the scientists, their teams and hospitals involved in my son's case. I have never publicly named the hospitals or doctors involved in my son's case. Our simple goal was to help put a spotlight on a growing very serious problem. We wanted to stimulate discussion about how imperative it is for hospitals to reduce their infection rates by all available means. In my opinion, hospitals were not leading this discussion, as they should. This is the positive outcome we wanted to see come from Raymond's ordeal. In Missouri, the policymakers concluded that public reporting was the most important way for consumers to pick the best and safest hospitals. Other states are adopting similar measures, and still other states are taking other approaches. I can't tell you for sure that Missouri has adopted the best approach. I hope that in ten years we will look back on the Missouri approach and recognize that it was a good first step, but that it evolved and improved.

I respectfully ask this Committee and Congress to study all of the approaches under consideration by the states today, as well as the Centers for Disease Control. I encourage you to collaborate with CDC and other government experts to study what works. I encourage you to include the medical community and hospital community. I urge them to embrace this issue of hospital-acquired infections and to earnestly look for solutions to this major health threat with a level of commitment they have not universally shown to date. This effort needs their expertise. And, I believe it is critically important to include individual consumers in this process, people such as myself who have been touched by hospital-acquired infections. This effort needs their motivation.

Together, I believe we can make huge advances toward minimizing the devastating consequences of these all too frequent infections so that other hospital patients do not have to become a statistic like my son, Raymond.

Thank you, Mr. Chairman and Members of the committee.

PREPARED STATEMENT OF RAYMOND T. WAGNER III

Mr. Chairman and Members of the Committee:

My name is Raymond Wagner. Thank you for allowing me to speak to you today. I just wanted to add that I appreciate the Committee for considering this issue of hospital-acquired infections. As my Dad outlined, I had a tough time during that year following my sledding accident. I missed a lot during that year, but I also grew a lot.

I am very thankful to the doctors who helped cure my infection. I am also thankful to my Mom and Dad and all of my friends and teachers who helped me.

I think this hearing is a good way to begin to look at this problem of hospital staph infections so that no other teenagers like me, or new babies, or older people like my Grandparents have to go through what I went through and my family went through.

Thank you very much.

MR. WHITFIELD. Without objection, go ahead.

[Video.]

MR. WHITFIELD. Well, thank you, Mr. Wagner, and we appreciate that video from your son.

Your son was injured December 24, 2002--

MR. WAGNER. Yes, sir.

MR. WHITFIELD. --and he had surgery and went home, what, the next day or two, right?

MR. WAGNER. The next day.

MR. WHITFIELD. And then how long was it before he received a clean bill of health from the infection being over with?

MR. WAGNER. He took his last antibiotic pill on Thanksgiving Day the following year, so it was nearly a full year later, and then we return to the doctor periodically every couple of months for the following year, so it was approximately maybe during the second year that we felt that we were out of the woods. So it was over a year process.

MR. WHITFIELD. I do appreciate your testimony. Now, in your testimony, you used the word "quiet paralysis." You said that there's been a quiet paralysis in the medical and hospital community. Now, would you elaborate on that a little bit for me?

MR. WAGNER. Yes, sir. In my experience, both as a father of Raymond, the patient, and in my subsequent involvement in this effort to pass a law in Missouri, it became fairly clear to me that hospitals have not, up to that point, embraced this issue fully. They were oftentimes resistant to the public reporting. I know that there are many issues which need to be addressed which were highlighted in the opening statements and are highlighted in my statement as well, but the word infection is a difficult word for even hospitals to speak when you are there as a patient, or in my case, the father of a patient. We really weren't told that we had a staph infection until well into his treatments for these sorts of things, and so I think that there's been resistance. Certainly as I have tracked legislation in other States across the country, oftentimes it is the hospital

that is resisting adopting any sort of legislation and taking this first step to dealing with this problem.

MR. WHITFIELD. So I take it during this process, you had a number of discussions with the hospital administrators. Is that true?

MR. WAGNER. I did. I met with infectious disease professionals in a number of the hospitals throughout the State of Missouri during the course of this legislation. We included them in the drafting of the legislation. The bill itself went through some 10 different revisions. The medical association came on board and assembled a team of medical doctors to look at it as well. It was important to me that the legislative process be inclusive of the professionals and that they had a buy into this, and we took advantage of their expertise.

The legislation also established an advisory committee which consisted of, I believe, eight medical professionals in addition to a couple of consumer representatives, and so there is ongoing inclusion of professionals in the drafting of the regulations.

MR. WHITFIELD. And you said that the Missouri Hospital Association worked with you closely as you formulated this legislation?

MR. WAGNER. The Missouri Hospital Association did work with us, and that was very fortunate. We started out this effort without including them. As I developed the legislation and worked with the Consumers Union, began to look at what had happened in other States--Illinois, Pennsylvania was looking at the time--I began to talk to sponsors and built the legislative support. Then the Hospital Association got on board and really helped to craft what I think ended up being a fine bill.

MR. WHITFIELD. Now, what were the major obstacles as you moved forward in passing this legislation? What concerns were raised about why we should not pass this kind of legislation?

MR. WAGNER. Well, there were a number of obstacles, and not all of them were addressed in legislation. There is a process where we continue to develop regulations with the legislation, but certainly Missouri has several teaching hospitals, and teaching hospitals have a different patient base and a different experience level than non-teaching hospitals. Missouri has several urban communities, St. Louis, Kansas City, Springfield, and then there are rural hospitals, and that presents issues.

And then there were concerns about the issue of risk-adjusted data which needed to be addressed, and was addressed to a large degree. The issue of the different practices in collecting statistics was one that came up and we attempted to deal with that. Some hospitals that were more meticulous about collecting their data might look less favorable than those who were not as meticulous. So these were a number of the hurdles that we needed to address, and then of course the basic science,

the statistical gathering, how to report it to the public, these were all issues that we dealt with. We worked closely with the Department of Health, the experts, who collaborated with the CDC, incorporated reliance upon the CDC into the legislation as well.

MR. WHITFIELD. I am assuming that as you became involved in this, you looked into some other States to see what legislation they had adopted. What States did you look to?

MR. WAGNER. Yes, Mr. Chairman, at the time Illinois had just passed legislation and that became a good starting point. Pennsylvania had adopted legislation. New York was considering legislation. Then I looked to a number of the reporting regulations in Missouri already. Missouri, like I am sure many States, requires extensive reporting from hospitals to the Department of Health, everything from child abuse to certain animal bites to rabies to venereal diseases. We are even required to report--it is slipping my mind right now. But in any event, we wanted to take some of these regulations and incorporate them into the statute as well.

MR. WHITFIELD. Now, in the healthcare field today, particularly with all of the litigation that is going on and people are always concerned about gigantic judgments against them, I am assuming, were there concerns on the part of the hospital about plaintiff lawyers using this kind of information to file more lawsuits against them?

MR. WAGNER. There was concern on the part of the hospitals about that. That was a concern that I personally am very sensitive about in my role with my own company and being aware of the litigious society that we live in today. And so we included a provision in the Missouri bill that stated plainly that none of the reports created by the Department of Health would create any sort of standards for purposes of any litigation. And after having vetted that through the hospital's attorneys and the attorneys for the various groups that were working with us, we felt comfortable that that would insulate the hospitals and provide the information, because the goal was to get the information out. I made it very plain that I wanted it to be lawsuit neutral, neither to enhance anybody's capacity to sue or impair anybody's capacity to sue.

MR. WHITFIELD. And in the other States that you looked at, do they have that same kind of provision?

MR. WAGNER. I do not believe so, Mr. Chairman. I don't know, but I don't recall seeing any at the time. I have not studied a number of the pending bills you mentioned. There are 20 to 30 pending in other States. I have looked at a number of these. I would suspect by now it has been included in some because it is a real concern that has to be dealt with. I did not want to put any sort of chilling effect on the hospitals.

MR. WHITFIELD. And what day was the Missouri law signed into effect?

MR. WAGNER. It was signed I believe June 28 of 2004.

MR. WHITFIELD. And what has the effect of that law been?

MR. WAGNER. Well, at this particular moment, the bill is still being implemented. We established effective dates that were fairly well-distanced into the future so that the Department of Health and Senior Services would have sufficient time to collaborate with CDC and other organizations to develop the appropriate regulations. So we established that the first report would be published on December 31 of 2006. The data has just started coming in as of the first part of this year. We categorized different types of infections. We focused on Class I type surgeries because we thought those would be least likely to be tainted, and that information is now just starting to roll in. It will be coming in in quarters and the reports will be published in 12-month rolling increments, commencing December 31, 2006.

MR. WHITFIELD. Now your son did not have a complicated fracture, per se, was it? I mean, he did not have the skin punctured or anything like that?

MR. WAGNER. He did not have his skin punctured, which had his skin been punctured, the circumstances might have been different. It might be more understandable that he had an infection because he might have acquired it in the community, but he arrived in the hospital with certainly a fractured humerus bone at the elbow, and he required surgery and manipulation of the bones and a couple of pins, but the skin was unbroken when he arrived in the hospital. The infection appeared at the site of the surgery.

MR. WHITFIELD. Mr. Wagner, my time is expired. Thank you.

I recognize Mr. Stupak for 10 minutes.

MR. STUPAK. Thank you, and thank you, Mr. Wagner, for appearing here today.

Knowing what you know now about the causes of hospital-acquired infections and the specific steps that can be taken to prevent them, do you think that public reporting is sufficient to stop it?

MR. WAGNER. I don't think public reporting alone, Congressman, is sufficient. It is a step. It is one of the arrows in the quiver, if you will. I think there needs to be standardized training, I think there needs to be a very conscious level of attention to hospital practices, processes have to be streamlined and focused upon in connection with infectious disease.

Reporting, I think, will be an important step. It will certainly give consumers a tool. It will help to establish best practices. No hospital is going to want to see their numbers look inferior compared to other

hospitals in the community, so they are going to raise their own standards and so on, but it is not the total solution, no, sir.

MR. STUPAK. Well, I missed part of your testimony because I had to meet with some other folks here, but does the Missouri bill do anything other than public reporting?

MR. WAGNER. The Missouri bill does do other things besides public reporting. It requires hospitals to establish a monitoring practice of their own internal infectious disease procedures, some of which is done when--

MR. STUPAK. Infectious disease or through infectious medical procedures which lead to--like we know intravenous--

MR. WAGNER. They are required to monitor their own procedures aimed at reducing infections and infectious diseases they implement to ensure precautions so that the patients don't get the--

MR. STUPAK. Well, has the Missouri Hospital Association done anything to try--much like we did in Michigan, much like the Keystone where you actually put forth practices to reduce infections?

See, my concern is I would think that a consumer, it would be more important not to know what the infection rate is, but what is the hospital doing to reduce the infections?

MR. WAGNER. Yes. Well, certainly the Department of Health is preparing guidance and brochures on the legislation. Information has been provided to hospitals and to patients as to how to handle their stay in a hospital. Comment cards are made available to the patients under the legislation. There is a provision which encourages hospital staff to report violations or practices that would be susceptible to infections, and they would be protected from any sort of retaliation.

MR. STUPAK. So have the infection rates gone down? It has been less than two years since this bill has been signed, I think you said it was June 28, 2004. Have you seen any change in infection rates in Missouri, or is it more just the reporting of infection rates?

MR. WAGNER. At this point, sir, I could not quantify or could not give an opinion as to whether or not the infection rate has gone down. The first report has not yet come out. The law is still in the implementation phase.

Now to the extent that public awareness has increased, this legislation and the regulations and the procedures have received widespread attention throughout the State of Missouri, and consumers, I think we have had the deaths of a couple of prominent individuals in the State. A county executive for St. Louis County died of a staph infection; one of our former coaches for the Rams and broadcasters recently passed away, and so on, so attention has been focused on this and that has

perhaps had a positive impact, but I would not be able to articulate any quantifiable data at this point.

MR. STUPAK. You indicate in questions from the Chairman that the legislation in Missouri--and you took great pains to make it lawsuit neutral. How about terminology neutral for the average consumer, because in preparing for the hearing here, CDC uses the word, and hopefully I am saying it right, nosocomial infection--

MR. WAGNER. Nosocomial.

MR. STUPAK. The average person doesn't know what the heck that is, so I would hope that Missouri law, besides worrying about litigation, would also have legislation that would break down these words so the consumer could understand it.

MR. WAGNER. That is a very fair point, and I will make a point to raise that at our next advisory meeting as we continue to develop what the website will look like and the information we put forward. The bill itself, we named it "The Nosocomial Act of 2004," reduction act, I believe.

Largely, we--and again, in an interest to getting the hospitals to work with us, we avoided the term hospital-acquired infection to appear to be disparaging in any way to the hospitals, so we used a more technical term.

MR. STUPAK. Yeah, but then you probably lost the consumers. Nosocomial Legislation Act of 2004, that doesn't really warm my heart or do anything to really get me focused on the issue.

MR. WAGNER. Well, my hope or my expectation is that consumers are not going to be aware of the law, per se, they are going to be aware of the result between the hospital administrators. For example, when I took my son to a hospital, we appeared at one hospital, I talked to the doctor and I asked him if he was the best doctor to do this surgery.

MR. STUPAK. Right.

MR. WAGNER. He said there was another hospital down the road that did more surgeries on elbows, so I consulted with my pediatrician, and we put our son in an ambulance and sent him down the road. If this law were in effect, I would trust that my pediatrician would be aware of the technicalities and be aware of the reports and might have said to me, you know, Ray, you are better off staying where you are with Raymond as opposed to going down the road, and so on and so forth.

So I think between consumers and also the doctors, that it should have a positive impact.

MR. STUPAK. Sure, but the best surgeon for your son's case may not have had privileges at the hospital with the lowest infection rates, if that was all you are basing it upon.

MR. WAGNER. But at least at that point, Congressman, I would have been able to ask myself, am I willing to trade an environment where maybe he does not have the best surgeon, but they have a lower likelihood that he is going to be infected with a staph infection or an MRSA or VRE or some other deadly infection? At least then I would have been able to make a more informed decision. As it was, I did not have that information. I took him to the hospital down the road, and I probably would have been better served to keep him at the original hospital, take my chances with the fine doctor who attended to him, even though he was less experienced with pediatric children and perhaps had less experience with growth plates on the elbows and so on and so forth. But my son maybe would not have acquired the infection.

MR. STUPAK. Well before--and I appreciate everything you have done to try to bring this to public attention, and also try to lower infection rates, but after this whole incident, would you have known before all this where to even begin to look on infection rates in the hospital? Was there anything in Missouri which would allow you to access any kind of information as to infection rates of certain hospitals throughout Missouri?

MR. WAGNER. At the present time, there is no such mechanism. There is no opportunity for either consumers directly or their internist, or in my case, the pediatrician, to know. And that, of course, is what gave rise to my--

MR. STUPAK. Absolutely.

MR. WAGNER. --interest in doing this.

MR. STUPAK. And there is what, about six States now who are using this field of knowledge?

MR. WAGNER. As I understand it, six States that have passed legislation and are in the process of implementing reporting. I think only one State so far has produced reports, and in some other 20, I think it is closer to 30, States are considering legislation.

Each of the bills are slightly different. They all have a common thread, and I think in the course of a few years we should have a pretty good sampling of perhaps what works, working in cooperation with the professionals here in this hearing room and CDC and the other organizations.

MR. STUPAK. Let me ask you one more question. Mr. Murphy sort of alluded to it in his opening statement, and I believe one of the witnesses from Pennsylvania is going to testify that if Congress would crack down and not pay Medicare or Medicaid payments to a hospital if the Medicare or Medicaid patient had an infection as sort of a way to financially bring about a change in infection rates, do you think that would be an appropriate approach?

MR. WAGNER. I think it is an approach which could and should be discussed. It is certainly an approach, as I listen to those remarks, that I thought about is done with highway dollars and considerable public policy, I think, is established tied to highway funding and so on and so forth. So I think it is something that could provide the additional incentive for States to take the steps within those States, working with CDC to come up with the right formula.

In the Missouri bill, another provision did direct that a hospital receiving any State funding not receive some or all of that State funding if it is not implementing and complying with the mandates of the law, and I suspect that will have a positive impact.

MR. STUPAK. Two quick questions. There are probably some infections we can't anticipate or get control of, so how do you separate those from the preventable? Secondly, did Missouri law put in any financial incentives to help the hospitals develop an infection prevention program?

MR. WAGNER. On your first question, there is no doubt in my mind that there are infections which are not going to be stopped no matter what is done by way of regulations or laws or anything else, and certainly--

MR. STUPAK. Do you know a percentage?

MR. WAGNER. I don't.

MR. STUPAK. Three percent, five percent?

MR. WAGNER. I suspect it is probably--certainly you should ask one of the other professionals--double digits. I am confident, but those infections which are preventable through attention to details such as hand washing, the isolation--I can go on and on and on--I think are going to be significant and substantial and are going to reduce those 90,000 people that die, and that was a statistic compiled in the '90s, it is probably more today. It is going to reduce that substantially, but there are going to be infections acquired in a community that are brought into the home, infections that cannot be stopped no matter what.

My hope, at least when comparing hospital to hospital, that those statistics will wash in the end and there will be, over time, we will be able to see a fluctuation in the infections which can be managed and controlled.

You asked secondly if there were any financial incentives. There were no financial incentives. There was money allocated even before the bill was passed, which was sort of a statement from the legislature about how strongly it felt to implement the bill and to take the steps to develop the computer system.

MR. STUPAK. Thanks for your time and testimony.

MR. WAGNER. Thank you very much.

MR. WHITFIELD. The gentleman from Texas, Dr. Burgess is recognized for 10 minutes.

MR. BURGESS. Thank you, Mr. Chairman, and Mr. Wagner, thank you for being here and sharing what I am sure is sometimes a difficult story to relate.

Can you help us just a little bit? I know you abbreviated this in your testimony for the sake of time, but go through the timeline with us a little bit about the day the injury occurred. Your child was taken to the first hospital and received a diagnosis, diagnostic x-rays in the emergency room at that hospital?

MR. WAGNER. On December 24, 2002, Christmas Eve--

MR. BURGESS. Christmas Eve, approximately what period of time did you spend in the first hospital?

MR. WAGNER. We took him into the first hospital--I drove him there through the snow. The x-rays were taken, he was given some shots of, I believe, morphine in his arm. His coat was cut off of him, and within the hour or so, we had the x-rays. I was consulting with the orthopedic surgeon on call and at the same time, I had reached out to his pediatrician by phone and we had gone through the process where I summoned up some of the nerviness within me to ask the doctor if he was the appropriate doctor to be doing this surgery. The bone was crossways in the elbow. It was in three or four pieces--

MR. BURGESS. And it involved the growth plate?

MR. WAGNER. I was concerned of the growth plate. So we had him on the ambulance to hospital number two probably 2-1/2 hours after he entered hospital number one.

MR. BURGESS. And then the surgery took place?

MR. WAGNER. The surgery took place a couple of hours later. We arrived at the first hospital about 3:00 in the afternoon, when I should have been arriving at my in-law's home, and then the surgery commenced around 9:00 and interestingly, I knew the surgeon who performed the surgery, a college friend of mine. I knew many of the nurses and people there in the hospital. The surgery was completed around 10:30, 11:00, the doctor came to see me. Then Raymond was in the hospital, I stayed in the hospital, his mother as well, the two of us were there, and we brought him home, I believe around 8:00 in the morning or so, the following morning.

MR. BURGESS. To the best of your knowledge, were any antibiotics administered during the hospitalization, during the surgery?

MR. WAGNER. I don't know, sir.

MR. BURGESS. Neither do I know whether that would be a common practice. I was just wondering.

MR. WAGNER. I know nowadays through my involvement in this project, this cause, that that is something that should receive, perhaps, more attention.

MR. BURGESS. Certainly, if Dr. Murphy gets his way and they get punished by Medicare, yeah, that's a dissance. They will get the antibiotics with the surgery.

But in any case, then how many days later was it that the infection cropped up, the symptoms of infection?

MR. WAGNER. He probably acquired a fever within a day or so of being home, and we called the doctor and the hospital. And they said well, this is normal given the trauma that he has been through with the elbow. And we called back the next day and at some point, he was administered an antibiotic at that point that we picked up, again, without having seen the infection. Then we brought him into the hospital and they looked at the dressing and so on and so forth, and then we were back and forth to the doctor a couple of times. The infection didn't go away and it was actually I believe his dentist that said, you know, you need to get him into the hospital and you need to get him in there now. We went, and that is when he was received and--

MR. BURGESS. So the first antibiotics would have been about three days after surgery on oral antibiotics?

MR. WAGNER. I believe that is correct. I could certainly check. I have copies of his records. I could be more specific if you like.

MR. BURGESS. I have got to say, it is very commendable that you thought enough to ask the doctor if he was the right guy to do the surgery. I don't know that I would have, even as someone who has some experience in the healthcare field, I don't know whether I would have had the knowledge to ask that question.

Do you think, if this were to happen and that law already was on the books, do you think you would have asked about the hospital's infection rate?

MR. WAGNER. You know, that is an excellent question and I have asked myself that in my mind, and there is a very good chance that I would not have known the law was on the books, or that that information would be available to me. But that is okay because one, I consulted with the pediatrician and I am confident that she would have known about it and she would have a sense for which hospitals in the community are more prone to infections over other ones, and she would be able to say to me, you know, Ray, again, you ought to go down to this hospital or that hospital, or stay away from this hospital.

And then, I think even more importantly, the hospitals would know that the report is there, and they would be tracking it and they would be

comparing themselves with other hospitals in the community, and they would establish best practices--

MR. BURGESS. Let me interrupt you there, because--and it has been a few years since I have been in the hospital. But I seem to recall us talking about things like infection rates pretty regularly in hospital board meetings and executive committee meetings. So I guess part of the statement that I would question is would your pediatrician have know? Perhaps this was information that was already available, but maybe not information that was monitored by a non-surgical specialist, by a pediatrician. I mean, I think if I knew that in my primary hospital, we have got a problem with MRSA, I am going to think twice before going to the operating room. Because none of us want from the patients family to be sure, but you know, as a physician you don't want to have to go through this type of ordeal. Do we know anything about the infection rate at either of the two hospitals you were in that night, the first hospital or the secondary receiving hospital?

MR. WAGNER. Congressman, no, I don't know anything about the infection rates, which of course, was the origin for me wondering why that was, and why I didn't know that or why it would not be available.

But, if I might just quickly go back to your first observation about internal infection and the discussion you had when you were on staff and the attention that hospitals give. All hospitals do give attention to their own infection rates. I have become very clear on that point. Many of them have infectious disease departments and monitor this sort of thing. The problem is they don't share it with anybody else, and they don't share it, then you don't have any comparisons about one hospital to the next, and each of them, I've come to understand, has their own constraints in terms of resources and what level of attention those infection rates get. I have seen in some of the most prominent hospitals in Missouri their graphs and their charts of how they track this stuff internally. The problem is something is lost in the translation from that internal observation and attention as compared to the next one, in my opinion. That is part of the paralysis that I believe I--

MR. BURGESS. I will tell you thee is a pretty prolific grapevine in the hospital, just among doctors and nurses. If there is a problem, generally at least doctors who use the operating room are aware of that, but that information also is, as I recall, the Joint Commission for Accreditation of Hospitals, at least in Texas, that is information that they are interested in, infection rates and MRSA rates.

I guess I would just wonder if that is not something that is known at some point along the line, but that information was never shared with you.

MR. WAGNER. It certainly was not shared with me, and from all my involvement in Missouri with the hospitals, the doctors, the Department of Health and so on and so forth, I don't believe that there is comprehensive infectious disease information made available to the Department of Health, and certainly, is it not made available to patients.

What can be obtained and what was obtained during the course of legislative activities were how many people on death certificates where it was noted that people died of, you know, infections, MRSA, VRE, and so on and so forth. But that certainly is not a sample.

MR. BURGESS. But, you know, just listening to your story, too, it is also possible that the collitization with the staph occurred in the x-ray department in the first hospital, and the second hospital may have had an absolutely clean infection rate until your son's case. So that can be information that might be helpful.

One of the things that I do want us to think about, and in this county, where people are generally healthy, have high health literacy, and can stay away from those neighborhoods where infection rates might be expected to be higher than the foreign neighborhoods. If we are not careful about how we construct this, we should be very careful to make it a positive reinforcement and not a negative reinforcement, and Mr. Chairman, you have been very indulgent. I will yield back.

MR. WAGNER. Thank you, Doctor, and I completely agree with your last comment as well. That is hopefully where some of the risk adjustment will come into play.

MR. WHITFIELD. Mr. Inslee is recognized for 10 minutes.

MR. INSLEE. Thank you, Mr. Wagner, thank you for being here. I want to ask you kind of a hard question, and I appreciate your being here. You are Vice President at Enterprise rental cars?

MR. WAGNER. Right.

MR. INSLEE. One of the hard things of our job is figuring out when a regulatory scheme is appropriate, because regulatory screening equals cost on business. There are truths of the time which are tough to deal with, businesses normally sort of reject regulatory schemes.

In this case, you have suggested this effort to make sure that consumers are aware of disparate results by different hospitals. Let us say that someone suggested in the rental car industry, rental car companies are to disclose their fatalities per mile or your fatalities per accident or something so that the consumer can make decisions. I suspect if someone proposed that, good-hearted people around the car industry would say well, we have different customer bases. It is hard to compare apples with oranges. There is no proven record that this recordkeeping will really advance safety, that kind of thing.

I just wonder if you could give us your thoughts on why it is appropriate in this context in a hospital situation to give the consumer this information, this sort of compiled data, given where not maybe other industries in other contexts even involving safety issues.

MR. WAGNER. Thank you for that question, Congressman, and I don't particularly find that to be a hard question as perhaps you suggested. I think coming from representing corporations, I certainly understand the perspective that less regulation is better, and corporations certainly pursue that, and I do on behalf of my company from time to time. But I think when it comes to protecting the sickest among us, the people that use our hospitals, I think that is a very legitimate place for government to interject itself and to perhaps establish parameters and even a regulatory scheme, if possible. Particularly if the regulated, if you will, the hospitals, the medical community are not doing everything that they can on their own to address the situation.

I think during the course of the Missouri legislation, there were just a few people along the road that scratched their head and said, you know, Ray, how do you find yourself in this position? And I found myself with new partners that I did not have before, but at the end of the day, the bill passed unanimously in the State of Missouri, save one vote in the House of Representatives. All Republicans, 100 percent of them signed on to the bill or voted for it, and nearly all Democrat members of the legislature. It was viewed as, certainly, a pro-consumer, pro-patient bill that we talked about, and it was viewed as a pro-business bill. I was somewhat embarrassed throughout the course of this every time that I explained to my employer that I was going back into the hospital for my son, that my employer was picking up the expenses of all of these costs, except the countless deductibles, co-pays, and so on and so forth, out-of-network expenditures that I had, but it was a tremendous cost burden on employers, from a time standpoint away from my day-to-day responsibilities, the costs that went into this, I don't know what they are. At one point, I got a little bit of a look at them. I am sure they are well over $100,000 that was factored into the base that led to the following year's co-pays and deductibles and benefits provided to all my colleagues. And so it was very much a pro-business bill in concept as well.

MR. INSLEE. Did you consider more vigorous efforts to require specific anti-infection protocols or, for instance, one of our witnesses later today will suggest that if Medicare would stop paying for infections that exceed a certain rate, that that would be an incentive that would be more effective than this one of public information. Did you consider that or do you have any comments about those ideas?

MR. WAGNER. We did not consider any sort of punitive or incentive steps like that. We wanted to ensure that the legislation was manageable. We articulated particular types of surgeries and then as we became more adept at particular types of procedures as a State would, the Department, then others could be added by regulations. So the only punitive measure that is in there is the withholding of State funds if a hospital's funds that are otherwise provided to a hospital, if a hospital is not complying with the legislation. And then the public reporting speaks for itself, and some of the other monitoring provisions and so on and so forth could be dealt with during the course of licensure of each of the facilities on an annual basis.

So there are those ramifications, but there was, at this point in time, and from what I understand in my conversations with the Department of Health and through my involvement on the advisory committee, I was appointed to be a consumer representative on this advisory committee. The procedures, the data collection, the statistical methodology that has been put forward for them to use is being well received and the information is coming in.

MR. INSLEE. Thank you. I will ask you privately how you get your son of that age to wear a tie later.

Thank you very much.

MR. WHITFIELD. Well, Mr. Wagner, we genuinely appreciate your being here today, and your testimony was quite helpful to us. I think everyone has completed their questions, so you are dismissed and we wish you the very best. Tell your son we appreciate him testifying as well.

MR. WAGNER. Thank you, Mr. Chairman, thank you, members of the committee. It was a pleasure to be here. Thank you for looking at this issue.

MR. WHITFIELD. At this time, I will call the second panel which consists of one person, and that is Dr. Denise Cardo, who is the Chief of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention in the U.S. Department of Health and Human Services. Dr. Cardo, we welcome you and we look forward to your testimony.

As you are aware, this is an investigatory hearing, and it is our policy at these hearings to have our witnesses testify under oath. Do you have any difficulty with testifying under oath today?

DR. CARDO. No.

MR. WHITFIELD. And I assume you do not have a lawyer either?

DR. CARDO. No.

MR. WHITFIELD. So if you would stand.

[Witness sworn.]

MR. WHITFIELD. Thank you. You are under oath, Dr. Cardo, and we would welcome you to give your 5-minute opening statement.

STATEMENT OF DR. DENISE CARDO, CHIEF, DIVISION OF HEALTHCARE QUALITY PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DR. CARDO. Good afternoon, Mr. Chairman and members of the subcommittee. I am Dr. Denise Cardo, Director of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention, CDC. I am pleased to be here today to describe the activities the CDC has undertaken in monitoring and preventing healthcare-associated infections.

CDC provides leadership in surveillance, outbreak investigations, laboratory research, and prevention of healthcare-associated infections. CDC is committed to protecting the Nation's health and helping all Americans receive the best and safest care when they go to a hospital or other healthcare facility.

Healthcare-associated infections are infections that patients acquire during the course of receiving medical treatment for other conditions. These infections are a threat to patient safety. Based on 2002 data, CDC estimates that each year, there are approximately 1.7 million healthcare-associated infections in U.S. hospitals, with 99,000 associated deaths.

An increase in public awareness of this severe problem has led to a call for public disclosure of healthcare infection rates in the United States through mandatory reporting. Information about healthcare-associated infections can lead to an increased focus on infection control and prevention. CDC's experience has shown that sharing information for local action can prevent infections and improve patient safety.

Educating clinicians, decision-makers, and the public about the prevention of healthcare-associated infections is an important benefit of the dialogue created by the public reporting movement. Through voluntary reporting from a national network of sentinel hospitals, CDC has monitored healthcare-associated infections since 1970, using the surveillance methods of the National Nosocomial Infections Surveillance System, also known as NNIS. This systematic collection and analysis of data on healthcare-associated infections has provided critical information to improve infection prevention and control.

The purpose of surveillance is not simply to count and characterize infections, but most importantly, to control and prevent them. Hospitals that participated in the NNIS system have reduced rates of infections. For example, the rates of bloodstream infections for vascular catheters,

known as central lines, decreased during the period of 1990 to 2004, as you can see here in the graphic.

Working with a group of hospitals participating in the Pittsburgh Regional Healthcare Initiative, also using NNIS, we demonstrated that these infections could be reduced even more. This collaboration resulted in a 68 percent reduction in the rate of bloodstream infections during 2001 and 2004, as you can see here in this graphic.

This experience highlights the importance of regional data for local action to prevent healthcare-associated infections. It also underscores the confidence participants had in the NNIS standards that allow fair comparisons among facilities.

CDC has developed a web-based surveillance system called the National Healthcare Safety Network, or NHSN, to replace NNIS. This system provides the ability for facilities to analyze their own data and to tailor their infections to meet their greatest needs. As a result of CDC's discussions with States, technical enhancements of NHSN are planned to better support public reporting.

In February 2005, the Healthcare Infection Control Practices Advisory Committee, in collaboration with CDC and professional organizations, published guidance for public reporting of healthcare-associated infections. This document includes recommendations to States considering legislation for mandatory reporting of healthcare-associated infections, and also highlights strategies to avoid potential unintended consequences.

CDC supports national standards as a key to consistency in case finding, data collection, trend analysis, risk adjustments, and comparisons across surveillance sites and jurisdictions. CDC also supports the use of electronic data for surveillance as a way to streamline case detection and reporting.

In conclusion, healthcare-associated infections are a threat to patient safety. While many organizations are working hard to prevent infections in U.S. hospitals, this issue continues to be a challenge and more needs to be done. Public reporting of healthcare-associated infections can be a tool for increased adherence to recommendations. Individuals at the Federal, State, and local levels in the public and private sectors need to work together to improve strategies to meet this healthcare challenge. CDC is strategically positioned to continue to provide leadership in this area.

Thank you very much for your attention, and I will be happy to answer any questions you may have.

[The prepared statement of Dr. Denise Cardo follows:]

PREPARED STATEMENT OF DR. DENISE CARDO, CHIEF, DIVISION OF HEALTHCARE QUALITY PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon Mr. Chairman and Members of the Subcommittee. I am Dr. Denise Cardo, Director of the Division of Healthcare Quality Promotion of the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am pleased to be here today to describe the activities CDC has undertaken in monitoring and preventing healthcare-associated infections. CDC provides leadership in surveillance, outbreak investigations, laboratory research, and prevention of healthcare-associated infections. Knowledge gained through these activities is used by CDC to 1) assess the magnitude, trends, and risk factors of healthcare-associated infections; 2) detect new patterns and mechanisms of antimicrobial resistance; 3) detect infections and adverse events related to new procedures performed in healthcare; and 4) develop new strategies to prevent healthcare-associated infections.

Healthcare-associated Infections: The Hidden Harm of Healthcare

As the nation's health protection agency, CDC is committed to helping all Americans receive the best and safest care when they are treated at a hospital or other healthcare facility. CDC has defined twenty-one specific health protection goals to prioritize and focus its work and investments and measure progress. Our Division has been designated as the lead for the goals to increase the number of healthcare settings that provide safe, effective, and satisfying patient care. Healthcare-associated infections are infections that patients acquire during the course of receiving medical treatment for other conditions; these infections are a threat to patient safety. An increasing public awareness of this serious problem has led to a call for public disclosure of healthcare infection rates in the United States through mandatory reporting of information related to healthcare-associated infections.

Healthcare-associated infections in the hospital are among the most common adverse events in healthcare. CDC estimates there are approximately 1.7 million healthcare-associated infections in U.S. hospitals and 99,000 associated deaths each year. There are approximately 4.5 infections per 100 hospital admissions, 9.3 infections per 1000 patient days in Intensive Care Units (ICUs), and 2 surgical site infections per 100 operations. These estimates are based on best available data, but some infections are known to be underreported, so the actual number of healthcare-associated infections may be higher.

Estimates of the economic impact of healthcare-associated infections vary because of differences in how the data are defined and analyzed. Data from published studies indicate the estimated cost of healthcare-associated infection, adjusted to 2004 dollars, ranges from $10,500 per case for bloodstream, urinary tract, and pneumonia infections to $111,000 per case for antibiotic-resistant bloodstream infection in transplant patients.

Who is at Risk for Healthcare-associated Infections?

Healthcare-associated infections are defined as infections affecting patients who receive either medical or surgical treatments. The procedures and devices used to treat patients can also place them at increased risk for healthcare-associated infections. A patient's skin, the natural protection against bacteria entering the blood, is continually compromised by the insertion of needles and tubes to deliver life saving medicine. Microbial pathogens can be transmitted through tubes and devices that are going into patients, providing a pathway into the blood stream and lungs. Because of the number of procedures and the seriousness of patient conditions, patients treated in the ICU have the highest risk of healthcare-associated infections.

The frequency of healthcare-associated infections varies by body site. In the United States from 1990-2004, the most frequent healthcare-associated infections reported to the National Nosocomial Infections Surveillance (NNIS) system, overall, were urinary tract infections (34%), followed by surgical site infections (17%), bloodstream infections (14%), and pneumonia (13%).

Bacterial Species Causing Healthcare-associated Infections

To understand the problem of healthcare-associated infections, it is vitally important to recognize the intertwined problem of antimicrobial resistance. Infections that are acquired in hospitals and other healthcare settings are frequently caused by bacteria that have become resistant to multiple antimicrobial drugs. These organisms have gained resistance while remaining highly infectious and are easily spread in healthcare settings. Efforts to prevent healthcare-associated infections must therefore be strategically interwoven into efforts that address increasing antimicrobial resistance.

Resistant infections contribute substantially to healthcare costs, illness, and death. Although a number of different bacteria can cause these infections, there are a few that cause the majority of diseases. Of particular concern is the bacteria known as methicillin-resistant *Staphylococcus aureus* or MRSA. MRSA was first recognized as a cause of healthcare-associated infections in the 1960's and has become commonplace in many hospitals in the United States. According to CDC surveillance, MRSA was the cause of 29% of *Staphylococcus aureus* infections acquired by patients in intensive care units in 1991. By 2003, that number had increased to 60%. The number of MRSA infections among hospitalized patients in the United States has been estimated to be at least 126,000 per year. Because of the tremendous impact of MRSA and other resistant bacteria as causes of healthcare-associated infections, an integrated approach to detection, control, and prevention is required and is being recommended by CDC.

Investigation and Response

Bacteria and other microbial pathogens causing healthcare-associated infections are constantly changing. As new antibiotics are released, the organisms find ways to develop resistance. As new devices are used in hospitals, the organisms find new or unexpected ways to infect patients. The dynamic nature of healthcare-associated infections requires a vigilant eye for detecting and responding to these emerging threats.

CDC serves as a national leader for investigating outbreaks of healthcare-associated infections along with state and local health departments. Discussions or calls from concerned clinicians and infection control professionals often prompt further investigation. During investigations involving contaminated medical devices or medication, CDC works with the Food and Drug Administration to recall contaminated devices and medicines if necessary to prevent further infections and save patients' lives. For some outbreaks, CDC sends its own epidemiologists, physicians, and scientists to hospitals to interview patients and staff, to review medical records and to test for microbial contamination of devices or of the environment. During investigations, CDC staff interview and gather information from patients and family members. Information from these investigations have a direct impact on controlling and preventing healthcare-associated infections at these facilities, but also directly lead to improvements in national infection control guidelines and in development of definitions used for public reporting in those states mandating it. For example, CDC epidemic intelligence service officers were recently deployed to North Carolina to investigate increases in reports of cases caused by *Clostridium difficile*, a bacterium that causes over 200,000 cases of healthcare-associated diarrheal disease each year. Interviews with patients and family members are leading to a better understanding of the characteristics of the illness and the source of infection. In addition to prevention of infections, this information is being used to make practical

definitions available for use in public reporting for states that are considering making *Clostridium difficile* infection reportable as was recently done in Ohio.

Prevention

CDC 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 guidelines serve as the standard of care in U.S. hospitals and guide the clinical practices of physicians, nurses and other providers. However, full adherence to these recommendations in clinical practice remains a challenge. For example, CDC developed and disseminated evidence-based guidelines to prevent surgical site infections. Subsequent assessment of adoption of these practices among U.S. surgeons has shown that adherence to these recommendations needs to be improved. CDC has successfully partnered with the Centers for Medicare and Medicaid Services (CMS), surgical societies, and other stakeholders to design and launch a national initiative for prevention of surgical site infections. In addition, CDC guidelines have served as the basis for national healthcare quality initiatives such as the Institute for Healthcare Improvement's 100,000 Lives Campaign, and the Surgical Care Improvement Project. These collaborations help to standardize clinical practice, translate policy into practice, and reduce healthcare-associated infections.

Monitoring Infections

Through voluntary reporting from a national network of sentinel hospitals, CDC has monitored healthcare-associated infections since 1970 using the surveillance methods of the NNIS system. With these data, CDC has provided hospitals nationwide with infection rates that they use to track their progress in prevention and control efforts.

More than just a reporting mechanism, NNIS has set standards that have been used by hospitals and healthcare researchers internationally to measure healthcare-associated infections and to document progress with adherence to infection control practices. Standard definitions for surveillance and standard approaches to data collection and analysis have allowed clinicians and hospital staff to gauge how well they are preventing infectious disease outcomes such as bloodstream infections, pneumonias, urinary tract infections, and surgical site infections. Because hospitals may have very different kinds of patients, rates of healthcare-associated infections can be calculated to account for differences in severity of illness or in the complexity of procedures performed. The use of these "risk-adjusted rates" allows facilities to more accurately compare their own progress in infection prevention and control to other facilities as well as to their own rates in the past.

The purpose of surveillance is not simply to count and characterize healthcare-associated infections, but most importantly to control and prevent them. The data are only as good as our ability to improve the quality of healthcare and to minimize and eliminate infections. For this reason, CDC built into NNIS, and now into the recently launched web-based surveillance system called the National Healthcare Safety Network (NHSN), the ability for facilities to analyze their own infection data and to tailor their activities to meet their greatest needs. This feedback, coupled with quality improvement initiatives to increase adherence to CDC infection control practice standards, can reduce healthcare-associated infections.

National Data for Local Action

The systematic collection and analysis of data on healthcare-associated infections yields critical information that can improve infection prevention and control. Hospitals that participated in the NNIS system have been successful in reducing rates of specific infection types across the spectrum of healthcare-associated infections.

During 1990-2004, rates of infections from medical devices decreased for three main body sites: the respiratory tract, urinary tract, and bloodstream, which are all monitored in ICUs. Bloodstream infections from tubes or catheters used to monitor patients or deliver medicine directly into major blood vessels (central lines) decreased substantially over the 14-year period. They decreased by 54% in medical ICUs, by 43% in coronary ICUs, 43% in surgical ICUs, and 27% in pediatric ICUs. For urinary catheter-associated infections, similar decreases among these same four ICU types ranged from 43% to 61%. Trends of ventilator-associated pneumonia rates were assessed through 2001 and substantially decreased from 31% to 58% among these same ICU types. These data are derived from CDC's NNIS and NHSN systems, which have proved to be instrumental in initiating change by effectively providing hospitals feedback about their own infection rates resulting in these significant decreases.

One example of how the system has led to improvement in healthcare-associated infection rates comes from a hospital in New York. Linda Greene is an Infection Control Professional whose 500-bed hospital in New York has participated in the NNIS system since 1995. She states, "We have made significant improvements in several areas as a result of being able to utilize infection data which is reliable, valid, and risk adjusted. We are then able to turn this data into information which allows care providers to improve both the outcomes of care as well as those processes most closely associated with these outcomes." She reports that one specific project resulted in a 75% reduction in central line-associated bloodstream infections over 2 years resulting in a drop in attributable mortality to zero and preventing more than one million dollars in costs. Their reduction has been statistically significant and sustainable.

At the core of efforts to share prevention solutions is the use of healthcare-associated infection data as a common measurement and feedback tool. Using a standardized form of measuring healthcare-associated infections, such as the kind NNIS and NHSN provide, allows hospitals to communicate with one another about the impact of their prevention efforts in a meaningful and credible way and spread the word about prevention strategies that work.

Regional Data for Local Action

The Pittsburgh Regional Healthcare Initiative includes approximately 40 healthcare facilities in the Pittsburgh area with the goal of eliminating preventable healthcare-associated infections. Working closely with our prevention partners in southwestern Pennsylvania and elsewhere, CDC is using NHSN to collect data in standardized ways and collect process measures (e.g., selected practices used during central line insertion, such as correctly preparing the skin) and outcome measures (e.g., selected healthcare-associated infections such as central line-associated bloodstream infections) in the participating hospitals in the Pittsburgh area. These data and the successful prevention methods are shared with clinicians and hospitals. Our work there suggests that hospitals are eager for this type of productive sharing of regional information. For example, a bloodstream infection prevention initiative involved over 70% of the eligible hospitals in Pittsburgh metropolitan statistical area, and included a wide range of facilities from the very smallest community hospitals to the very largest tertiary care facilities.

This CDC-supported collaboration in Pennsylvania resulted in a 68% reduction in the rate of central line-associated bloodstream infections during the period April 2001--March 2005, a reduction that is estimated to result in at least 40 lives saved every year among the group of intensive care units that participated. Strategies perceived as

important to this success include the involvement of leadership; feedback of unit-, facility-, and region-specific rates of healthcare-associated infections using the NHSN system; measurement and feedback of adherence to recommended practices; and real-time response to infections. These experiences with Pittsburgh Regional Healthcare Initiative highlight the importance of regional data for local action to prevent healthcare-associated infections and underscore the confidence participants had in NNIS standards that allowed fair comparisons among facilities. We need standard definitions and data collection tools in order to compare, share, and improve practices. Standardized process and outcome measures for national healthcare performance for hospitals, nursing homes, and other settings have been endorsed by several agencies and organizations, including other U.S. federal agencies and other organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Public Reporting of Healthcare-associated Infections

An increasing public awareness of the serious problem of healthcare-associated infections and the uses of data collection have led to a call for public disclosure of healthcare infection rates in the United States. Since 2002, seven states have enacted legislation mandating hospitals and other healthcare organizations to report healthcare-associated infection rates. These states are Florida, Illinois, Missouri, Nevada, New York, Pennsylvania, and Virginia. All but Nevada include a provision for public disclosure. In addition, 22 states have 2006 legislative activity underway and six states have bills requiring further study on the issue.

CDC believes that information about healthcare-associated infections can lead to an increased focus on infection control and prevention. In addition, CDC experience has shown that sharing information for local action can improve patient safety. CDC believes that educating clinicians, decision makers, and the public about the prevention of healthcare-associated infections is an important benefit of the dialogue created by the healthcare-associated infection public reporting movement.

In order to better guide the states considering legislation for mandatory reporting of healthcare-associated infection information, CDC partnered with the Healthcare Infection Control Practices Advisory Committee, the Council for State and Territorial Epidemiologists, the Association for Professionals in Infection Control and Epidemiology (APIC), and the Society for Healthcare Epidemiology of America (SHEA) to develop guidance for public reporting of healthcare-associated infections.

These recommendations include 1) to use established public health surveillance methods when designing and implementing mandatory healthcare-associated infection reporting systems; 2) to create multidisciplinary advisory panels, including persons with expertise in the prevention and control of healthcare-associated infections, to monitor the planning and oversight of public reporting systems for healthcare-associated infection; 3) to choose appropriate process and outcome measures based on facility type and phase-in measures to allow time for facilities to adapt and to permit ongoing evaluation of data validity; and 4) to provide regular and confidential feedback of performance data to healthcare providers. As more research and experience becomes available, the recommendations will be updated.

CDC's experience with Pittsburgh Regional Healthcare Initiative and other groups indicates that monitoring healthcare-associated infections through both process measures and outcome measures is desirable. When deciding what should be recommended, the Healthcare Infection Control Practices Advisory Committee and partners considered infections with simple definitions and existing measurement recommendations by CDC, JCAHO and CMS.

Over time, any standard will need to be revised when new scientific information becomes available and as medical practice evolves. It is clear from CDC's experience that a reporting system will produce quality data when the infrastructure includes trained

infection control personnel, maintenance of manual and automated data collection systems and databases, analysis and interpretation of findings, creation of evidence-based recommendations, and feedback to healthcare professionals to effect change in practices.

CDC supports national standards as a key to consistency in case finding, data collection, trend analysis, risk adjustment, and comparisons across surveillance sites and jurisdictions. As the science of risk adjustment advances, CDC will lead the effort to incorporate these advances into the system in order to respond better to future national and state needs or requests. CDC also supports use of electronic data for surveillance as a way to streamline case detection and reporting, provided the electronic data are sufficiently detailed and reliable for those purposes. The design of NHSN will accommodate transmission of data in electronic form from hospital systems to CDC. As electronic health record systems are more widely adopted, NHSN is well positioned to accept electronic data that originate in clinical care.

It has been recognized that with the benefits that public reporting may bring, there is also the potential for unintended consequences. Mandatory public reporting that does not incorporate sound surveillance principles and reasonable goals may divert resources to reporting infections and collecting data for risk adjustment and away from patient care and prevention. Such reporting also could result in unintended disincentives to treat patients at higher risk for healthcare-associated infection. Lastly, publicly reported healthcare-associated infection rates can mislead stakeholders if inaccurate information is disseminated. Therefore, in a mandatory public report of healthcare-associated infection information, the limitations of current methods should be clearly communicated within the publicly released report. Research and evaluation of existing and future healthcare-associated infection reporting systems is needed to answer questions about 1) the comparative effectiveness and efficiency of public reporting systems and 2) the occurrence and prevention of unintended consequences. Ongoing evaluation of public reporting will be needed to confirm the appropriateness of the methods used and the validity of the results.

Building on NNIS Success – NHSN

To enhance the potential for public reporting, enable even more healthcare facilities to participate in a national surveillance system, and use recent advances in information technology, CDC launched the NHSN in 2005. NHSN is a secure, Internet-based system that builds on the working relationships and surveillance standards established in NNIS. The system is built using standard approaches for information exchange consistent with the HHS National Health Information Technology Initiative. Through NHSN, participating hospitals can report to CDC and can join a group (e.g., a state reporting agency or healthcare system) allowing the agency or healthcare system to see their data. Additionally, the data can be entered once but can be used for multiple purposes, both for guiding prevention programs in the hospital and for public reporting. This removes parallel, redundant data entry. As a result of CDC's discussions with states about NHSN, technical enhancements are planned to better support public reporting. CDC is expanding its training and user support for NHSN and is adding information technology capacity to handle the anticipated increase in system use.

Virginia now requires the use of NHSN and Missouri recommends that NHSN be used for purposes of public reporting. Other states, including New York, are considering the use of NHSN. CDC is working with various state colleagues regarding the option of using NHSN to meet their needs and to define the roles and responsibilities of CDC and state agencies if NHSN is selected for use. Wide adoption and adherence to nationally standardized infection criteria, data collection protocols, and statistical methods enables NHSN to be used more effectively for public reporting across states. The ability to compare data produced through a standards-based approach will increase the value of healthcare-associated infection reporting for the public, policy makers, and practitioners.

Conclusion

Healthcare-associated infections are a threat to patient safety. While many organizations are working hard to prevent infections and fight antimicrobial resistance in U.S. healthcare settings, this issue continues to be a challenge. These problems are larger than any one institution or agency can solve alone. Individuals at the federal, state, and local levels, in the public and private sector, need to work together to improve strategies to meet this healthcare challenge. The information derived from public reporting of healthcare-associated infections can be a catalyst for increased adherence to recommendations, while steering public and private efforts to develop new strategies to prevent healthcare-associated infections. CDC is strategically positioned to continue to provide leadership in this area.

Thank you very much for your attention. I will be happy to answer any questions you may have.

MR. WHITFIELD. Dr. Cardo, thank you. And before I ask questions, I do want to ask unanimous consent that we introduce this exhibit binder into the record, and I believe you all have seen this. So ordered.

[The information follows:]

EXHIBIT INDEX

Ex. #	Description	Date
1	Missouri Hospital Infection Control act of 2004 (SB 1279)	8/28/04
2	Map of State Public Reporting Legislation, prepared by the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)	2/22/06
3	CDC Response to Committee's Letter Requesting Information on Hospital-Acquired Infections dated September 21, 2005	10/19/05
4	CDC Chart: Central Line-Associated Bloodstream Infection Rates, By ICU Type, 1990-2004	March 2006
5	"Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee," *American Journal of Infection Control* (pp. 217-226)	May 2005
6	PHC4 Research Brief: "Hospital-Acquired Infections in Pennsylvania" (Issue No. 5)	7/1/05
7	PHC4 Research Brief: "Reducing Hospital-Acquired Infections: The Business Case" (Issue No. 8)	11/1/05
8	PHC4 Research Brief: "Hospital-Acquired Infections in Pennsylvania: Numbers Rise As Data Submission Improves, Additional Insurance Payments Could Total $613.7 Million" (Issue No. 9)	3/29/06
9	Presentation by Dr. Richard P. Shannon, Chair, Department of Medicine, Allegheny General Hospital: "Eliminating Hospital Acquired Infections: Is it Possible? Is it Sustainable? Is it Worth it?"	
10	Doctors Medical Center of Modesto Response to Committee's Letter Requesting Information on Hospital-Acquired Infection dated September 21, 2005	10/18/05
11	Tenet Model Infection Control Program Plan	5/20/05
12	New York Presbyterian Hospital Response to Committee's Letter Requesting Information on Hospital-Acquired Infection dated September 21, 2005	11/30/05
13	MetroHealth Medical Center Response to Committee's Letter Requesting Information on Hospital-Acquired Infection dated September 21, 2005	10/10/05
14	MHA Keystone Center for Patient Safety and Quality: documents re. HAI initiative in ICUs	10/13/05
15	Joint Project of Johns Hopkins School of Medicine and Michigan Hospital Association: "Statewide Efforts to Improve Care in Intensive Care Units" (10/1/03 through 9/30/05)	
16	"Improving ICU Care: It Takes a Team," *Healthcare Executive* (Peter Pronovost, M.D., Ph.D, and Chris Goeschel, R.N.; pp. 15-22)	March/ April 2005

SB 1279	Creates the Missouri Hospital Infection Control Act of 2004

Sponsor:	*Steelman*	*Co-Sponsor (s)*	
LR Number:	4608L.07T	**Fiscal Note:**	4608-07
Committee:	Aging, Families, Mental & Public Health		
Last Action:	06/28/04 - Signed by Governor	**Journal page:**	
Title:	HCS SS SCS SB 1279		
Effective Date:	August 28, 2004		

Full Bill Text | All Actions | Available Summaries | Senate Home Page | List of 2004 Senate Bills

Current Bill Summary

HCS/SS/SCS/SB 1279 - This act creates the "Missouri Nosocomial Infection Control Act of 2004" to encourage health care facilities to take appropriate actions to decrease the risk of infection.

SECTION 192.020 - The Department shall include MRSA and VRE in its list of communicable diseases.

SECTION 192.067 - The Department shall have the authority to collect, analyze, and disclose nosocomial infection data from patient records.

SECTION 192.131(1)-(2) - This section provides definitions for "advisory panel", "antibiogram", and "antimicrobial". Every laboratory performing culture and sensitivity testing on humans in Missouri shall submit data on health care associated infections to the Department.

The data to be reported shall be defined by the Department. By July 1, 2005, the data must include the number of patients or isolates by hospital, ambulatory surgical center, and other facility who are infected with MRSA and VRE.

SECTION 192.131(3)-(5) - All information collected pursuant to this section shall be confidential. However, this information shall be available to the appropriate facility or professional licensing authorities. The Advisory Panel shall develop a plan, using the collected data, to create a system that enhances the ability of health care providers to track preventable infections and monitors trends relating to antibiotic-resistant microbes. The Advisory Panel and the Department must conform to standards adopted by the Centers for Disease Control and Prevention.

SECTION 192.665 - This section adds new definitions for "nosocomial infection", "nosocomial infection incidence rate", and "other facility".

SECTION 192.667(1)-(11) - The Department must collect data on nosocomial infection incidence rates from hospitals, ambulatory surgical centers, and other appropriate facilities. By July 1, 2005, the Department must promulgate rules regarding the standards and procedures for the collection and reporting of nosocomial infection incidence rates and these rules shall be based upon the methodologies established by the Centers for Disease Control and Prevention National Nosocomial Infection Surveillance System and the recommendations of the Infection Control Advisory Panel.

The Infection Control Advisory Panel shall make a recommendation, based on certain factors, to the Department regarding the implementation of nosocomial infection data collection, analysis, and reporting. If the Department chooses the requirements of the Centers for Disease Control Prevention's National Nosocomial Infection Surveillance System instead of the requirements listed in this section, then hospitals and ambulatory surgical centers that opt to participate in the federal program must provide the necessary data as a condition for licensure. Any hospital or ambulatory surgical center which does not voluntarily participate in the federal program shall be required to abide by the requirements enumerated in subsections 2,3, and 6 through 12

of this section.

SECTION 192.667(11)-(14) - Physician's offices shall be exempt from the reporting and disclosure of infection incidence rates. In consultation with the Advisory Panel, the Department must disseminate reports to the public, based on data compiled over a twelve-month period and updated quarterly thereafter, that show for each hospital, ambulatory surgical center, and other facility a risk-adjusted nosocomial infection incidence rate for class I surgical site infections, ventilator-associated pneumonia, central line-related bloodstream infections, and other infections defined by rule by the Department. By December 31, 2006, these reports shall also be published on the Department's website and shall be annually distributed to the Governor and the General Assembly.

SECTION 192.667(15)-(17) - If the Hospital Industry Data Institute fails by July 31, 2008 and annually thereafter to publish a report of Missouri's compliance with the quality of care measures established by the Centers for Medicare and Medicaid Services, the Department shall have the authority to collect and publish this information. This information shall also be available to the Department for the licensing of hospitals and ambulatory surgical centers pursuant to Chapter 197, RSMo.

SECTION 197.150 - Hospitals, ambulatory surgical centers, and other facilities must have procedures for monitoring compliance with infection control regulations and standards. These procedures must be coordinated with administrative and personnel staff. The infection control program shall include the surveillance of personnel, with a portion of the surveillance done without the staff's knowledge. However, this unobserved surveillance requirement cannot be considered grounds for licensure enforcement actions until the Department establishes clear and verifiable criteria for determining compliance.

SECTION 197.152 - Infection control officers and other employees shall be protected from retaliation from any hospitals, ambulatory surgical centers, or other facilities. Any interference in the duties of an infection control officer shall be reported to the hospital and ambulatory

surgical center supervisors. Infection control officers have the authority to order the termination of any practice that falls outside the standard of care in infection control. The hospital or ambulatory surgical center infection control committee must convene as soon as possible to review any termination action. Employees who report infection control concerns in good faith shall not be subject to retaliation or discrimination.

SECTION 197.154 - By July 1, 2005, the Department must promulgate rules establishing certain standards for the infection control programs, which shall based upon nationally recognized standards.

SECTION 197.156 - "Nosocomial infection outbreaks" are defined by the Centers for Disease Control and Prevention within a defined time period. The Department shall define the time period based upon the number of infected patients in a facility.

SECTION 197.158 - Beginning June 1, 2006, all hospitals and ambulatory surgical centers shall provide each patient an opportunity to submit complaints, comments, or suggestions relating to the quality of care received.

SECTION 197.160 - The Department shall have access to all information compiled by hospitals, ambulatory surgical centers, and other facilities related to infection control practices, rates, and treatments. The failure to provide access to this information shall be grounds for a full or partial licensure suspension or revocation. If a hospital, ambulatory surgical center, or other facility willfully impedes access to this information, then the Department has the authority to direct any state agency to suspend all or a portion of state payments until the Department receives the information.

SECTION 197.162 - For the licensing of hospitals and ambulatory surgical centers, the Department shall give special attention to infection control practices and shall direct these facilities to set quantifiable measures of performance for reducing nosocomial infections. The Department must annually prepare a report on infection control standards and compliance. The report shall be distributed to the General Assembly and the Governor.

SECTION 197.165 - The Department must appoint an "Infection Control Advisory Panel", which shall consist of thirteen members. Any reasonable expenses of the Panel shall be paid from private donations made specifically to the "Infection Control Advisory Panel Fund", which is created in the State Treasury.

SECTION 197.294 - No information disclosed by the Department to the public pursuant to this act shall be used to establish a standard of care in a civil action.

This act is identical to SCS/HS/HCS/HB 1477 & 1563 (2004).
LORIE TOWE

SECOND REGULAR SESSION

[TRULY AGREED TO AND FINALLY PASSED]

HOUSE COMMITTEE SUBSTITUTE FOR

SENATE SUBSTITUTE FOR

SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 1279

92ND GENERAL ASSEMBLY

2004

4608L.07T

AN ACT

To repeal sections 192.020, 192.067, 192.138, 192.665, 192.667, and 197.293, RSMo, and to enact in lieu thereof seventeen new sections relating to health care facilities, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 192.020, 192.067, 192.138, 192.665, 192.667, and 197.293, RSMo, are repealed and seventeen new sections enacted in lieu thereof, to be known as sections 192.020, 192.021, 192.067, 192.131, 192.138, 192.665, 192.667, 197.150, 197.152, 197.154, 197.156, 197.158, 197.160, 197.162, 197.165, 197.293, and 197.294, to read as follows:

192.020. **1.** It shall be the general duty and responsibility of the department of health and senior services to safeguard the health of the people in the state and all its subdivisions. It shall make a study of the causes and prevention of

diseases. It shall designate those diseases which are infectious, contagious, communicable or dangerous in their nature and shall make and enforce adequate orders, findings, rules and regulations to prevent the spread of such diseases and to determine the prevalence of such diseases within the state. It shall have power and authority, with approval of the director of the department, to make such orders, findings, rules and regulations as will prevent the entrance of infectious, contagious and communicable diseases into the state.

2. The department of health and senior services shall include in its list of communicable or infectious diseases which must be reported to the department methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococcus (VRE).

192.021. This act shall be known and may be cited as the "Missouri Nosocomial Infection Control Act of 2004". The purpose of the act is to decrease the incidence of infection within health care facilities in this state.

192.067. 1. The department of health and senior services, for purposes of conducting epidemiological studies to be used in promoting and safeguarding the health of the citizens of Missouri under the authority of this chapter is authorized to receive information from patient medical records. **The provisions of this section shall also apply to the collection, analysis, and disclosure of nosocomial infection data from patient records collected pursuant to section 192.667.**

2. The department shall maintain the confidentiality of all medical record information abstracted by or reported to the department. Medical information secured pursuant to the provisions of subsection 1 of this section may be released by the department only in a statistical aggregate form that precludes and prevents the identification of patient, physician, or medical facility except that medical information may be shared with other public health authorities and coinvestigators of a health study if they abide by the same confidentiality restrictions required of the department of health and senior services **and except as otherwise authorized by the provisions of sections 192.665 to 192.667**. The department of health and senior services, public health authorities and coinvestigators shall use the information collected only for the purposes provided for in this section **and section 192.667**.

3. No individual or organization providing information to the department in accordance with this section shall be deemed to be or be held liable, either civilly or criminally, for divulging confidential information unless such individual organization acted in bad faith or with malicious purpose.

4. The department of health and senior services is authorized to reimburse medical care facilities, within the limits of appropriations made for that purpose, for the costs associated with abstracting data for special studies.

5. Any department of health and senior services employee, public health authority or coinvestigator of a study who knowingly releases information which violates the provisions of this section shall be guilty of a class A misdemeanor and, upon conviction, shall be punished as provided by law.

192.131. 1. As used in this section, the following terms shall mean:

(1) "Advisory panel", the infection control advisory panel created by section 197.165, RSMo;

(2) "Antibiogram", a record of the resistance of microbes to various antibiotics;

(3) "Antimicrobial", the ability of an agent to destroy or prevent the development of pathogenic action of a microorganism;

(4) "Department", the department of health and senior services.

2. Every laboratory performing culture and sensitivity testing on humans in Missouri shall submit data on health care associated infections to the department in accordance with this section. The data to be reported shall be defined by regulation of the department after considering the recommendations of the advisory panel. Such data may include antibiograms and, not later than July 1, 2005, shall include but not be limited to the number of patients or isolates by hospital, ambulatory surgical center, and other facility or practice setting with methicillin-resistant staphylococcus aureus (MRSA) or vancomycin-resistant enterococcus (VRE).

3. Information on infections collected pursuant to this section shall be subject to the confidentiality protections of this chapter but shall be

available in provider-specific form to appropriate facility and professional licensure authorities.

4. The advisory panel shall develop a recommended plan to use laboratory and health care provider data provided pursuant to this chapter to create a system to:

(1) Enhance the ability of health care providers and the department to track the incidence and distribution of preventable infections, with emphasis on those infections that are most susceptible to interventions and that pose the greatest risk of harm to Missouri residents;

(2) Monitor trends in the development of antibiotic-resistant microbes, including but not limited to methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococcus (VRE) infections.

5. In implementing this section, the advisory panel and the department shall conform to guidelines and standards adopted by the centers for disease control and prevention. The advisory panel's plan may provide for demonstration projects to assess the viability of the recommended initiatives.

192.138. Other provisions of the law to the contrary notwithstanding, requirements imposed by state law or regulation that institutions defined under chapters 197, RSMo, and 198, RSMo, make notifications concerning patients who are diagnosed as having reportable infectious or contagious diseases shall apply to such institutions provided that such notifications are consistent with federal laws and rules and regulations imposed thereunder governing the confidentiality of records of patients receiving medical assistance under the provisions of federal law [and further provide that such institutions failing to make such notifications shall not be deemed to have violated any state law or regulation requiring notification or considered civilly liable unless such institutions acted in bad faith or with malicious purpose].

192.665. As used in this section [and], section 192.667, **and sections 197.150 to 197.165, RSMo**, the following terms mean:

(1) "Charge data", information submitted by health care providers on current charges for leading procedures and diagnoses;

(2) "Charges by payer", information submitted by hospitals on amount billed to Medicare, Medicaid, other government sources and all nongovernment sources combined as one data element;

(3) "Department", the department of health and senior services;

(4) "Financial data", information submitted by hospitals drawn from financial statements which includes the balance sheet, income statement, charity care and bad debt and charges by payer, prepared in accordance with generally accepted accounting principles;

(5) "Health care provider", hospitals as defined in section 197.020, RSMo, and ambulatory surgical centers as defined in section 197.200, RSMo;

(6) "Nosocomial infection", as defined by the national Centers for Disease Control and Prevention and applied to infections within hospitals, ambulatory surgical centers, and other facilities;

(7) "Nosocomial infection incidence rate", a risk-adjusted measurement of new cases of nosocomial infections by procedure or device within a population over a given period of time, with such measurements defined by rule of the department pursuant to subsection 3 of section 192.667 for use by all hospitals, ambulatory surgical centers, and other facilities in complying with the requirements of the Missouri nosocomial infection control act of 2004;

(8) "Other facility", a type of facility determined to be a source of infections and designated by rule of the department pursuant to subsection 11 of section 192.667;

(9) "Patient abstract data", data submitted by hospitals which includes but is not limited to date of birth, sex, race, zip code, county of residence, admission date, discharge date, principal and other diagnoses, including external causes, principal and other procedures, procedure dates, total billed charges, disposition of the patient and expected source of payment with sources categorized according to Medicare, Medicaid, other government, workers' compensation, all commercial payors coded with a common code, self-pay, no charge and other.

192.667. 1. All health care providers shall at least annually provide to the

department charge data as required by the department. All hospitals shall at least annually provide patient abstract data and financial data as required by the department. Hospitals as defined in section 197.020, RSMo, shall report patient abstract data for outpatients and inpatients. Within one year of August 28, 1992, ambulatory surgical centers as defined in section 197.200, RSMo, shall provide patient abstract data to the department. The department shall specify by rule the types of information which shall be submitted and the method of submission.

2. **The department shall collect data on required nosocomial infection incidence rates from hospitals, ambulatory surgical centers, and other facilities as necessary to generate the reports required by this section. Hospitals, ambulatory surgical centers, and other facilities shall provide such data in compliance with this section.**

3. No later than July 1, 2005, the department shall promulgate rules specifying the standards and procedures for the collection, analysis, risk adjustment, and reporting of nosocomial infection incidence rates and the types of infections and procedures to be monitored pursuant to subsection 12 of this section. In promulgating such rules, the department shall:

(1) Use methodologies and systems for data collection established by the federal Centers for Disease Control and Prevention National Nosocomial Infection Surveillance System, or its successor; and

(2) Consider the findings and recommendations of the infection control advisory panel established pursuant to section 197.165, RSMo.

4. The infection control advisory panel created by section 197.165, RSMo, shall make a recommendation to the department regarding the appropriateness of implementing all or part of the nosocomial infection data collection, analysis, and public reporting requirements of this act by authorizing hospitals, ambulatory surgical centers, and other facilities to participate in the federal Centers for Disease Control and Prevention's National Nosocomial Infection Surveillance System, or its successor. The advisory panel shall consider the following factors in developing its recommendation:

(1) Whether the public is afforded the same or greater access to facility-specific infection control indicators and rates than would be provided under subsections 2, 3, and 6 to 12 of this section;

(2) Whether the data provided to the public are subject to the same or greater accuracy of risk adjustment than would be provided under subsections 2, 3, and 6 to 12 of this section;

(3) Whether the public is provided with the same or greater specificity of reporting of infections by type of facility infections and procedures than would be provided under subsections 2, 3, and 6 to 12 of this section;

(4) Whether the data are subject to the same or greater level of confidentiality of the identity of an individual patient than would be provided under subsection 2, 3, and 6 to 12 of this section;

(5) Whether the National Nosocomial Infection Surveillance System, or its successor, has the capacity to receive, analyze, and report the required data for all facilities;

(6) Whether the cost to implement the nosocomial infection data collection and reporting system is the same or less than under subsections 2, 3, and 6 to 12 of this section.

5. Based on the affirmative recommendation of the infection control advisory panel, and provided that the requirements of subsection 12 of this section can be met, the department may or may not implement the federal Centers for Disease Control and Prevention Nosocomial Infection System, or its successor, as an alternative means of complying with the requirements of subsections 2, 3, and 6 to 12 of this section. If the department chooses to implement the use of the federal Centers for Disease Control Prevention Nosocomial Infection System, or its successor, as an alternative means of complying with the requirements of subsections 2, 3, and 6 to 12 of this section, it shall be a condition of licensure for hospitals and ambulatory surgical centers which opt to participate in the federal program to permit the federal program to disclose facility-specific data to the department as necessary to provide the public reports required by the department. Any hospital or ambulatory surgical center which does not voluntarily participate in the

National Nosocomial Infection Surveillance System, or its successor, shall be required to abide by all of the requirements of subsections 2, 3, and 6 to 12 of this section.

6. The department shall not require the resubmission of data which has been submitted to the department of health and senior services or the department of social services under any other provision of law. The department of health and senior services shall accept data submitted by associations or related organizations on behalf of health care providers by entering into binding agreements negotiated with such associations or related organizations to obtain data required pursuant to section 192.665 and this section. A health care provider shall submit the required information to the department of health and senior services:

(1) If the provider does not submit the required data through such associations or related organizations;

(2) If no binding agreement has been reached within ninety days of August 28, 1992, between the department of health and senior services and such associations or related organizations; or

(3) If a binding agreement has expired for more than ninety days.

[3.] **7.** Information obtained by the department under the provisions of section 192.665 and this section shall not be public information. Reports and studies prepared by the department based upon such information shall be public information and may identify individual health care providers. The department of health and senior services may authorize the use of the data by other research organizations pursuant to the provisions of section 192.067. The department shall not use or release any information provided under section 192.665 and this section which would enable any person to determine any health care provider's negotiated discounts with specific preferred provider organizations or other managed care organizations. The department shall not release data in a form which could be used to identify a patient. Any violation of this subsection is a class A misdemeanor.

[4.] **8.** The department shall undertake a reasonable number of studies and publish information, including at least an annual consumer guide, in collaboration with health care providers, business coalitions and consumers

based upon the information obtained pursuant to the provisions of section 192.665 and this section. The department shall allow all health care providers and associations and related organizations who have submitted data which will be used in any report to review and comment on the report prior to its publication or release for general use. The department shall include any comments of a health care provider, at the option of the provider, and associations and related organizations in the publication if the department does not change the publication based upon those comments. The report shall be made available to the public for a reasonable charge.

[5.] **9.** Any health care provider which continually and substantially, as these terms are defined by rule, fails to comply with the provisions of this section shall not be allowed to participate in any program administered by the state or to receive any moneys from the state.

[6.] **10.** A hospital, as defined in section 197.020, RSMo, aggrieved by the department's determination of ineligibility for state moneys pursuant to subsection [5] **9** of this section may appeal as provided in section 197.071, RSMo. An ambulatory surgical center as defined in section 197.200, RSMo, aggrieved by the department's determination of ineligibility for state moneys pursuant to subsection [5] **9** of this section may appeal as provided in section 197.221, RSMo.

[7. No rule or portion of a rule promulgated under the authority of section 192.665 and this section shall become effective unless it has been promulgated pursuant to the provisions of section 536.024, RSMo.]

11. The department of health may promulgate rules providing for collection of data and publication of nosocomial infection incidence rates for other types of health facilities determined to be sources of infections; except that, physicians' offices shall be exempt from reporting and disclosure of infection incidence rates.

12. In consultation with the infection control advisory panel established pursuant to section 197.165, RSMo, the department shall develop and disseminate to the public reports based on data compiled for a period of twelve months. Such reports shall be updated quarterly and shall show for each hospital, ambulatory surgical center, and other facility a risk-adjusted nosocomial infection incidence rate for the following types of

infection:

(1) Class I surgical site infections;

(2) Ventilator-associated pneumonia;

(3) Central line-related bloodstream infections;

(4) Other categories of infections that may be established by rule by the department.

The department, in consultation with the advisory panel, shall be authorized to collect and report data on subsets of each type of infection described in this subsection.

13. In the event the provisions of this act are implemented by requiring hospitals, ambulatory surgical centers, and other facilities to participate in the federal Centers for Disease Control and Prevention National Nosocomial Infection Surveillance System, or its successor, the types of infections to be publicly reported shall be determined by the department by rule and shall be consistent with the infections tracked by the National Nosocomial Infection Surveillance System, or its successor.

14. Reports published pursuant to subsection 12 of this section shall be published on the department's Internet website. The initial report shall be issued by the department not later than December 31, 2006. The reports shall be distributed at least annually to the governor and members of the general assembly.

15. The Hospital Industry Data Institute shall publish a report of Missouri hospitals' and ambulatory surgical centers' compliance with standardized quality of care measures established by the federal Centers for Medicare and Medicaid Services for prevention of infections related to surgical procedures. If the Hospital Industry Data Institute fails to do so by July 31, 2008, and annually thereafter, the department shall be authorized to collect information from the Centers for Medicare and Medicaid Services or from hospitals and ambulatory surgical centers and publish such information in accordance with subsection 14 of this section.

16. The data collected or published pursuant to this section shall be

available to the department for purposes of licensing hospitals and ambulatory surgical centers pursuant to chapter 197, RSMo.

17. The department shall promulgate rules to implement the provisions of section 192.131 and sections 197.150 to 197.160, RSMo. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2004, shall be invalid and void.

197.150. The department shall require that each hospital, ambulatory surgical center, and other facility have in place procedures for monitoring and enforcing compliance with infection control regulations and standards. Such procedures shall be coordinated with administrative staff, personnel staff, and the quality improvement program. Such procedures shall include, at a minimum, requirements for the facility's infection control program to conduct surveillance of personnel with a portion of the surveillance to be done in such manner that employees and medical staff are observed without their knowledge of such observation, provided that this unobserved surveillance requirement shall not be considered to be grounds for licensure enforcement action by the department until the department establishes clear and verifiable criteria for determining compliance. Such surveillance also may include monitoring of the rate of use of hand hygiene products.

197.152. 1. Infection control officers as defined in federal regulation and other hospital and ambulatory surgical center employees shall be protected against retaliation by the hospital or ambulatory surgical center for reporting infection control concerns pursuant to section 197.285 and shall be entitled to the full benefits of that section. Such infection control officers shall report any interference in the performance of their duties by their supervisors to the hospital or ambulatory surgical center compliance officer established by and empowered to act pursuant

to section 197.285.

2. Infection control officers as defined in federal regulation shall also have the authority to order the cessation of a practice that falls outside accepted practices as defined by appropriate state and federal regulatory agencies, accreditation organizations, or the standards adopted by the Centers for Disease Control and Prevention or the Association of Professionals in Infection Control and Epidemiology. The hospital or ambulatory surgical center may require that such a cessation order of an infection control officer be endorsed by the hospital or ambulatory surgical center chief executive officer or his or her designee before taking effect. The hospital or ambulatory surgical center infection control committee shall convene as soon as possible to review such cessation order and may overrule or sustain the directive of the infection control officer. The department shall promulgate rules governing documentation of such events.

3. Members of the medical staff who report in good faith infection control concerns to the hospital or ambulatory surgical center administration or medical staff leadership shall not be subject to retaliation or discrimination for doing so. Nothing in this section shall prevent or shield medical staff members from being subject to professional review actions for substandard care or breach of standards established in hospital policy, rules, or medical staff bylaws.

197.154. No later than July 1, 2005, the department shall review and update its current regulations governing hospital and ambulatory surgical center infection control programs. Such standards shall be based upon nationally recognized standards and shall include, but not be limited to, standards for:

(1) Maintaining databases to be used for infection tracking;

(2) Developing hospital protocols related to aseptic technique and infection control practices including but not limited to handwashing, isolation, and other infection control policies;

(3) Developing appropriate corrective action plans and follow-ups for any deficiencies identified in hospital infection control practices;

(4) Conducting root cause analysis and follow-up of sentinel events, as defined by the Joint Commission on Accreditation of Health Organizations, attributable to nosocomial infections; and

(5) Ensuring that hospital and ambulatory surgical center policies and medical staff bylaws are in place to promote and enforce compliance with infection control policies.

197.156. For purposes of reporting nosocomial infection outbreaks as required by department rule, the term "nosocomial infection outbreaks" shall mean infections as defined by the national Centers for Disease Control and Prevention within a defined time period. The time period shall be defined by the department based upon the number of infected patients in a facility.

197.158. Every hospital and ambulatory surgery center shall, beginning June 1, 2006, provide each patient an opportunity to submit to the hospital or ambulatory surgical center administration complaints, comments, and suggestions related to the care they received or their personal observations related to the quality of care provided. The department shall promulgate rules to implement this section.

197.160. The department of health and senior services shall have access to all data and information held by hospitals, ambulatory surgical centers, and other facilities related to their infection control practices, rates, or treatments of infections. Failure to provide such access shall be grounds for full or partial licensure suspension or revocation pursuant to section 197.293, sections 197.010 to 197.100, or sections 197.200 to 197.240. If the department determines that the hospital, ambulatory surgical center, or other facility is willfully impeding access to such information, the department shall be authorized to direct all state agencies to suspend all or a portion of state payments to such hospital until such time as the desired information is obtained by the department.

197.162. The department shall in its licensure of hospitals and ambulatory surgical centers give special attention to infection control practices and shall direct hospitals and ambulatory surgical centers to set quantifiable measures of performance for reducing the incidence of nosocomial infections in Missouri. The department shall prepare an

annual report on infection control standards and compliance, which shall be shared with the governor and the general assembly.

197.165. 1. The department shall appoint an "Infection Control Advisory Panel" for the purposes of implementing section 192.667 and 192.131, RSMo.

2. Members of the infection control advisory panel shall include:

(1) Two public members;

(2) Three board-certified or board-eligible physicians licensed pursuant to chapter 334, RSMo, who are affiliated with a Missouri hospital or medical school, active members of the society for health care epidemiology of America, and have demonstrated interest and expertise in health facility infection control;

(3) One physician licensed pursuant to chapter 334, RSMo, who is active in the practice of medicine in Missouri and who holds medical staff privileges at a Missouri hospital;

(4) Four infection control practitioners certified by the certification board of infection control and epidemiology, at least two of whom shall be practicing in a rural hospital or setting and at least two of whom shall be registered professional nurses licensed under chapter 335, RSMo;

(5) A medical statistician with an advanced degree in such specialty; and

(6) A clinical microbiologist with an advanced degree in such specialty;

(7) Three employees of the department, representing the functions of hospital and ambulatory surgical center licensure, epidemiology and health data analysis, who shall serve as ex officio nonvoting members of the panel.

3. Reasonable expenses of the panel shall be paid from private donations made specifically for that purpose to the "Infection Control Advisory Panel Fund", which is hereby created in the state treasury. If such donations are not received from private sources, then the provisions of this act shall be implemented without the advisory panel.

197.293. 1. In addition to the powers established in sections 197.070 and 197.220, the department of health and senior services shall use the following standards for enforcing hospital and ambulatory surgical center licensure regulations promulgated to enforce the provisions of sections 197.010 to 197.120, **sections 197.150 to 197.165,** and sections 197.200 to 197.240:

(1) Upon notification of a deficiency in meeting regulatory standards, the hospital or ambulatory surgical center shall develop and implement a plan of correction approved by the department which includes, but is not limited to, the specific type of corrective action to be taken and an estimated time to complete such action;

(2) If the plan as implemented does not correct the deficiency, the department may either:

(a) Direct the hospital or ambulatory surgical center to develop and implement a plan of correction pursuant to subdivision (1) of this subsection; or

(b) Require the hospital or ambulatory surgical center to implement a plan of correction developed by the department;

(3) If there is a continuing deficiency after implementation of the plan of correction pursuant to subdivision (2) of this subsection and the hospital or ambulatory surgical center has had an opportunity to correct such deficiency, the department may restrict new inpatient admissions or outpatient entrants to the service or services affected by such deficiency;

(4) If there is a continuing deficiency after the department restricts new inpatient admissions or outpatient entrants to the service or services pursuant to subdivision (3) of this subsection and the hospital or ambulatory surgical center has had an opportunity to correct such deficiency, the department may suspend operations in all or part of the service or services affected by such deficiency;

(5) If there is a continuing deficiency after suspension of operations pursuant to subdivision (4) of this subsection, the department may deny, suspend or revoke the hospital's or ambulatory surgical center's license pursuant to section 197.070 or section 197.220.

2. Notwithstanding the provisions of subsection 1 of this section to the

contrary, if a deficiency in meeting licensure standards presents an immediate and serious threat to the patients' health and safety, the department may, based on the scope and severity of the deficiency, restrict access to the service or services affected by the deficiency until the hospital or ambulatory surgical center has developed and implemented an approved plan of correction. Decisions as to whether a deficiency constitutes an immediate and serious threat to the patients' health and safety shall be made in accordance with guidelines established pursuant to regulation of the department of health and senior services and such decisions shall be approved by the bureau of health facility licensing in the department of health and senior services, or its successor agency, or by a person authorized by the regulations to approve such decisions in the absence of the director.

197.294. No information disclosed by the department to the public pursuant to sections 192.020, 192.021, 192.067, 192.131, 192.138, 192.665, and 192.667, RSMo, and sections 197.150, 197.152, 197.154, 197.156, 197.158, 197.160, 197.162, 197.165, and 197.293 shall be used to establish a standard of care in a private civil action.

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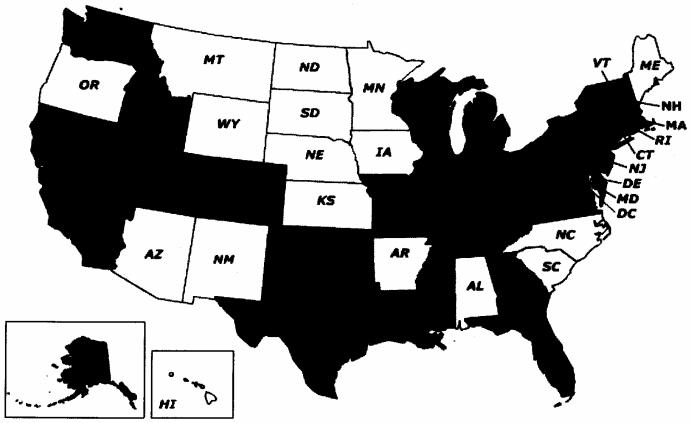
Mandatory Reporting of Infection Rates: Where does your state stand?

To view, double click on a state or select from the drop down menu.

- States with study bills
- States with 2006 legislative activity
- Mandates public reporting of infection rates
- Mandates reporting **only** to state government

- Select a State -

Current as of February 22, 2006.



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TAB 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

NOV 01 2005

OCT 19 2005

The Honorable Ed Whitfield
Chairman
Committee on Oversight and
Investigations
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Whitefield:

Thank you for your letter regarding public reporting standards for healthcare-associated infections (HAI) in hospitals. For more than 30 years, the Centers for Disease Control and Prevention (CDC) has been a national leader for surveillance and prevention of HAIs in the United States. Through voluntary reporting from a national network of hospitals, CDC has monitored HAIs since 1970. This surveillance system, now known as the National Healthcare Safety Network (NHSN), has provided hospitals nationwide with benchmark data for prevention and control efforts. With increased national focus on public reporting of HAIs, CDC, guided by the Healthcare Infection Control Practices Advisory Committee (HICPAC), reviewed the published literature on effectiveness of public reporting of HAIs. While HICPAC concluded there currently is not enough evidence to determine whether mandatory public reporting of HAIs will reduce infection rates, the advisory committee developed and published consensus recommendations to assist those who are tasked with designing and implementing public reporting systems.

These recommendations are to (1) use established public health surveillance methods when designing and implementing mandatory HAI reporting systems; (2) create multidisciplinary advisory panels, including persons with expertise in the prevention and control of HAIs, to monitor the planning and oversight of HAI public reporting systems; (3) choose appropriate process and outcome measures based on facility type and phase in measures to allow time for facilities to adapt and to permit ongoing evaluation of data validity; and (4) provide regular and confidential feedback of performance data to healthcare providers. The specific details of these recommendations are provided in a report from CDC, published in the *American Journal of Infection Control* in May 2005. While the value of mandatory HAI reporting for healthcare quality improvement and consumer choice has yet to be determined, HAI surveillance has been shown to be an essential element of infection control programs. As a result, CDC continues its strong support for HAI surveillance and encourages hospitals to share and compare their data in ways that foster demonstrable improvements in patient safety. In addition, CDC provides consultation to many states with initiatives underway for mandatory public reporting of HAI data.

CDC and its partners in public health surveillance have long recognized the value of uniform national reporting standards for conditions of public health importance. National standards for reporting HAIs have been in use through CDC's National Nosocomial Infections Surveillance (NNIS) system and are now incorporated into the NHSN. CDC supports national standards as a key to consistency in case finding, data collection, trend analysis, risk adjustment, and comparisons across surveillance sites and jurisdictions. In keeping with the consensus recommendations developed by HICPAC for mandatory HAI public reporting systems, a single set of national data standards for HAI reporting should be used because it is sound surveillance practice. However, whether a national standard for reporting HAI yields benefits for both consumers and healthcare providers likely will depend on multiple factors, not just data standards alone. Sufficient operational resources for surveillance, scrupulous attention to the quality and completeness of case finding and data collection, and the timeliness and accessibility of surveillance reports are among the other key determinants of benefits of mandatory reporting for consumers and healthcare providers.

CDC's experience with maintaining the reporting standards in NHSN provides useful guidance for the challenges that must be addressed to establish and implement a national reporting standard for HAI. During development and design of national reporting standards, the criteria used to define and classify HAIs should include both clinical findings and the results of laboratory and other tests. Achieving initial agreement on these criteria requires technical expertise across multiple disciplines and a well-organized process for discussion and decision-making. CDC's experience with NHSN indicates that monitoring HAIs through both process measures (e.g., central line insertion practices) and outcome measures (e.g., central line-associated bloodstream infections) is desirable. Over time, any standard will need to be revised when new scientific information becomes available and as medical practice evolves. In many instances, decisions about data standards involve identifying and affirming a standard that is already available and widely used; in other instances new standards must be developed. Throughout the development of the standards, there must also be consideration of the costs and benefits of various methods for data collection.

From an operational perspective, disseminating and implementing a national standard for reporting purposes will involve a complex set of communications, training, data collection, evaluation, and maintenance activities. It is clear from CDC's experience that a reporting system will produce quality data when the infrastructure includes trained infection control personnel, maintenance of manual and automated data collection systems and databases, analysis and interpretation of findings, and feedback to users to affect change in practices. Finally, a national reporting standard should be implemented in phases to allow time for facilities to adapt and to permit ongoing evaluation of data validity.

CDC is not a regulatory agency and therefore has no authority to mandate participation in the NHSN. However, CDC recognizes the need to collect information from all types of healthcare facilities and has improved the NHSN so it can be expanded to meet this need.

CDC recognizes states may want to take advantage of the standardized methodology, technical infrastructure, and functionality of the NHSN and has encouraged them to consider using NHSN to meet their needs. Advantages of the NHSN include standard definitions and protocols and several data sharing options by which hospitals can report HAI data. The NHSN group functionality, with enhancements, can be used to fulfill the requirements of various state reporting laws. However, risk adjustment techniques currently available in NHSN will need to be improved in order to account for hospitals with fewer than 100 beds as well as other healthcare facilities and to respond to future national/state needs or requests.

Thank you so much for your attention to this important public health matter. I also will provide a copy of this letter to Chairman Joe Barton who cosigned your letter.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director

TAB 4

Central Line-Associated Bloodstream Infection Rates, By ICU Type, 1990-2004*
CDC
Rate per 1000 Central line days
10
8
6
4
2
0
1990 1992 1994 1996 1998 2000 2002 2004
Year
Coronary
Medical
Pediatric
Surgical
SAFER • HEALTHIER • PEOPLE™

special article

Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee

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Since 2002, 4 states have enacted legislation that requires health care organizations to publicly disclose health care–associated infection (HAI) rates. Similar legislative efforts are underway in several other states. Advocates of mandatory public reporting of HAIs believe that making such information publicly available will enable consumers to make more informed choices about their health care and improve overall health care quality by reducing HAIs. Further, they believe that patients have a right to know this information. However, others have expressed concern that the reliability of public reporting systems may be compromised by institutional variability in the definitions used for HAIs, or in the methods and resources used to identify HAIs. Presently, there is insufficient evidence on the merits and limitations of an HAI public reporting system. Therefore, the Healthcare Infection Control Practices Advisory Committee (HICPAC) has not recommended for or against mandatory public reporting of HAI rates. However, HICPAC has developed this guidance document based on established principles for public health and HAI reporting systems. This document is intended to assist policymakers, program planners, consumer advocacy organizations, and others tasked with designing and implementing public reporting systems for HAIs. The document provides a framework for legislators, but does not provide model legislation. HICPAC recommends that persons who design and implement such systems 1) use established public health surveillance methods when designing and implementing mandatory HAI reporting systems; 2) create multidisciplinary advisory panels, including persons with expertise in the prevention and control of HAIs, to monitor the planning and oversight of HAI public reporting systems; 3) choose appropriate process and outcome measures based on facility type and phase in measures to allow time for facilities to adapt and to permit ongoing evaluation of data validity; and 4) provide regular and confidential feedback of performance data to healthcare providers. Specifically, HICPAC recommends that states establishing public reporting systems for HAIs select one or more of the following process or outcome measures as appropriate for hospitals or long-term care facilities in their jurisdictions: 1) central-line insertion practices; 2) surgical antimicrobial prophylaxis; 3) influenza vaccination coverage among patients and healthcare personnel; 4) central line-associated bloodstream infections; and 5) surgical site infections following selected operations. HICPAC will update these recommendations as more research and experience become available.
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Consumer demand for health care information, including data about the performance of health care providers, has increased steadily over the past decade.

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Many state and national initiatives are underway to mandate or induce health care organizations to publicly disclose information regarding institutional and physician performance. Mandatory public reporting of health care performance is intended to enable stakeholders, including consumers, to make more informed choices on health care issues.

Public reporting of health care performance information has taken several forms. Health care performance reports (report cards and honor rolls) typically describe the outcomes of medical care in terms of mortality, selected complications, or medical errors and, to a lesser extent, economic outcomes. Increasingly, process measures (ie, measurement of adherence to recommended health care practices, such as hand hygiene) are being used as an indicator of how well an

organization adheres to established standards of practice with the implicit assumption that good processes lead to good health care outcomes. National health care quality improvement initiatives, notably those of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the Centers for Medicare & Medicaid Services (CMS), and the Hospital Quality Alliance, use process measures in their public reporting initiatives.

Health care–associated infections (HAIs) are infections that patients acquire during the course of receiving treatment for other conditions (see Appendix 1 for full definition of this and other terms used in this document). In hospitals alone, HAIs account for an estimated 2 million infections, 90,000 deaths, and $4.5 billion in excess health care costs annually[1]; however, few of the existing report cards on hospital performance use HAIs as a quality indicator. Since 2002, 4 states (Illinois, Pennsylvania, Missouri, and Florida) have enacted legislation mandating hospitals and health care organizations to publicly disclose HAI rates. Similar legislative efforts are underway in several other states.

Because of the increasing legislative and regulatory interest in this area, the Healthcare Infection Control Practices Advisory Committee (HICPAC) conducted a scientific literature review to evaluate the merits and limitations of HAI reporting systems. We found no published information on the effectiveness of public reporting systems in reducing HAIs. Therefore, HICPAC has concluded that there is insufficient evidence at this time to recommend for or against public reporting of HAIs.

However, to assist those who will be tasked with designing and implementing such reporting systems, HICPAC presents the following framework for an HAI reporting system and recommendations for process and outcome measures to be included in the system. The framework and recommendations are based on established principles for public health and HAI surveillance. This document is intended primarily for policymakers, program planners, consumer advocacy organizations, and others who will be developing and maintaining public reporting systems for HAI. The document does not provide model legislation.

This document represents the consensus opinion of HICPAC. HICPAC is a federal advisory committee that was established in 1991 to provide advice and guidance to the Department of Health and Human Services and CDC regarding surveillance, prevention, and control of HAIs and related events in healthcare settings (*www.cdc.gov/ncidod/hip/HICPAC/Hicpac.htm*). These recommendations also have been endorsed by the Association for Professionals in Infection Control and Epidemiology, the Council of State and Territorial Epidemiologists, and the Society for Healthcare Epidemiology of America. These recommendations will be updated as new information becomes available.

ESSENTIAL ELEMENTS OF A PUBLIC REPORTING SYSTEM FOR HAIs

As a first step, the goals, objectives, and priorities of a public reporting system should be clearly specified and the information to be monitored should be measurable to ensure that the system can be held accountable by stakeholders. The reporting system should collect and report healthcare data that are useful not only to the public, but also to the facility for its quality improvement efforts. This can be achieved by selection of appropriate measures and patient populations to monitor; use of standardized case-finding methods and data validity checks; adequate support for infrastructure, resources, and infection control professionals; adjustment for underlying infection risk; and production of useful and accessible reports for stakeholders, with feedback to healthcare providers. The planning and oversight of the system should be monitored by a multidisciplinary group composed of public health officials, consumers, health care providers, and health care infection control professionals.

Identifying Appropriate Measures of Health Care Performance

Monitoring both process and outcome measures and assessing their correlation is a comprehensive approach to quality improvement. Standardized process and outcome measures for national health care performance for hospitals, nursing homes, and other settings have been endorsed through the National Quality Forum (NQF) voluntary consensus process.[2-4] NQF also has developed a model policy on the endorsement of proprietary performance measures.[5] Several other agencies and organizations, including CDC, CMS, the Agency for Healthcare Quality and Research, JCAHO, the Leapfrog organization, and the National Committee for Quality Assurance, also have developed health care quality measures. Health care performance reports should identify the sources and endorsers of the measures and the sources of the data used (eg, administrative or clinical).

Process measures. Process measures are desirable for inclusion in a public reporting system because the target adherence rate of 100% to these practices is unambiguous. Furthermore, process measures do not require adjustment for the patient's underlying risk of infection. Process measures that are selected for inclusion in a public reporting system should be those that measure common practices, are valid for a variety of health care settings (eg, small, rural versus large, urban hospitals); and can be clearly specified

(eg, appropriate exclusion and inclusion criteria). Process measures meeting these criteria include adherence rates of central line insertion practices and surgical antimicrobial prophylaxis and coverage rates of influenza vaccination for health care personnel and patients/residents (Table 1). Collection of data on one or more of these process measures already is recommended by the NQF and required by CMS and JCAHO for their purposes.

Outcome measures. Outcome measures should be chosen for reporting based on the frequency, severity, and preventability of the outcomes and the likelihood that they can be detected and reported accurately.[14] Outcome measures meeting these criteria include central line–associated, laboratory-confirmed primary bloodstream infections (CLA-LCBI) in intensive care units (ICU) and surgical site infections (SSI) following selected operations (Table 2). Although CLA-LCBIs and SSIs occur at relatively low rates, they are associated with substantial morbidity and mortality and excess health care costs. Also, there are well-established prevention strategies for CLA-LCBIs and SSIs.[6,10] Therefore, highest priority should be given to monitoring these two HAIs and providers' adherence to the related processes of care (ie, central-line insertion practices for CLA-LCBI and surgical antimicrobial prophylaxis for SSIs).

Use of other HAIs in public reporting systems may be more difficult. For example, catheter-associated urinary tract infections, though they may occur more frequently than CLA-LCBIs or SSIs, are associated with a lower morbidity and mortality; therefore, monitoring these infections likely has less prevention effectiveness relative to the burden of data collection and reporting. On the other hand, HAIs such as ventilator-associated pneumonia, which occur relatively infrequently but have substantial morbidity and mortality, are difficult to detect accurately. Including such HAIs in a reporting system may result in invalid comparisons of infection rates and be misleading to consumers.

Monitoring of process and outcome measures should be phased in gradually to allow time for facilities to adapt and to permit ongoing evaluation of data validity.

Identifying Patient Populations for Monitoring

CDC[16] and other authorities[17] no longer recommend collection or reporting of hospital-wide overall HAI rates because 1) HAI rates are low in many hospital locations (which makes routine inclusion of these units unhelpful), 2) collecting hospital-wide data is labor intensive and may divert resources from prevention activities, and 3) methods for hospital-wide risk adjustment have not been developed. Rather than hospital-wide rates, reporting rates of specific HAI for specific hospital units or operation-specific rates of SSIs is recommended.[16] This practice can help ensure that data collection is concentrated in populations where HAIs are more frequent and that rates are calculated that are more useful for targeting prevention and making comparisons among facilities or within facilities over time.

Case-Finding

Once the population at risk for HAIs has been identified, standardized methods for case-finding should be adopted. Such methods help to reduce surveillance bias (ie, the finding of higher rates at institutions that do a more complete job of case-finding). Incentives to find cases of HAI may be helpful. Conversely, punitive measures for hospitals that report high rates may encourage underreporting.

Traditional case-finding methods for HAIs include review of medical records, laboratory reports, and antibiotic administration records. However, these standard case-finding methods can be enhanced. For example, substantially more SSIs are found when administrative data sources (eg, *International Classification of Diseases, 9th Revision* [ICD-9], discharge codes) are used in combination with antimicrobial receipt to flag charts for careful review.[18,19] However, the accuracy of case-finding using ICD-9 codes alone likely varies by HAI type and by hospital. Therefore, ICD-9 discharge codes should not be relied upon as the sole source of case finding for HAI monitoring systems.

Traditional HAI case-finding methods were developed in an era when patients' lengths of hospitalization were much longer than they are today, allowing most HAIs to be detected during the hospital stay. However, for SSIs in particular, the current climate of short stays and rapid transfers to other facilities makes accurate detection difficult because as many as 50% of SSIs do not become evident until after hospital discharge or transfer.[20] Since there is no consensus on which postdischarge surveillance methods are the most accurate and practical for detection of SSIs,[10] the limitations of current case-finding methods should be recognized if SSIs are selected for inclusion in mandatory reporting systems.

Validation of Data

A method to validate data should be considered in any mandatory reporting system to ensure that HAIs are being accurately and completely reported and that rates are comparable from hospital to hospital or among all hospitals in the reporting system. The importance of validation was emphasized by a CDC study of the accuracy of reporting to the NNIS system, which found that although hospitals identified and

Table 1. Recommended process measures for a mandatory public reporting system on health care–associated infections

Events	Measures	Rationale for inclusion	Potential limitations
Central line insertion (CLI) practices	Two measures (expressed as a percentage)[6]: **Numerators**: Number of CLIs in which: • Maximal sterile barrier precautions were used • Chlorhexidine gluconate (preferred), tincture of iodine, an iodophor, or 70% alcohol was used as skin antiseptic **Denominator**: Number of CLIs	Unambiguous target goal (100%) Risk-adjustment is unnecessary Proven prevention effectiveness[6]: • Use of maximal barrier precautions during insertion and chlorhexidine skin antisepsis have been shown to be associated with an 84% and 49% reduction in central line–associated bloodstream infection rates, respectively.[7,8]	Methods for data collection not yet standardized Manual data collection likely to be tedious and labor intensive, and data are not included in medical records
Surgical antimicrobial prophylaxis (AMP)	Three measures (expressed as a percentage)[9]: **Numerators**: Number of surgical patients: • Who received AMP within 1 hour prior to surgical incision (or 2 hours if receiving vancomycin or a fluoroquinolone) • Who received AMP recommended for their surgical procedure • Whose prophylactic antibiotics were discontinued within 24 hours after surgery end time **Denominator**: All selected surgical patients	Unambiguous target goal (100%) Risk-adjustment is unnecessary Proven prevention effectiveness[10]: • Administering the appropriate antimicrobial agent within 1 hour before the incision has been shown to reduce SSIs • Prolonged duration of surgical prophylaxis (>24 hrs) has been associated with increased risk of antimicrobial-resistant SSI	Manual data collection may be tedious and labor intensive, but data can be abstracted from medical records
Influenza vaccination of patients and health care personnel	Two measures (each expressed as a percentage of coverage)[11]: **Numerators**: Number of influenza vaccinations given to eligible patients or healthcare personnel **Denominators**: Number of patients or healthcare personnel eligible for influenza vaccine	Proven prevention effectiveness[11-13]: • Vaccination of high-risk patients and health care personnel has been shown to be effective in preventing influenza	Manual data collection may be tedious and labor intensive

reported most of the HAIs that occurred, the accuracy varied by infection site.[15]

Resources and Infrastructure Needed for a Reporting System

A reporting system can not produce quality data without adequate resources. At the institution level, trained personnel with dedicated time are required, eg, infection control professionals to conduct HAI surveillance. At the system level, key infrastructure includes instruction manuals, training materials, data collection forms, methods for data entry and submission, databases to receive and aggregate the data, appropriate quality checks, computer programs for data analysis, and standardized reports for dissemination of results. Computer resources within reporting systems must include both hardware and software and a standard user interface. In order to collect detailed data on factors such as use of invasive devises (eg, central lines), patient care location within the facility, type of operation, and extensive data

Table 2. Recommended outcome measures for a mandatory public reporting system on health care–associated infections

Events	Measures	Rationale for inclusion	Potential limitations
Central line–associated laboratory-confirmed primary bloodstream infection (CLA-LCBI)*	**Numerator:** Number of CLA-LCBI	Overall, an infrequent event but one that is associated with substantial cost, morbidity, and mortality	LCBI* can be challenging to diagnose since the definition includes criteria that are difficult to interpret (eg, single-positive blood cultures from skin commensal organisms may not represent true infections). To offset this limitation, a system could include only those CLA-LCBI identified by criterion 1, which will result in smaller numerators and therefore will require longer periods of time for sufficient data accumulation for rates to become stable/meaningful.
	Denominator: Number of central-line days in each population at risk, expressed per 1,000	Reliable laboratory test available for identification (ie, positive blood culture)	Standard definition of central line* requires knowing where the tip of the line terminates, which is not always documented and can therefore lead to misclassification of lines
	Populations at risk: Patients with central lines cared for in different types of intensive care units (ICUs)*	Prevention guidelines exist[6] and insertion processes can be monitored concurrently	
	Risk stratification: By type of ICU	Sensitivity*: 85%; predictive value positive (PVP)*: 75%[15]	
	Frequency of monitoring: 12 months per year for ICU with ≤ 5 beds; 6 months per year for ICU with > 5 beds		
	Frequency of rate calculation: Monthly (or quarterly for small ICUs) for internal hospital quality improvement purposes		
	Frequency of rate reporting: Annually using all the data to calculate the rate		
Surgical site infection (SSI)*	**Numerator:** Number of SSI for each specific type of operation*	Low frequency event but one that is associated with substantial cost, morbidity, and mortality	Rates dependent on surveillance intensity, especially completeness of post-discharge surveillance (50% become evident after discharge and may not be detected)
	Denominator: Total number of each specific type of operation, expressed per 100	Prevention guidelines exist[10] and certain important prevention processes can be monitored concurrently	SSI definitions include a "physician diagnosis" criterion, which reduces objectivity
	Risk stratification: Focus on high-volume operations and stratify by type of operation and National Nosocomial Infections Surveillance (NNIS) SSI risk index*	Sensitivity*: 67%; PVP*: 73%[15]	
	Alternate risk adjustment: For low-volume operations, adjust for risk by using the standardized infection ratio*		

*See Glossary (Appendix 1).

dictionaries and coding schema must be developed and maintained.

HAI Rates and Risk Adjustment

For optimal comparison purposes, HAI rates should be adjusted for the potential differences in risk factors. For example, in the NNIS system, device-associated infections are risk adjusted by calculating rates per 1,000 device-days (eg, CLA-LCBI per 1,000 central line–days) and stratifying by unit type.[21-23] For that system, risk adjustment of SSIs is done by calculating of operation-specific rates stratified by a standardized risk index.[23-25] Although these methods do not incorporate

all potential confounding variables, they provide an acceptable level of risk adjustment that avoids the data collection burden that would be required to adjust for all variables.

Risk adjustment is labor intensive because data must be collected on the entire population at risk (the denominator) rather than only the fraction with HAIs (the numerator). Risk adjustment can not correct for variability among data collectors in the accuracy of finding and reporting events. Further, current risk-adjustment methods improve but do not guarantee the validity of inter-hospital comparisons, especially comparisons involving facilities with diverse patient populations (eg, community versus tertiary-care hospitals).

Valid event rates are facilitated by selecting events that occur frequently enough and at-risk populations that are large enough to produce adequate sample sizes. Unfortunately, use of stratification (eg, calculation of rates separately in multiple categories) for risk adjustment may lead to small numbers of HAIs in any one category and thereby yield unstable rates, as is the case of a small hospital with low surgical volume.

Producing Useful Reports and Feedback

Publicly released reports must convey scientific meaning in a manner that is useful and interpretable to a diverse audience. Collaboration between subject matter experts, statisticians, and communicators is necessary in developing these reports. The reports should provide useful information to the various users and highlight potential limitations of both the data and the methods used for risk adjustment. In a new reporting system, data should be examined and validated before initial release; in addition, sufficient sample size should be accumulated so that rates are stable at the time of public release. Lastly, feedback of performance data should be given to health care providers regularly so that interventions to improve performance can be implemented as quickly as possible. For example, feedback of SSI rates to surgeons has been shown to be an important component of strategies to reduce SSI risk.[26]

ADAPTING ESTABLISHED METHODS FOR USE IN MANDATORY REPORTING SYSTEMS

Where appropriate, developers of reporting systems should avail themselves of established and proven methods of collecting and reporting surveillance data. For example, many of the methods, attributes, and protocols of CDC's NNIS system may be applicable for public reporting systems. A detailed description of the NNIS methodologies has been described elsewhere,[23] and additional information on NNIS is available at *www.cdc.gov/ncidod/hip/surveill/nnis.htm*.

Most reporting systems, such as NNIS, use manual data collection methods. In most instances, information in computer databases, when available, can be substituted for manually collected data.[27,28] However, when manual data collection is necessary, alternate approaches include limiting reporting to well-defined and readily identifiable events, using simpler and more objective event definitions,[29] and sampling to obtain denominators.[30] These approaches could decrease the burden of data collection and improve the consistency of reporting among facilities. If data collection were simplified, expanding the number of infection types and locations in which they are monitored may become more feasible.

POTENTIAL CONSEQUENCES OF MANDATORY PUBLIC REPORTING SYSTEMS

Mandatory reporting of HAIs will provide consumers and stakeholders with additional information for making informed health care choices. Further, reports from private systems suggest that participation in an organized, ongoing system for monitoring and reporting of HAIs may reduce HAI rates.[31,32] This same beneficial consequence may apply to mandatory public reporting systems. Conversely, as with voluntary private reporting, mandatory public reporting that doesn't incorporate sound surveillance principles and reasonable goals may divert resources to reporting infections and collecting data for risk adjustment and away from patient care and prevention; such reporting also could result in unintended disincentives to treat patients at higher risk for HAI. In addition, current standard methods for HAI surveillance were developed for voluntary use and may need to be modified for mandatory reporting. Lastly, publicly reported HAI rates can mislead stakeholders if inaccurate information is disseminated. Therefore, in a mandatory public report of HAI information, the limitations of current methods should be clearly communicated within the publicly released report.

RESEARCH AND EVALUATION NEEDS

Research and evaluation of existing and future HAI reporting systems will be needed to answer questions about 1) the comparative effectiveness and efficiency of public and private reporting systems and 2) the incidence and prevention of unintended consequences. Ongoing evaluation of each system will be needed to confirm the appropriateness of the methods used and the validity of the results.

RECOMMENDATIONS

The Healthcare Infection Control Practices Advisory Committee proposes four overarching recommendations

regarding the mandatory public reporting of HAIs. These recommendations are intended to guide policymakers in the creation of statewide reporting systems for health care facilities in their jurisdictions.

1. Use established public health surveillance methods when designing and implementing mandatory HAI reporting systems. This process involves:
   a. selection of appropriate process and outcome measures to monitor;
   b. selection of appropriate patient populations to monitor;
   c. use of standardized case-finding methods and data validity checks;
   d. provision of adequate support and resources;
   e. adjustment for underlying infection risk; and
   f. production of useful and accessible reports to stakeholders.

Do not use hospital discharge diagnostic codes as the sole data source for HAI public reporting systems.

2. Create a multidisciplinary advisory panel to monitor the planning and oversight of the operations and products of HAI public reporting systems. This team should include persons with expertise in the prevention and control of HAIs.
3. Choose appropriate process and outcome measures based on facility type, and phase in measures gradually to allow time for facilities to adapt and to permit ongoing evaluation of data validity. States can select from the following measures as appropriate for hospitals or long term care facilities in their jurisdictions.
   a. Three process measures are appropriate for hospitals and one (iii below) is appropriate for long term care facilities participating in a mandatory HAI reporting system (Table 1).
      i. Central line insertion practices (with the goal of targeting ICU-specific CLA-LCBIs can be measured by all hospitals that have the type of ICUs selected for monitoring (eg, medical or surgical).
      ii. Surgical antimicrobial prophylaxis (with the goal of targeting SSI rates) can be measured by all hospitals that conduct the operations selected for monitoring.
      iii. Influenza vaccination coverage rates for health care personnel and patients can be measured by all hospitals and long term care facilities. For example:
         - Coverage rates for health care personnel can be measured in all hospitals and long term care facilities.
         - Coverage rates for high-risk patients can be measured in all hospitals.
         - Coverage rates for all residents can be measured in all long term care facilities.
   b. Two outcome measures are appropriate for *some* hospitals participating in a mandatory HAI reporting system (Table 2).
      i. CLA-LCBIs.
      ii. SSIs following selected operations.

Hospitals for which these measures are appropriate are those in which the frequency of the HAI is sufficient to achieve statistically stable rates. To foster performance improvement, the HAI rate to be reported should be coupled with a process measure of adherence to the prevention practice known to lower the rate (see 3ai and 3aii). For example, hospitals in states where reporting of SSIs is mandated should monitor and report adherence to recommended standards for surgical prophylaxis (see 3aii).

4. Provide regular and confidential feedback of performance data to health care providers. This practice may encourage low performers to implement targeted prevention activities and increase the acceptability of the public reporting systems within the health care sector.

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Appendix 1. Glossary

- **Central line**. A vascular infusion device that terminates at or close to the heart or in one of the great vessels. In the National Healthcare Safety Network (NHSN), the system replacing NNIS, the following are considered great vessels for the purpose of reporting central line infections and counting central line days: aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, and common femoral veins.

Note. In neonates, the umbilical artery/vein is considered a great vessel.

Note. Neither the location of the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of these vessels or in or near the heart to qualify as a central line. *Note:* Pacemaker wires and other noninfusion devices inserted into central blood vessels or the heart are *not* considered central lines.

- **CLA-LCBI**. *See laboratory-confirmed primary bloodstream infection.*
- **Confounding**. The distortion of the apparent effect of an exposure on risk brought about by the association with other factors that can influence the outcome.[33] Risk adjustment is performed to minimize the effects of patient co-morbidities and use of invasive devices (the confounding factors) on the estimate of risk for a unit or facility (the exposure).
- **Device-associated infection**. An infection in a patient with a device (eg, ventilator or central line) that was used within the 48-hour period before the infection's onset. If the time interval was longer than 48 hours, compelling evidence must be present to indicate that the infection was associated with use of the device. For catheter-associated urinary tract

infection (UTI), the indwelling urinary catheter must have been in place within the 7-day period before positive laboratory results or signs and symptoms meeting the criteria for UTI were evident.[23]

- **Health care–associated infection**. A localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that 1) occurs in a patient in a health care setting (eg, a hospital or outpatient clinic), 2) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting, and 3) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC.[23] (See also *Nosocomial*.)
- **Intensive-care unit (ICU)**. A hospital unit that provides intensive observation, diagnostic, and therapeutic procedures for adults and/or children who are critically ill. An ICU *excludes* bone marrow transplant units and nursing areas that provide step-down, intermediate care or telemetry only. The type of ICU is determined by the service designation of the majority of patients cared for by the unit (ie, if 80% of the patients are on a certain service [eg, general surgery], then the ICU is designated as that type of unit [eg, surgical ICU]). An ICU with approximately equal numbers of medical and surgical patients is designated as a combined medical/surgical ICU.[23]
- **Laboratory-confirmed primary bloodstream infection (LCBI)**. A primary bloodstream infection identified by laboratory tests with or without clinical signs or symptoms; most often associated with the use of catheters or other invasive medical devices. For the CDC surveillance definition of LCBIs, please see reference 14 or *www.cdc.gov/ncidod/hip/surveill/nnis.htm*.
- **NNIS SSI risk index**. A score used to predict a surgical patient's risk of acquiring a surgical-site infection. The risk index score, ranging from 0 to 3, is the number of risk factors present among the following: 1) a patient with an American Society of Anesthesiologists' physical status classification score of 3, 4, or 5,[34] b) an operation classified as contaminated or dirty infected,[35,36] and c) an operation lasting over T hours, where T depends upon the operation being performed.[25] Current T values can be found in the NNIS Report at *www.cdc.gov/ncidod/hip/surveill/nnis.htm*.
- **Nosocomial**. Originating or taking place in a hospital.
- **Outcomes**. All the possible results that may stem from exposure to a causal factor or from preventive or therapeutic interventions[53] (eg, mortality, cost, and development of a health care–associated infection).
- **Predictive value positive**. The proportion of infections reported by a surveillance or reporting system that are true infections.[14,15]
- **Private reporting system**. A system that provides information about the quality of health services or systems for the purposes of improving the quality of the services or systems. By definition, the general public is not given access to the data; instead, the data are typically provided to the organization or health care workers whose performance is being assessed. The provision of these data is intended as an intervention to improve the performance of that entity or person.
- **Process measure**. A measure of recommended infection control or other practices (eg, adherence with hand hygiene recommendations).
- **Public reporting system**. A system that provides the public with information about the performance or quality of health services or systems for the purpose of improving the performance or quality of the services or systems.
- **Risk adjustment**. A summarizing procedure for a statistical measure in which the effects of differences in composition (eg, confounding factors) of the populations being compared have been minimized by statistical methods (eg, standardization and logistic regression).[33]
- **Sensitivity**. The proportion of true infections that are reported by a surveillance or reporting system. May also refer to the ability of the reporting system to detect outbreaks or unusual clusters of the adverse event (in time or place).[14,15]
- **SSI Risk Index**. See *NNIS SSI Risk Index*.
- **Standardized infection ratio**. The standardized infection ratio as used in this document is an example of indirect standardization in which the observed number of surgical site infections (SSIs) is divided by the expected number of SSIs. The expected number of SSIs is calculated by using NNIS SSI risk index category-specific data from a standard population (eg, the NNIS system data published in the NNIS Report) and the number of operations in each risk index category performed by a surgeon, a surgical subspecialty service, or a hospital. (Detailed explanation and examples can be found in Horan TC, Culver DH. Comparing surgical site infection rates. In: Pfeiffer JA, editor. APIC text of infection control and epidemiology. Washington, DC: Association for Professionals in Infection Control, 2000. p. 1-7.)
- **Surgical site infection (SSI)**. An infection of the incision or organ/space operated on during a surgical procedure. For the CDC surveillance definition of an SSI, see reference 14 or *www.cdc.gov/ncidod/hip/surveill/nnis.htm*.
- **Surveillance**. The ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health.[14]

Issue No. 5 • July 2005

PHC4 Research Briefs

Hospital-acquired Infections in Pennsylvania

In January 2004, Pennsylvania hospitals began submitting data on hospital-acquired infections to the Pennsylvania Health Care Cost Containment Council (PHC4). While concerns remain about whether all hospitals are fully complying with this new initiative, the first year of data collected provides some eye-opening information for all parties involved in the delivery and payment of hospital care. In 2004, hospitals reported 11,668 hospital-acquired infections, that is, 7.5 hospital-acquired infections per 1,000 patients admitted to Pennsylvania's general acute care hospitals. 15.4 percent or 1,793 of these patients died. $2 billion in additional hospital charges and 205,000 additional hospital days were associated with the hospital admissions in which these devastating infections occurred. However, until all Pennsylvania hospitals have met the current PHC4 reporting requirements for hospital-acquired infection data, the full impact of these infections remains unknown.

PHC4's Call to Action

Early last year, the Pennsylvania Health Care Cost Containment Council (PHC4) began collecting information on infections that patients contract while in the hospital, a groundbreaking step that few states have undertaken. This new initiative, which began January 1, 2004, is in response to growing concern about hospital-acquired infections, which can result in compromised quality of care for the patient, prolonged hospital stays, increased costs, and death. This data collection effort is designed to assist in the effort to reduce the number of these infections by providing current, accurate data to providers, purchasers, and consumers of health care.

Beginning January 1, 2004, hospitals were required to start submitting data to PHC4 on the following types of hospital-acquired infections:

1. **Surgical site infections for orthopedic surgery, neurosurgery, and surgery related to the circulatory system**
2. **All device-related infections for:**
   - **Foley catheter-associated urinary tract infection**
   - **Ventilator-associated pneumonia**
   - **Central line-associated bloodstream infection**

As of January 1, 2006 hospitals will be required to submit data on all hospital-acquired infections to PHC4.

The United States has seen an increase in hospital-acquired infections in recent decades. A review published in the *New England Journal of Medicine* cited several studies reporting national estimates. Between 1975 and 1995, the incidence of hospital-acquired infections per 1,000 bed days increased by 36.1 percent. The author noted that "these adverse events affect approximately 2 million patients each year in the United States and result in some 90,000 deaths."

In 2004, there were 1.9 million admissions to Pennsylvania hospitals. This analysis focuses on the 1,562,600 admissions to 173 general acute care hospitals. These hospitals reported 11,668 hospital-acquired infections to PHC4.

Type of Infection	Number of Hospital-acquired Infections Reported by Hospitals
Surgical Site	1,317
Urinary Tract	6,139
Pneumonia	1,335
Bloodstream	1,932
Multiple Infections	945
Total	11,668

Hospital-acquired infections are life threatening.

Of the 11,668 patients with a hospital-acquired infection, 15.4 percent died, compared to a mortality rate of 2.4 percent for patients who did not have a hospital-acquired infection. The difference in mortality rates equated to an *additional* 1,510 deaths for those patients with hospital-acquired infections—446 with bloodstream infections, 423 with urinary tract infections, 393 with pneumonia, and 8 with surgical site infections. The remaining deaths were associated with multiple infections.

Mortality rates were highest, 31.9 percent, for patients reported as having ventilator-associated pneumonia. The mortality rates for patients reported as having central line-associated bloodstream infections and Foley catheter-associated urinary tract infections were 25.6 percent and 9.4 percent respectively, while patients with hospital-acquired surgical site infections had a mortality rate of 3.1 percent.

Hospital admissions related to the 11,668 hospital-acquired infections reported by hospitals for 2004 were associated with an *additional:*

- **1,510 deaths**
- **205,000 hospital days**
- **$2 billion in hospital charges**

Hospital-acquired infections are costly.

The hospital admissions in which patients contracted hospital-acquired infections, as reported to PHC4 for 2004, were associated with more than 205,000 *additional* hospital days and $2 billion in *additional* hospital charges, when compared to hospitalizations for patients who did not have a hospital-acquired infection.

The average additional length of stay for patients who contracted either a bloodstream infection or pneumonia was about 26 days. Patients with urinary tract infections spent an average of 12.4 additional days in the hospital, while those with surgical site infections spent an average of 7.8 additional days.

Hospital admissions in which patients contracted bloodstream infections amounted to an additional $609 million in hospital charges. Additional charges for hospitalizations related to patients with Foley catheter-associated urinary tract infections were over $472 million. Additional charges for hospitalizations related to ventilator-associated pneumonia were over $427 million. Hospital admissions in which patients contracted surgical site infections were associated with over $104 million in additional hospital charges. The remaining hospital charges were associated with multiple infections.

Hospital-acquired infections are a grave concern to the purchasers of health care.

Given the persistent increases in health care costs, purchasers of health care, including Pennsylvania businesses and labor organizations, are concerned about their ability to purchase quality care for their employees and members. A look at the payments made by the majority of third-party health insurance carriers in Pennsylvania explains

their concerns. Payment data for 2003 (2004 was not available) were screened for diagnosis codes that may indicate the presence of a hospital-acquired infection (*possible* infection). Table 1 displays the differences in payments, length of stay, and mortality for hospitalizations without an infection and those with a *possible* hospital-acquired infection.

In 2003 the average payment for a hospital admission in which a patient contracted an infection was $29,320. Assuming that the average payment remained the same for 2004, third party insurance payments for the 11,668 hospital-acquired infections identified by hospitals would amount to over $342 million.

Hospital-acquired infections were likely underreported for 2004.

Results from the first year of data collection indicate that while some hospitals worked hard to meet the hospital-acquired infection data collection requirements, other hospitals provided minimal information.

There was a steady increase each quarter of 2004 in the number of hospital-acquired infections reported. Yet, submission disparities among hospitals raised concerns regarding the accuracy and completeness of the reported data.

For the fourth quarter of 2004, there were several notable disparities among hospitals' data submissions. Just 17 percent of the hospitals submitted more than one-half of all the hospital-acquired infections reported. Several large hospitals submitted invalid hospital-acquired infection data for the majority of their discharges. Sixteen hospitals, including several large hospitals, reported no hospital-acquired infections. Although reporting no hospital-acquired infections does not necessarily raise concerns for smaller hospitals (they may not offer complex clinical services such as intensive care and certain surgical procedures), it does raise concerns regarding the reliability of data submitted by large hospitals that routinely provide these services.

One of the major concerns regarding the hospital-acquired infection data collected in 2004 is the discrepancy between the number of hospital-acquired infections reported by hospitals and the number of infections that were billed for by hospitals.

In order to better understand this discrepancy, PHC4 screened the 2004 hospital billing data for diagnoses that may indicate the presence of a hospital-acquired infection. While not all infections are acquired in the hospital—many patients enter the hospital with certain types of infections—results from this screening process suggest the possibility of more hospital-acquired infections than reported to PHC4. Both the reported and possible hospital acquired infection numbers

Table 1.
Hospital Admissions Covered by Third-Party Insurance, 2003

Type of Infection	Number	Average Payment	Average Length of Stay in Days	Percent Died
Surgical Site	242	$24,223	13.1	0.8
Urinary Tract	1,379	$18,589	9.7	1.9
Pneumonia	948	$28,691	12.2	5.9
Bloodstream	528	$40,129	15.4	13.8
Multiple Infections	260	$71,325	23.9	11.9
Any of the Above Infections	3,357	$29,320	12.6	5.6
Without an Infection	102,657	$8,319	3.4	0.7

Table 2.
Number of Reported and Possible Hospital-Acquired Infections, 2004

	Hospital-Acquired Infections (as reported by hospitals)	Possible Hospital-Acquired Infections (as identified through a diagnosis screening process)
Number of Patients with Infections	**11,668**	**115,631***
Number of Infections by Type:		
Surgical Site	1,317	4,132
Urinary Tract	6,139	69,466
Pneumonia	1,335	32,090
Bloodstream	1,932	21,458
Multiple Infections	945	*

* The number of *patients* does not match the number of *infections* because some patients had more than one infection. In those instances each infection was counted once under each type of infection present.

are important because all infections are taxing the health care system.

Table 2 provides information on the number of reported hospital-acquired infections and the number of infections identified through the screening process as *possible* hospital-acquired infections.

Conclusion

The hospital-acquired infection data reported to PHC4 by Pennsylvania general acute care hospitals clearly demonstrate the importance of this new, groundbreaking initiative. Although the number of infections that patients contracted while in the hospital was likely underreported, the 1,510 additional deaths, 205,000 additional hospital days, and $2 billion in additional hospital charges for the hospital admissions associated with the hospital-acquired infections reported in 2004 are compelling figures.

Accurate and complete data collection along with dissemination of information to all stakeholders are essential components of health care improvement initiatives. Reducing hospital-acquired infections is imperative to reducing health care costs for consumers, payors, and hospitals themselves and to improving the quality of care and quality of life for patients in Pennsylvania hospitals.

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The Pennsylvania Health Care Cost Containment Council (PHC4) periodically releases *Research Briefs* on health care topics relevant to public policy interest.

PHC4 is an independent state agency created to collect, analyze, and disseminate information designed to improve the quality and restrain the cost of health care.

Issue No. 8 • November 2005

PHC4 Research Briefs

Reducing Hospital-acquired Infections: The Business Case

In July 2005, the Pennsylvania Health Care Cost Containment Council (PHC4) issued a landmark research brief that detailed the cost and quality implications of hospital-acquired infections in Pennsylvania. This follow-up brief provides a closer look at these infections in terms of payor implications. One new finding is that the financially strapped Medicare and Medicaid programs were billed for 76 percent of the reported hospital-acquired infections in 2004. Medicare and Medicaid were billed for 7,870 and 1,028 hospital-acquired infections, respectively. As a result, Pennsylvania and federal taxpayers footed the bill for an additional $1.4 billion in hospital charges. Commercial insurers also incurred substantial costs – an extra $604 million in hospital charges.

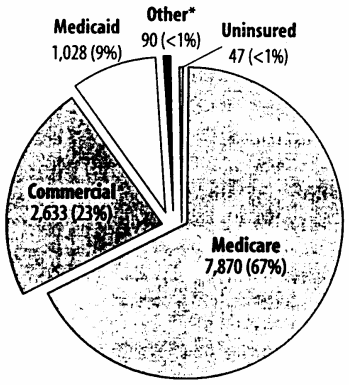
The rate of reported hospital-acquired infections varies by payor type.

According to data confirmed and reported by Pennsylvania hospitals, there were 7.5 hospital-acquired infections per 1,000 hospital admissions in 2004. Among the major payor categories, the number of hospital-acquired infections per 1,000 hospitalizations were 9.9 (Medicare), 5.2 (Medicaid), 4.9 (Commercial), and 2.1 (Uninsured).

Medicare and Medicaid were billed for 76 percent of the reported hospital-acquired infections.

In PHC4's last brief, it was reported that the hospital admissions in which the 11,668 hospital-acquired infections occurred resulted in an additional $2 billion in hospital charges, compared to hospitalizations in which patients did not have hospital-acquired infections. In 2004, Medicare and Medicaid were billed for 76 percent of the total reported hospital-acquired infections. Medicare and Medicaid were billed for 7,870 and 1,028 hospital-acquired infections, respectively. The hospital admissions in which these infections were contracted amounted to an additional $1 billion in hospital charges for Medicare patients and an additional $372 million in hospital charges for Medicaid patients.

Figure 1. Number of Reported Hospital-acquired Infections, by Payor, 2004



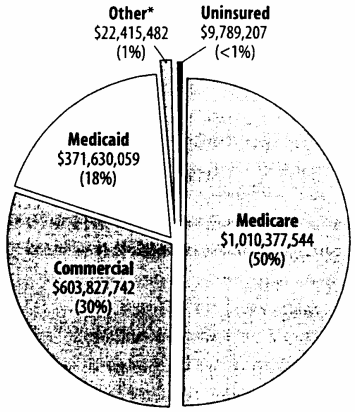
* Includes other government payors and hospitalizations where the payor was unknown or invalid.

Last summer, PHC4 issued a groundbreaking research brief, *Hospital-acquired Infections in Pennsylvania.* Its publication marked the first time that any state released data about the quality and cost consequences of hospital-acquired infections. This brief revealed that Pennsylvania's general acute care hospitals reported 11,668 hospital-acquired infections in 2004. The hospital admissions in which these infections occurred were associated with 1,510 additional deaths, 205,000 additional hospital days and $2 billion in additional hospital charges, as compared to hospital admissions in which hospital-acquired infections had not occurred.

Like the first brief, this analysis focuses on the 1,562,600 admissions to the state's 173 general acute care hospitals. Here is a summary of the 2004 data that was submitted to PHC4.

Type of Infection	Number of Reported Hospital-acquired Infections
Surgical Site	1,317
Urinary Tract	6,139
Pneumonia	1,335
Bloodstream	1,932
Multiple Infections	945
Total	11,668

Figure 2. Additional Hospital Charges Associated with Hospital-acquired Infections, by Payor, 2004



* Includes other government payors and hospitalizations where the payor was unknown or invalid.

There are notable differences in average charges between hospitalizations with and without reported hospital-acquired infections. The average charges for Medicare patients with an infection topped $160,000, about $128,000 more than Medicare patients without an infection. The gap among Medicaid patients was even more pronounced. The average charges for Medicaid patients with an infection were more than $391,000, while the averages charges for Medicaid patients without an infection were just under $30,000.

The average length of stay for Medicare patients who contracted a hospital-acquired infection was 20.0 days, compared to 5.4 days for Medicare patients who did not have a hospital-acquired infection. Medicaid patients

Table 1. The Impact of Hospital-acquired Infections on Medicaid and Medicare Patients, 2004

	Medicare Patients		Medicaid Patients	
	With Infections	Without Infections	With Infections	Without Infections
Average Hospital Charges	$160,305	$31,921	$391,218	$29,710
Average Hospital Stay in Days	20.0	5.4	33.5	4.1
In-hospital Mortality Rate	16.1%	3.7%	16.0%	1.1%

with such infections spent an average of 33.5 days in the hospital, compared to 4.1 days for Medicaid patients who did not acquire an infection during their hospital stay.

The mortality rates for Medicare and Medicaid patients with hospital-acquired infections were significantly higher than the rates for Medicare and Medicaid patients without such infections. Of the 7,870 Medicare patients with hospital-acquired infections, 16.1 percent – or 1,266 patients – died, compared to 3.7 percent of the Medicare patients without infections. Of the 1,028 Medicaid patients with hospital-acquired infections, 16.0% (164) died, compared to 1.1% of Medicaid patients without infections.

Commercial insurers were billed for almost 23 percent of the reported hospital-acquired infections.

Commercial insurers also incurred substantial costs due to hospital-acquired infections in 2004. They were billed for almost 23 percent of the reported hospital-acquired infections, which added about $604 million in extra hospital charges. The average charges for a hospital admission in which a commercially insured patient contracted a hospital-acquired infection were almost $258,000, compared to $28,000 for admissions in which commercially insured patients did not get an infection.

Table 2. The Impact of Hospital-acquired Infections on Commercially Insured Patients, 2004

	Commercially Insured Patients	
	With Infections	Without Infections
Average Hospital Charges	$257,706	$28,375
Average Hospital Stay in Days	24.3	3.7
In-hospital Mortality Rate	12.8%	1.1%

Paying for hospitalizations involving hospital-acquired infections is especially burdensome to the uninsured.

Even though hospitalizations for uninsured patients made up less than one percent of the reported hospital-acquired infections in 2004, these hospitalizations had particular financial implications for the individuals affected. The average charges for a stay in which uninsured patients contracted an infection reached almost $230,000, compared to $21,000 for uninsured patients without an infection. Whereas government and commercial payors can negotiate large

discounts for hospital charges, people without insurance have no such purchasing power and may bear full responsibility for charges that can be two to three times higher than those accepted by most insurers.[1]

The mortality rate for uninsured patients with hospital-acquired infections was 19.1 percent, compared to 2.2 percent for uninsured patients without infections. The average length of stay for uninsured patients who contracted a hospital-acquired infection was 21.1 days, compared to 3.0 days for uninsured patients who did not have a hospital-acquired infection.

For each payor category, the hospital admissions related to the 11,668 hospital-acquired infections reported in 2004 were associated with an *additional:*

	Deaths	Hospital Days	Hospital Charges
Medicare	978	114,546	$1,010,377,544
Medicaid	152	30,229	$371,630,059
Commercial	308	54,452	$603,827,742
Uninsured	8	850	$9,789,207

Conclusion

From the financial costs to extended hospital stays to potentially preventable deaths, hospital-acquired infections exact a heavy toll throughout Pennsylvania. Reducing hospital-acquired infections will save lives and money, and the first step toward this goal is the complete and accurate submission of data by Pennsylvania hospitals.

While there are many hospitals that are making a good faith effort to fully comply with the reporting requirements, it was noted in the first brief that there was wide variation in reporting levels among facilities in the state. *These disparities indicate that hospital-acquired infections are likely to be underreported for 2004.* Collectively, current reporting efforts must continue to improve – especially since hospitals will be required to submit data on <u>all</u> hospital-acquired infections to PHC4 beginning January 1, 2006.

The cost and quality issues highlighted in this follow-up brief present unique challenges to the consumers, purchasers, providers, policymakers, and payors of heath care. PHC4 is confident that the compelling figures will again serve as a call to action.

1. Marilyn Werber Serafini, October 18, 2003. "Sticker Shock," *National Journal*, pp. 3180-3186.

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Issue No. 9 • March 2006

PHC4 Research Briefs

Hospital-acquired Infections in Pennsylvania

Numbers Rise As Data Submission Improves, Additional Insurance Payments Could Total $613.7 Million

This report is the third in a series of research briefs covering the issue of hospital-acquired infections (HAIs) in Pennsylvania. Pennsylvania is one of a small number of states mandated to collect infection data and was the first state to report infection data (July 2005). This report covers the following topics:

- **Updated number of HAIs reported for the first nine months of 2005;**
- **Insurance payment data – PHC4 is now collecting and reporting actual third party payment data in addition to hospital charge data. The payment data is for the commercial carriers only—Medicare and Medicaid payment data is not available at this time. The payment data is for Calendar Year 2004 (2005 is not yet available).**
- **Compliance progress – The reported 2005 data shows significant improvements in HAI data submission by Pennsylvania hospitals.**

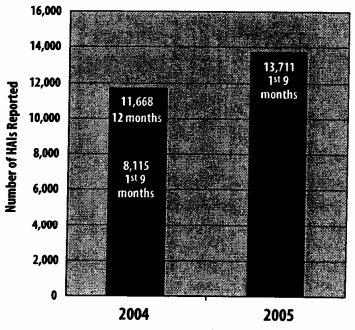
Key Findings

- During the first nine months of 2005, hospitals identified 13,711 HAIs, compared to 11,668 for 12 months of 2004. (Figure 1) *This increase most likely reflects improvements in hospitals' submission of data, as well as the expansion of data collection requirements for surgical site infections.*
- The average commercial insurance payment for hospitalizations involving a hospital-acquired infection in 2004 was $60,678, compared to $8,078 for hospitalizations without a hospital-acquired infection.
- Based on additional payments for the 1,119 HAI cases from commercial health insurers in 2004, the additional total payments from *all* payors for the 11,668 HAI cases in 2004 can be estimated at $613.7 million.

Problem is larger than initially estimated.

For the first nine months of 2005, Pennsylvania hospitals confirmed and reported 13,711 HAIs – a rate of 11.5 HAIs per 1,000 admissions. During the same period, 13.0 percent died, compared to 2.4 percent without HAIs. The average length

Figure 1
Number of Hospital-acquired Infections Reported
January 1, 2004 through September 30, 2005



of stay for patients with HAIs was 21.1 days, while those without HAIs averaged 4.5 days. The average hospital charge for patients with HAIs was $197,717, compared to $31,617 for those patients without HAIs.

For the first nine months of 2005, the hospitalizations in which these infections occurred were associated with approximately 1,456 additional deaths, 227,000 additional hospital days, and $2.3 billion in additional hospital charges—assuming that these HAIs could have been prevented and that patients who contracted them would have had similar mortality rates, lengths of stay, and hospital charges as those who did not contract such infections. (Table 1) These additional deaths, hospital days, and hospital charges are associated with the *hospital stay* in which these infections occurred and are not necessarily solely attributable to the hospital-acquired infection.

Table 1

Hospital admissions in which these hospital-acquired infections occurred were associated with an *additional*:

	2004: 12 months	2005: First 9 months
In-hospital deaths	1,510	1,456
Hospital days	205,000	227,000
Hospital charges	$2 billion	$2.3 billion

Insurance payment data

In addition to hospital charge data, PHC4 is now able to report commercial insurance payment data. The payment data in this report covers hospital admissions in 2004; 2005 data is not yet available, nor is data available for admissions paid for by Medicare and Medicaid.

In 2004, commercial health insurers paid for 1,119 of the 11,668 total HAI cases reported by Pennsylvania hospitals. The average payment for these cases was $60,678, seven and a half times the amount paid for those patients without an HAI ($8,078), and a difference of $52,600 per patient.

Commercial insurers paid an average of $52,600 more for patients with a hospital-acquired infection.

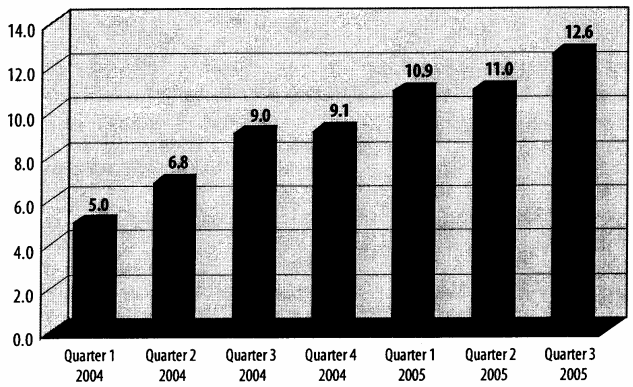
The additional payments for just those 1,119 patients total $58.8 million. Since Medicare and Medicaid data is not available, an all-payor total can only be estimated by applying the additional average commercial insurance payment figure to all payors. Using that extrapolation, the total additional payments for the 11,668 HAI cases in 2004 can be estimated at $613.7 million. A more precise figure will not be known until all payor data becomes available.

Table 2

Hospital Admissions Covered by Commercial Insurers, 2004

Type of Infection	Number	Average Payment	Average Length of Stay in Days	Percent Died
Surgical site	262	[illegible]	[illegible]	[illegible]
Urinary tract	388	[illegible]	[illegible]	[illegible]
Pneumonia	123	[illegible]	[illegible]	[illegible]
Bloodstream	249	[illegible]	[illegible]	[illegible]
Multiple infections	97	[illegible]	[illegible]	[illegible]
Any of the above infections	1,119	$60,678	21.2	10.7
Patients without any of the above infections	288,444	$ 8,078	3.4	0.7

Figure 2
Rate of Hospital-acquired Infections Per 1,000 Admissions
Quarter 1, 2004 through Quarter 3, 2005



Data submission improving

Since the inception of the required HAI reporting process in January of 2004, many hospitals have been working hard to more fully report the occurrence of HAIs in their institutions as part of their commitment to high quality care and improved patient safety in Pennsylvania. The last 21 months have shown consistent improvement in data submission as can be seen in Figure 2.

However, data submission disparities among hospitals exist, and there is still potential under-reporting occurring among hospitals across the Commonwealth, based on PHC4's evaluation of hospital characteristics, historical admission patterns and comparisons among similar hospitals.

Beginning January 1, 2004, hospitals were required to submit data on four types of hospital-acquired infections to PHC4:

1. Surgical site infections for orthopedic surgery, neurosurgery, and surgery related to the circulatory system
2. All device-related infections for
   - Indwelling catheter-associated urinary tract infection
   - Ventilator-associated pneumonia
   - Central line-associated bloodstream infection

Beginning July 1, 2005, hospitals were required to submit data on seven additional categories of surgical site infections. The added categories were for surgeries related to the following body systems:

- Endocrine system
- Gastrointestinal system
- Genitourinary system
- Reproductive system
- Respiratory system
- Skin and soft tissue
- Miscellaneous

As of January 1, 2006, hospitals are required to submit data on *all* hospital-acquired infections to PHC4.

The Pennsylvania Health Care Cost Containment Council's (PHC4's) landmark report on the number of hospital-acquired infections experienced in Pennsylvania hospitals in 2004 focused on 1,562,600 [illegible] admissions to 173 general acute care hospitals. This update provides hospital-acquired infection information for the 1,194,637 admissions to general acute care hospitals during the first three quarters of 2005 and compares hospital data submission efforts for these two time periods.

Pennsylvania Health Care Cost Containment Council
Marc P. Volavka, Executive Director
225 Market Street, Suite 400, Harrisburg, PA 17101
Phone: (717) 232-6787 • Fax: (717) 232-3821
www.phc4.org

The Pennsylvania Health Care Cost Containment Council (PHC4) periodically releases *Research Briefs* on health care topics relevant to public policy interest.

PHC4 is an independent state agency created to collect, analyze, and disseminate information designed to improve the quality and restrain the cost of health care.

Eliminating Hospital Acquired Infections

Is it Possible?
Is it Sustainable?
Is it Worth It?

Richard P. Shannon, MD
Department of Medicine
Allegheny General Hospital

The Key Message

- **The data must not only be reportable, but actionable.**
- **It's not about policies and procedures; it's about processes.**
- **You can come surprisingly close to eliminating hospital acquired infections with standardization as opposed to resources.**
- **Hospital acquired infections are costing hospitals and society millions of dollars, illustrating the conspiracy of error and waste .**

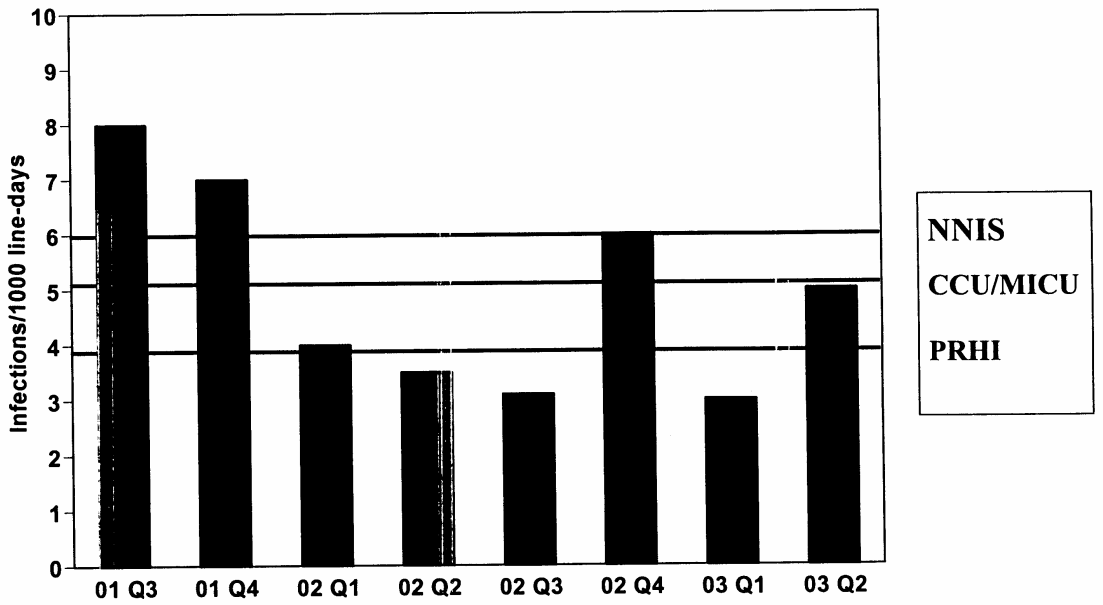
2

What Did We Know (*or think we knew*) Before?

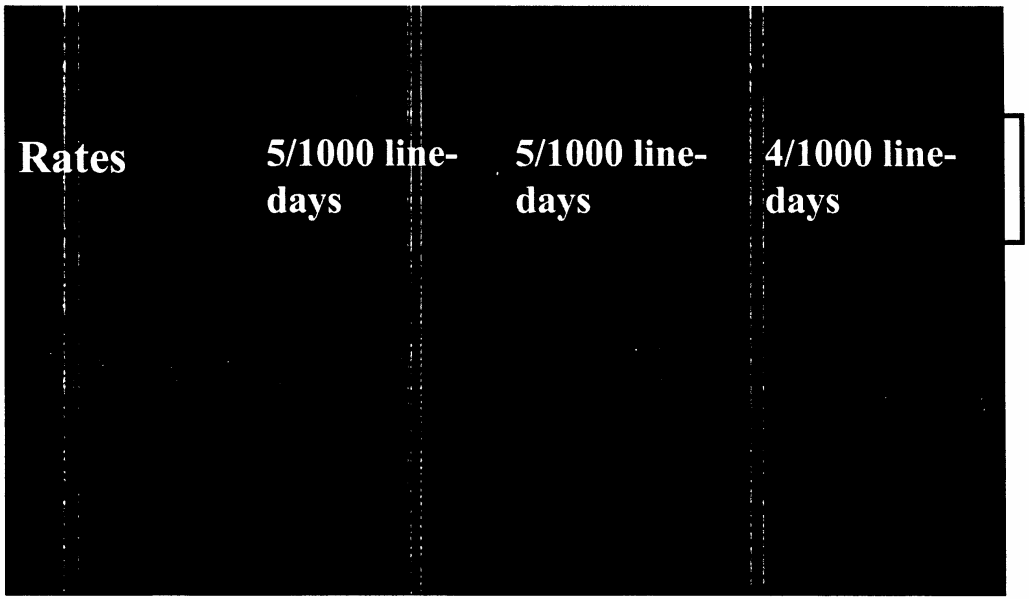
- **Our results were average and average is ok.**
- **CLABs/ HAI are inevitable. It is the price you pay for sophisticated, complex care.**
- **CLABs/HAI are benign and readily treated with antibiotics.**
- **CLABs HAI are a common accompaniment of complex care and covered in outlier payments.**

Problems With Bench Marking

The Difference Between Reporting and Actionable Data



Where Would You Want to Have a Central line Placed?



What Does *5.1 infections/ 1000 line days* Really Mean??

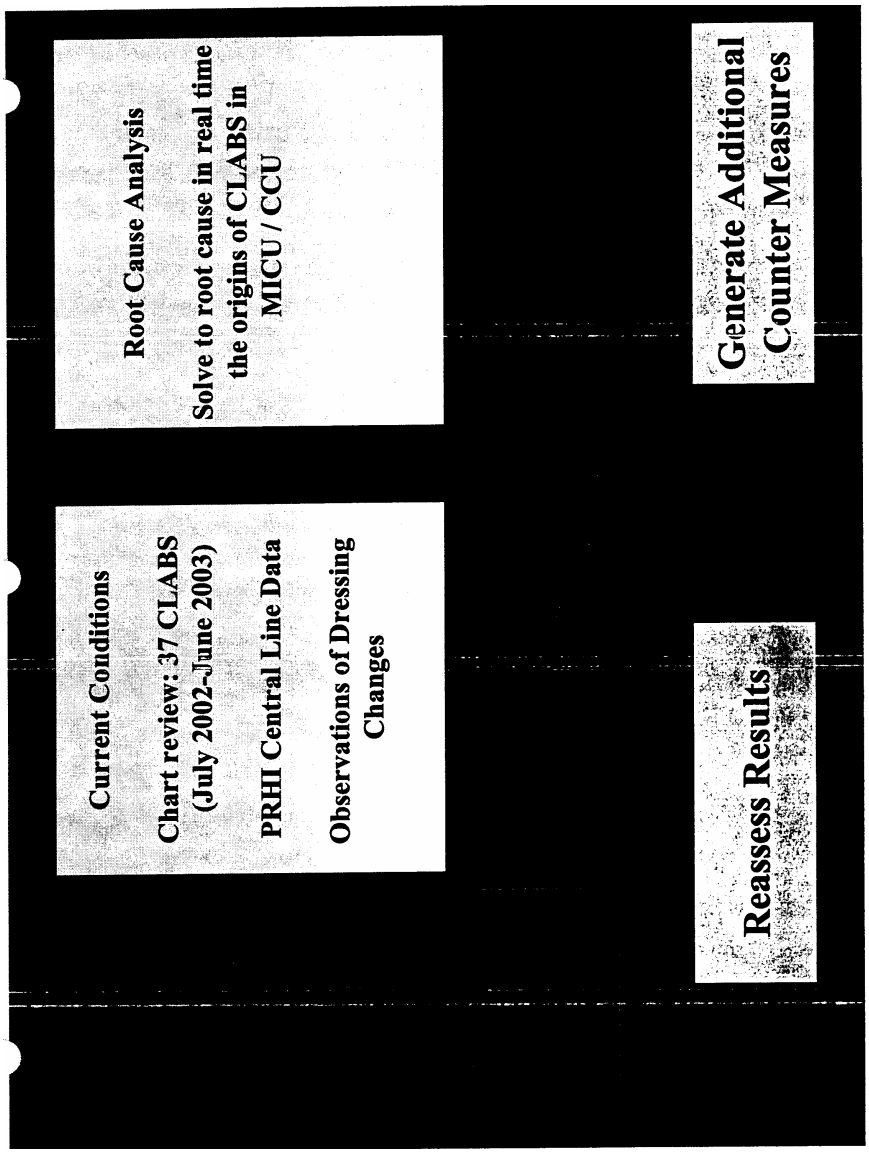
- 37 patients
- 49 infections
- 193 lines were employed (5.2 lines / patient)
- 1753 admissions
- 1063 patients had central access for more than 12 hours
- 1 out of 22 patients with a central line became infected.

What Did We Learn ?

- We were reporting only half of the actual CLABs.
- Central lines had a 4-5% chance of blood stream infection.
- Two-thirds of the infections involved virulent organisms . Twenty percent were MRSA.
- 19/37 patients died (51%).

What Did We Do?
PPC

- **Step 1: Set ambitious goals**
- **Step 2: Observe variations in work**
- **Step 3: Real time problem solving**
- **Step 4: Implement and test countermeasures**


Current Conditions
Chart review: 37 CLABS (July 2002-June 2003)
PRHI Central Line Data
Observations of Dressing Changes
Root Cause Analysis
Solve to root cause in real time the origins of CLABS in MICU / CCU
Generate Additional Counter Measures
Reassess Results

Variation in the Course of Work (Line Placement)

- No standard pre-procedure checklist
- Informed consent in 25% of procedures
- Eight different ways to "gown and glove"
- Six different ways to "prep and drape"
- Four different approaches to central veins
- Five different insertion kits
- 55% of procedures were documented

Variation in the Course of Work (Line Maintenance)

- No specified role
- No standardized definitions of "site at risk"
- No standardized dressing kit
- No standardized procedure for dressing change
- No standard record of line location and duration.

Understanding Problems Leads to Solutions

Real Time Problem Solving	Countermeasures
• Introducer linked and rewired	• Dysfunctional catheters should be replaced, not rewired
• Fem line in place > 96 hrs	• Replace all femoral lines within 12 hours
• Patient transferred with line in place for 21 days	• Replace line present on transfer
• Infected Groshon catheter	• Subclavian or PICC line preferred

Comparative Results		
	FY 2003 Traditional Approach	FY 2004 PPC Approach
ICU Admissions (n)	1753 ASG: 1.9	1798 ASG: 20
Patients with CLABs (n)	37	6
Age (years)	62 (24-80)	62 (50-74)
Gender (male/female)	22/15	3/3
Total CLABS	49	6
Lines	1063	1110
Line days	4683	5052
Overall rates (infections /1000 line days)	10.5	1.2
Deaths in patients with CLABs	19 (51%)	1 (16%)
Risk of CLAB	1 in 22	1 in 185

Additional Countermeasures

Real Time Problem Solving	Countermeasures
• Line Skills • Lines for a long time • Difficult access	• Education / Credentialing • *BioPatch* dressings • *Site Rite/ SonoSite* ultrasound • Micropuncture kits • Vascular access team • Antibiotic locks

Are the Results Sustainable ?

	FY 2004 PPC Approach	FY 2005 PPC Approach
ICU Admissions (n)	1798 ASG:2.0	1829 ASG:2.1
Patients with CLABs (n)	6	11
Age (years)	62 (50-74)	65 (39-71)
Gender (male/female)	3/3	4/7
Total CLABS	6	11
Lines	1110	1487
Line days	5052	6705
Overall rates (infections /1000 line days)	1.2	1.6
Deaths in patients with CLABs	1 (16%)	2 (18%)
Risk of CLAB	1 in 185	1 in 135

Why Did We Slip?

- 55% of the CLABs in FY05 were related to line placement issues
- We had not developed training for line placement
- Residents and fellows are masters of the "work around"
- We are using more and more PICC (new technology) without proper technique and training for nurses

Why Did We Slip?

- Informed consent 84%
- Pre-procedure checklist 96%
- Scrub/Gown/Glove 98%
- Drape/Prep 98%
- Site Selection/ Success 72%
- Line Dressing 100%
- Line Maintenance 98%

Central Line Training Module

Workers have to be given the training necessary to be successful

- **1 hour didactic with test**
- **"The Perfect Line Placement " Video**
- **Two Hours in the "Line training Simulator"**
- **Inter disciplinary (residents/fellows/nurses)**

February 28, 2006: CLAB Risk= 1 in 535 lines

	Traditional Approach FY 03	PPC Approach FY 04 Year 1	PPC Approach FY 05 Year 2	PPC Approach FY 06 (7 months) Year 3
ICU Admissions (n)	1753	1798 (+45)	1829 (+76)	1094
Atlas Severity Grade	1.9	2.0	2.1	2.2
Age (years)	62 (24-80)	62 (50-74)	65 (39-71)	64 (56-76)
Gender (M/F)	22/15	3/3	4/7	1 / 2
Central lines employed (n)	1110	1321* (211)	1487* (377)	1605*
Line-days	4687	5052*	6705*	6667*
Infections	49	6*	11*	3*
Patients Infected	37	6*	11*	3*
Rates (infections/ 1000 line-days)	10.5	1.2*	1.6*	0.45*
Deaths	19 (51%)	1 (16%)*	2 (18%)*	0 (0%)*
Reliability (# of lines placed to get 1 infection)	22	185*	135*	535*

The Conspiracy of Error and Waste

- **What is the cost of a CLAB in human and financial terms?**
- **What does society pay for healthcare associated infections (HAI)?**
- **Do hospitals and physicians make money on HAIs ?**

Case 1:

- **37 year old video game programmer, father of 4, admitted with acute pancreatitis secondary to hypertriglyceridemia.**
- **Day 3: developed hypotension, and respiratory failure**
- **Day 6 : fever and blood cultures positive for MRSA secondary to a femoral vein catheter in place for 4 days.**
- **Multiple infectious complications requiring exploratory laparotomy and eventually tracheostomy**
- **Day 86: Discharged to nursing home**
- **Highmark Select Blue**

Case 1

Charges and Costs Attributable to CLAB

	Charges	Cost
Primary and Secondary Total Before CLAB	0.00	0.00
Primary and Secondary Total After CLAB	290,357.00	63,827.56
Total Variable Cost	290,357.00	63,827.56
MICU Service After CLAB (82 days)	266,518.00	106,737.56
Floor Service After CLAB	0.00	0.00
Total Fixed Cost	266,518.00	106,737.56
Total Variable Cost	290,357.00	63,827.56
Total Fixed Cost	266,518.00	106,737.56
Total Cost Attributable to CLAB	556,875.00	**170,565.12**
Total Cost of Entire Stay	828,847.00	241,843.82
Attributable Cost as Percent of Total		70.53%

The Impact of CLABs on Gross Margin

	DRG 204/2721 (n=3)	DRG 191 (n=3)	DRG 483 (n=2)	Case 1
	Acute pancreatitis	Pancreatitis w cc	Pancreatitis w trach	
Revenue ($)	5,907	99,214	125,576	200,031
Expense	5,788	58,905	98,094	241,844
Gross Margin	119	40,309	27,482	-41,813
Costs attributable to CLAB				170,565
LOS	4	38	41	86

Case 3

- **49 year old obese female was admitted for elective surgical gastroplasty.**
- **She developed respiratory distress post operatively and was intubated for respiratory failure.**
- **On day 22, blood cultures were positive for *Staph epidermidis, enterococcus fecaelis, and Candida.***
- **The right femoral line tip grew all three organisms. The line was in place for 16 days.**
- **On hospital day 48, she was transferred to a SNF.**
- **Medicare/ Three Rivers**

Case 3

Charges and Costs Attributable to CLAB

	Charges	Cost
Primary and Secondary Total Before CLAB	96.00	16.93
Primary and Secondary Total After CLAB	36,075.00	5,856.10
Total Variable Cost	36,171.00	5,873.03
MICU Service After CLAB	91,644.00	35,136.14
Floor Service After CLAB	0.00	0.00
Total Fixed Cost	91,644.00	35,136.14
Total Variable Cost	36,171.00	5,873.03
Total Fixed Cost	91,644.00	35,136.14
Total Cost Attributable to Infection	127,815.00	**41,009.17**
Total Cost of Entire Stay	359,315.00	117,626.21
Attributable Cost as a Percent of Total		34.86%

The Impact of CLABs on Gross Margin

	DRG 288 (n=10)	DRG 483 (n=3)	Case 3
	Procedures for obesity	Trach w obesity surgery	
Revenue	22,023	153,566	101,521
Expense	12,100	148,969	117,626
Gross Margin	9,923	6,597	-16,105
Costs attributable to CLAB			41,009
LOS	6	51	47

The Losses Attributable to CLABs are Staggering

- Average reimbursement: $64,894
- Average Expense: $91,733
- Average Loss from Operations: -$26,839
- Total Loss from Operations:-$1,406,901 (54 total CLABs analyzed)
- In only 2 cases did the hospital make money!
- Average Age: 56 years
- Average LOS: 28 days (5-86)
- Only three patients were discharged to home!

Eliminating CLABs

- **Is it Possible?**

  Unquestionably, but not without each individual accepting responsibility
- **Is it Sustainable?**

  Not without training and surrendering autonomy
- **Is it Worth It?**

  - No patient wants one

  - We lose substantial amounts on each CLAB

  -The loss is fully attributable to the costs of the CLAB

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Eliminating VAP

- **July2004:**

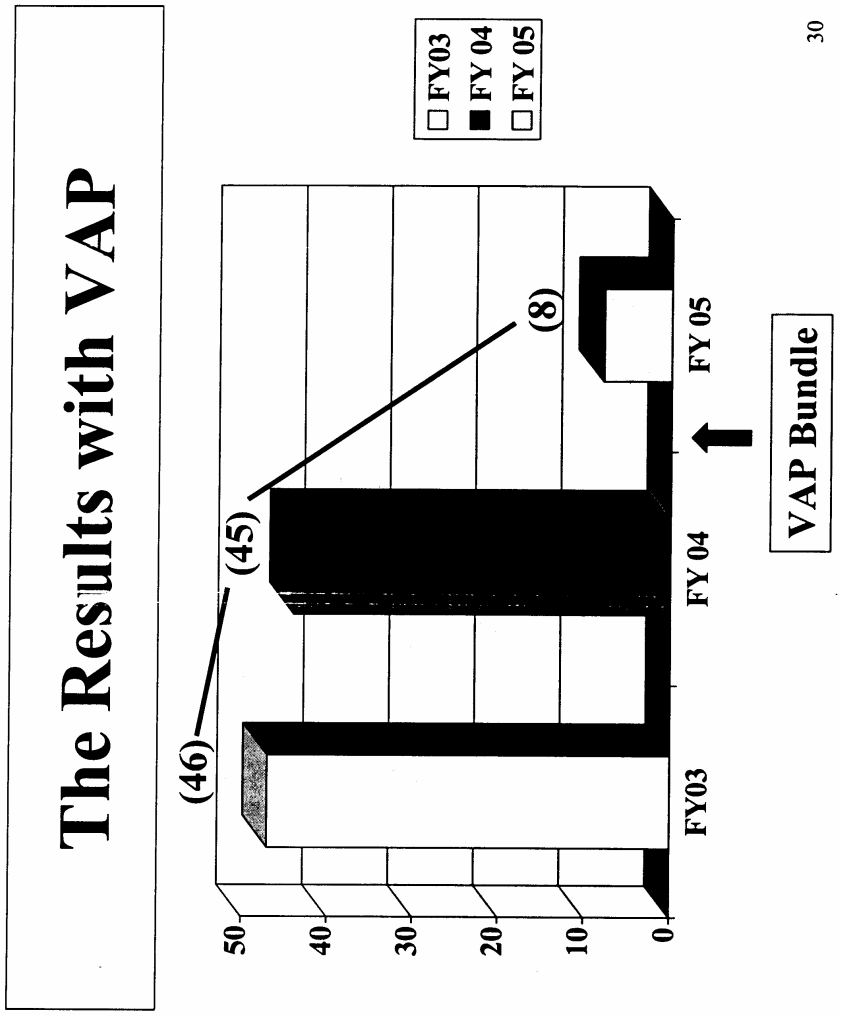
  We implemented "real time" problem solving around every VAP case

- **October, 2004:**

  We implemented countermeasures developed by the people doing the work (AGH VAP Bundle)

- **July, 2005:**

  We assessed improvement compared to data from the previous 2 years


The Results with VAP
FY03
FY 04
FY 05
50
40
30
20
10
0
(46)
(45)
(8)
FY03
FY 04
FY 05
VAP Bundle

30

Eliminating VAP: How Did We Do It?

- **Step 1: Elevate the head of the Bed 30°**
- **Step 2: Chlorhexidine mouthwash BID**
- **Step 3: Change vent tubing weekly**
- **Step 4: Change suction catheter daily**
- **Step 5: provide a hook for hanging resuscitation bag**

Total Added Cost: $17/ intubated patient

The Financial Losses due to VAP Are Sizable

(patient average)	Intubated Patients (FY 03-05) Total (N=2006)	
	VAP case (N=99, 5.1%)	Non-VAP case (N=1907, 94.9%)
Total Cost*	$87,318	$41,995
Reimbursement*	$62,883	$33,569
Profit/Loss	-$24,435	-$8,426
LOS	34.3	17.1
Days on Vent	27.8	10.2
ASG	2.6	2.7
AGE	62.7	63.3

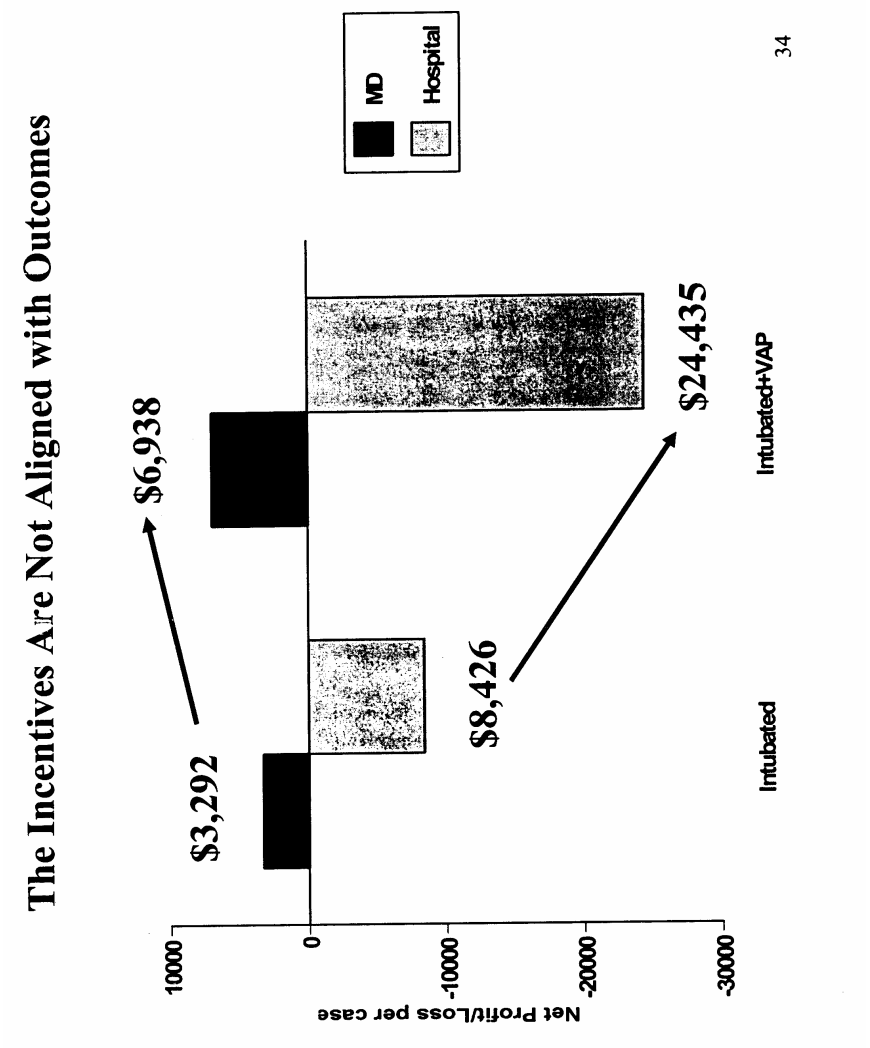
(*Excluded from the data are 57 non-VAP cases in fiscal year 04/05 due to the lack of reimbursement data on these cases)

Best Clinical Outcome Does Not Reward AGH

VAP vs. Non-VAP Separated into Clinical Outcomes

	Weaned (N=1029, 51.3%)		Trached (N=297, 14.8%)		Expired (N=680, 33.9%)	
(patient average)	VAP (N=26, 2.5%)	Non-VAP (N=1003, 97.5%)	VAP (N=46, 15.5%)	Non-VAP (N=251, 84.5%)	VAP (N=27, 4.0%)	Non-VAP (N=653, 96.0%)
Total Cost*	$73,357	$34,864	$117,033	$99,867	$50,139	$30,458
Reimbursement*	$45,365	$26,028	$94,883	$92,577	$25,233	$22,218
Profit	-$27,993	-$8,836	-$22,150	-$7,290	-$24,905	-$8,240
LOS	30.3	15.4	45.7	38.7	18.6	11.2
Days on Vent	20.3	6.4	40.1	32.1	14.3	7.7
ASG	2.5	2.5	2.6	2.7	2.8	3.1
AGE	58.8	60.1	61.4	64.1	69.3	67.6

(*Excluded from the data are 57 non-VAP cases in fiscal year 04/05 due to the lack of reimbursement data on these cases)


The Incentives Are Not Aligned with Outcomes
MD
Hospital
$6,938
$3,292
$8,426
$24,435
10000
0
-10000
-20000
-30000
Net Profit/Loss per case
Intubated
Intubated+VAP
34

Step 7 :Estimate the Cost of the Intervention

- Variable costs of the actual components

$ 0.4 / day	(chlorohexidine mouthwash)
+ $ 1.0 / day	(clear and blue ventilator tubes)
= $ 1.4 / day	
* 11.17 (average days on ventilator)	
= $15.64 / patient	
+ $ 0.58 / patient (Yankauer suction)	
+ $ 0.75 / patient (resuscitation bag hook)	
= **$17 (per patient)**	

- No other costs associated with implementation
  - no special training for nurses
  - little additional time for nurses to perform

Savings Are Likely to Far Exceed the Costs of Intervention

Cost of the Intervention	$10,897 (for all patients)	$17 (per patient) * 641 (no. of intubated patient in 03/04)
Nominal Savings	$16,010 (per one case)	The difference between the average profits of a VAP patient and a non-VAP patient **(= -$8,426 - (-$24,436))**

No. of prevented VAP cases	Nominal Savings	Cost of the Intervention	Actual Savings
1	$16,010	$10,897	**$5,113**
2	$32,020	$10,897	**$21,123**
|	|	|	|
10	$160,098	$10,897	**$149,201**

Eliminating VAPs

- **Is it Possible?**

  Unquestionably, with strict adherence to work standardization
- **Is it Sustainable?**

  -Not without better weaning protocols

  -Not without full time Critical Care physicians
- **Is it Worth It?**

  - No patient wants one

  - We lose substantial amounts on each VAP

  -The loss is fully attributable to the costs of the VAP

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CCU/MICU and HAI
A Big Return on Investment

- **Total Savings**
  - **CLAB= $1,235,765 (2 years)**
  - **VAP= $1,003,162 (1 year)**
- **Highmark PFP = $2,100,000**
- **HAI elimination Initiatives = +$4,338,927**
- **Investment = $34,927**
- **106 additional ICU admissions**
- **47 lives saved**

Summary

- Progress but by no means excellence
- Each class of HAI represent a enormous clinical and economic opportunity
- Training, commitment, and collaboration (not policies and guidelines) are needed.
- Excuses are no longer acceptable

TAB 10

Doctors
Medical Center
Tenet California

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Katherine Medeiros
Chief Executive Officer - Interim
tel: 209-576-3601
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October 18, 2005

VIA FACSIMILE (202) 225-1919
Mr. Andrew L. Snowdon
Oversight and Investigations Counsel
Office of Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
H2-316 Ford House Office Building
Washington, DC 20515-6115

Re: Doctors Medical Center of Modesto's response to the September 21, 2005 letter from the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations.

Dear Mr. Snowdon:

Enclosed in question and answer form, are the responses of Doctors Medical Center of Modesto to the questions put forth in the September 21, 2005 letter from The Honorable Joe Barton, Chairman and The Honorable Ed Whitfield, Chairman of the Subcommittee on Oversight and Investigations.

Sincerely,

Katherine Medeiros
Chief Executive Officer – Interim

Enclosure

RESPONSE OF DOCTORS MEDICAL CENTER OF MODESTO TO REQUEST FOR INFORMATION FROM HOUSE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

1. **Does Doctors Medical Center of Modesto monitor HAI rates?**

   a. **If not, please explain why not.**
   b. **If so, does Doctors Medical Center of Modesto monitor all HAIs or does it conduct targeted surveillance of specific high-risk departments, procedures, or types of infection?**
   c. **If Doctors Medical Center of Modesto does targeted surveillance, please identify the specific types of infection, departments, and/or procedures monitored.**
   d. **Please provide the rates for HAIs monitored by Doctors Medical Center of Modesto for calendar years 2003 and 204.**

Yes, Doctors Medical Center of Modesto ("DMC") monitors rates of hospital-acquired infections ("HAIs"). DMC has a dedicated Infection Control Department which is led by an Infection Control Coordinator ("ICC"). The ICC is charged with managing all infection surveillance, prevention and control activities and practices for clinical services across the entire facility. With respect to monitoring HAI rates, the ICC conducts daily reviews of data collected from the prior day's positive lab cultures, admitting diagnoses, and reports of patients presenting with high temperatures. Based on this information, the ICC performs daily rounds on patient care areas and targeted record review on patients with potential infections. Any infection identified as a result of this process is then categorized as either a community-acquired infection or a nosocomial infection (i.e., an infection not present or incubating at the time of admission and acquired due to, because of, or during hospitalization), using HAI criteria developed by the Centers for Disease Prevention and Control ("CDC"). All HAI data are tracked electronically. Patients with HAIs are monitored throughout their hospitalizations for appropriate precautions and interventions. DMC's ICC provides detailed HAI rate reports to the hospital's monthly Infection, Prevention and Therapeutic Committee ("IPT Committee"). Aggregated, department-specific outcomes are reported quarterly to Medical Staff departments.

In June 2005, Tenet Healthcare Corporation ("Tenet") became one of the first hospital systems to join the Institute for Healthcare Improvement's "100,000 Lives Campaign." The campaign is a coordinated national effort to implement six specific healthcare practice changes that have been shown to improve patient care and prevent avoidable deaths. Of the six recommended practice changes, three specifically address the prevention of HAIs. In

accordance with the three HAI campaign initiatives, DMC is in the process of implementing the following practices: prevention of central line infections through the implementation of a proven series of scientifically grounded steps (the "central line bundle"); prevention of surgical site infections ("SSIs") through the timely delivery of appropriate perioperative antibiotics; and the prevention of ventilator-associated pneumonia ("VAP") through the implementation of a proven series of scientifically based steps (the "ventilator bundle").

In addition to the "100,000 Lives Campaign" initiatives, Tenet facilities are in the process of implementing standardized practices for the prevention of catheter-associated urinary tract infections ("CAUTIs") as part of Tenet's comprehensive Infection Control Program, led by Jennifer Daley, M.D., Tenet's Senior Vice President of Clinical Quality and Chief Medical Officer. Dr. Daley, a former Vice President and Medical Director of Health Care Quality at Beth Israel Deaconess Medical Center and prior Director of the Center for Health System Design and Evaluation at Massachusetts General Hospital, is a nationally recognized expert on healthcare quality control measures. Tenet's Infection Control Program is based upon guidelines from the CDC, the Joint Commission of Healthcare Organizations ("JCAHO"), the Association for Professionals in Infection Control and Epidemiology ("APIC") and the Society for Healthcare Epidemiology of America ("SHEA"). Specific performance improvement targets include prevention of intravascular catheter-related infections, ventilator-associated pneumonia, SSIs and catheter-associated urinary tract infections. In addition, Tenet's Infection Control Program incorporates the JCAHO's National Patient Safety Goal to reduce the risk of HAIs, as well as the four CDC Healthcare Safety Challenges relating to infection control.

At this time, DMC respectfully declines to provide HAI rate data to the Subcommittee. In the absence of industry standard methodologies for calculating HAI rates, DMC believes that disclosure of HAI data intended for internal use would invite public misconceptions. In addition, elements of the requested data were gathered by peer review committees whose work is protected by the peer review privilege. Important state and federal public policy considerations support peer review confidentiality as demonstrated most recently by the federal patient safety legislation. DMC is open to discussions with the Subcommittee to address these concerns

2. To the extent that Doctors Medical Center of Modesto does monitor HAI rates, does it report such rates?

a. If not, please explain why not.
b. If so, how and when are these rates reported?

c. Does Doctors Medical Center of Modesto voluntarily report HAI rates to the CDC's National Nosocomial Infections Surveillance system or National Healthcare Safety Network?

d. Please describe any barriers that Doctors Medical Center of Modesto has identified to collecting data that could be publicly reported.

e. Please describe any risks to Doctors Medical Center of Modesto (real or perceived) associated with publicly reporting HAIs.

f. How can information on HAIs be better reported to consumers?

DMC utilizes its HAI data to focus its quality improvement efforts and to establish internal benchmarks. To that end, the hospital's ICC provides HAI data to the IPT Committee on monthly basis. Examples of reported HAI rates include, but are not limited to the following: bloodstream infections per 100 discharges; bloodstream infections per 100 patients; infection by service per 100 discharges; wound infection rates; VAP rates per 1000 ventilator days; and infections (all sites) per 100 discharges. In turn, the IPT Committee reports this HAI data to the Medical Executive Committee and the Governing Board at their regularly scheduled meetings. HAI rates are also made available to hospital administration and department directors.

DMC and other hospitals are not required to report HAI rates at the local, state or federal level. Because there are no standardized metrics for determining HAI rates that are appropriately risk-adjusted and broadly accepted in the provider community, DMC does not voluntarily report HAI rates to either the CDC's National Nosocomial Infections Surveillance system or the National Healthcare Safety Network. Without standardized calculation methodologies, like many other hospitals, DMC believes that public reporting of HAI rates fails to advance consumer understanding of hospital quality data. At its most basic, an HAI rate is meant to convey the prevalence of the HAI in a given population. Determining the numerator of an HAI ratio is a relatively straightforward proposition in light of widely accepted CDC guidance and definitions. Establishing the denominator, on the other hand, presents significant challenges. Currently, a variety of methodologies are used to calculate HAI rates, some much more stringent than others. Hospitals that employ higher standards to identify and track HAI data are evaluated by the same consumer standards as are hospitals that place less emphasis on HAI monitoring and prevention. Given that the former inevitably report higher HAI rates than the latter, the resulting data presented to consumers are skewed and misleading.

Perhaps most significantly, absent broadly accepted standardized methodologies to calculate HAI data and effective auditing processes to ensure compliance by providers with the established metrics, DMC believes that public reporting of HAI rates could ultimately undermine HAI monitoring and prevention initiatives. Fear of consumer and practitioner misconception not only would give hospitals an incentive to underreport HAI rates, but also

could compromise the integrity of internal hospital quality improvement processes. Thus, independent validation of HAI data reported from institutions would be necessary if measures were to be credible.

In order to effectively communicate HAI data in a manner that is of value to consumers, DMC believes that consumer input must first be solicited to best understand and address consumer concerns regarding HAIs and to develop a reporting format for complex clinical information that has meaning to consumers. To that end, DMC supports the development of standardized metrics for calculating HAI rates, such as the California Hospitals Assessment and Reporting Task Force ("CHART") which is working with the state government to establish a standardized hospital quality report card for California in context with the national efforts by the Centers for Medicare and Medicaid Services and JCAHO, among others. However, until standardized methodologies for calculation of HAIs are established, DMC believes that any public reporting of HAI data should be done in context and include statements that acknowledge the variability among methodologies for calculating HAI rates reported by hospitals.

The lack of standard measurement methodologies also raises concerns in personal injury litigation, as aggregate comparative data would mislead a fact findersif all hospitals are not using the same methodology to calculate HAI rates. Hospitals that accurately report their data and use more aggressive calculations could be penalized in litigation even though their efforts would actually lead to a greater reduction in HAIs over time. We also believe that non-standardized public reporting will discourage physicians and infection control practitioners from participating in the monitoring of HAIs. Currently, the monitoring of HAIs is directed by committees of the hospital whose work is protected by the peer review privilege. The individual physicians and staff who serve on these committees are generally immune from liability for their actions under the state peer review law, and non-standardized public reporting would erode this protection. Absent additional legal protections from discovery of this data, it will become increasingly difficult to find qualified physicians and personnel who are willing to participate in this process.

Obtaining accurate HAI data is an extremely time intensive and costly endeavor. DMC utilizes rigorous metrics to calculate HAI rates. For example, the hospital's VAP infection rate is calculated by dividing the incidence of infection by 1000 patient ventilator days. Use of this methodology necessarily relies upon the ability of the hospital to capture patient ventilator days. Currently, there are no automated systems available to track these data. As a result, the information must be collected manually, a process which is both time consuming and resource intensive. The lack of automated tracking information also presents significant internal auditing hurdles because any evaluation of HAI rate calculations requires manual review of patient medical records.

3. **Are Doctors Medical Center of Modesto's reported HAI rates adjusted to account for a patient's underlying risk of infection? If not, please explain why not. If so, please explain all such adjustments.**

DMC rates for hospital-acquired surgical site infections ("SSIs") are adjusted to account for patients' underlying risks of infection because the likelihood that a patient will develop an SSI is dependent upon factors such as type of surgery, the general health of the patient at the time of the operation, and the length of the operation. DMC uses a standard wound classification system widely accepted by infection control practitioners and recognized by the CDC to capture risk variation associated with different types of surgery.

4. **Please provide a detailed written description of Doctors Medical Center of Modesto's case-finding methods for identifying and tracking HAIs.**

   a. **Have these methods changed during the past five years? If so, please explain.**
   b. **Does Doctors Medical Center of Modesto conduct any type of post-discharge surveillance? If so, please describe.**

DMC's Infection Control Department is responsible for identifying and tracking HAIs. As described above, the hospital's ICC conducts daily reviews of data collected from the prior day's positive lab cultures, admitting diagnoses, and reports of patients presenting with high temperatures. Using this information, the ICC performs daily rounds on patient care areas and targeted record review on patients with potential infections. Infections identified as a result of this process are entered into the ICC's Infection Log. The ICC then analyzes each infection using criteria developed by the CDC to identify whether the infection is community-acquired or hospital-acquired. All data regarding HAIs are entered into both proprietary software and AICE Millenium (commercially available infection control software). These systems are used to track HAIs and to analyze HAI data by service, hospital unit, infection site, and surgeon (for SSIs). The ICC provides reports on a monthly basis to the hospital's IPT Committee that include rate tables and trending data for blood infections, wound infections, critical care infections, and ventilator-associated pneumonia. In addition, the ICC reports department-specific outcomes on a quarterly basis to medical staff departments. These monitoring and tracking methods have been consistently applied during the past five years. Shortly, DMC will phase in a new proprietary software program to replace the current system. This new program will provide standard surveillance methods, uniform CDC definitions of HAIs, and standardized methods for counting denominators for HAIs (e.g., ventilator days, catheter days for bloodstream and urinary tract infections, and

surgical site infection rates by surgical procedures.) This system will permit comparisons across Tenet hospitals.

DMC conducts post-discharge surveillance of Class I surgeries, i.e., surgeries that pose the least risk of a patient acquiring an infection. Class I surgeries are elective, non-traumatic, primarily closed surgeries where the respiratory, gastrointestinal, biliary and genitourinary tracts are not entered. On a monthly basis, the hospital's ICC generates a report that provides a comprehensive listing of each Class I surgery performed at the hospital during that month, stratified by surgeon. The ICC sends a form to each surgeon listing all operations performed by the surgeon identified by patient name and medical record number. Surgeons are asked to indicate on the form whether or not any wound infections developed from any of the listed procedures and then to return the form to the hospital's Infection Control Department. The ICC uses the response data to calculate Class I Surgery HAI rates. Significantly, the ability to calculate accurate SSI rates is largely dependent upon surgeon participation in the post-discharge surveillance process. DMC notes that of the 2144 inquiries sent to surgeons since 2003, 1518 responses were received (70.8%).

5. **Does Doctors Medical Center of Modesto have dedicated infection prevention and control personnel and/or specific technology for monitoring HAI rates?**

   a. **If so, please describe the number of full-time infection, prevention and control personnel employed by Doctors Medical Center of Modesto and the type(s) of technology used to monitor HAI rates.**
   b. **What additional resources would Doctors Medical Center of Modesto need to monitor HAI data more thoroughly?**

DMC employs a full-time, certified Infection Control Coordinator ("ICC") and a part-time (0.6 FTE) Infection Control Nurse ("ICN"). DMC's Infection Control Department also receives support from the hospital's Director of Clinical Quality Improvement and Tenet's Regional Chief Medical Officer. In addition, at Tenet's corporate level, seven infection control workgroups, comprised of over fifty employees from both Tenet's corporate office and various Tenet facilities, serve as a resource to the ICC and the ICN.

The ICC is responsible for managing DMC's infection control program, including the surveillance, monitoring and tracking of all HAI rates facility-wide. In addition, the ICC develops, implements and evaluates infection control training programs, coordinates reporting of infectious diseases to the Public Health agencies as required by Title XVII, and serves as primary consultant in the principles of infection control for employees of all hospital departments, patients and visitors. DMC's ICC and ICN use two software

programs, a proprietary infection control program and AICE Millenium (a commercial infection control monitoring program) to track and analyze HAI data.

Development of automated applications to track hospital device days (i.e., the total number of days a given type of device is used by patients) would also help to relieve the significant burden associated with monitoring HAI rates.

6. **What was Doctors Medical Center of Modesto's total budget for detecting, monitoring, and reporting HAIs in calendar years 2003 and 2004? What are the projected budgets for calendar years 2005 and 2006?**

At this time, DMC respectfully declines to provide budgetary details to the Subcommittee in light of the proprietary nature of the information.

7. **Does Doctors Medical Center of Modesto monitor any "process measures" associated with HAIs, including, but not limited to: adherence rates of hand washing, central-line insertion practices, and surgical antimicrobial prophylaxis; and coverage rates of influenza vaccination for healthcare personnel and patients?**

   a. **If not, please explain why not.**
   b. **If so, please describe such process measures and provide the adherence rates.**

DMC monitors multiple "process measures" associated with HAIs, including, but not limited to, adherence rates of hand washing and surgical antimicrobial prophylaxis, and coverage rates of influenza vaccination. DMC's Hand Hygiene protocol is intended to reduce microbial contamination and colonization of the hands in order to prevent transmission of pathogenic microorganisms among individuals. The protocol was developed in accordance with the CDC's "Guideline for Hand Hygiene in Health-Care Setting." Adherence to the protocol is monitored by measuring the volume of volume of antiseptic used per number of hospital discharges. As part of Tenet's Commitment to Quality initiative, DMC's Quality Department tracks and reports Surgical Infection Prevention ("SIP") data on a monthly basis. Specifically, DMC's Quality Department monitors the following three SIP indicators: prophylactic antibiotic administration within one hour prior to surgical incision; prophylactic antibiotic selection for surgical patients; and prophylactic antibiotics discontinued within 24 hours after surgery end time. DMC also tracks coverage rates of influenza vaccination as part of its Pneumonia Core Measures module during flu season. In addition, compliance with hospital protocols addressing HAI prevention, such as the Urinary Catheterization Procedure, the Ventilator Protocol, the Body Substance

Isolation Protocol, and the Precautions for Patients with Vancomycin-Resistant Enterococci ("VRE") Protocol, among others, is monitored by the ICC.

At this time, DMC respectfully declines to provide process measure adherence data to the Subcommittee. DMC believes that disclosure of data intended for internal use would invite public misconceptions given the lack of a common methodology for measurement. In addition, DMC believes that elements of the requested data are subject to peer review protection. DMC is open to discussions with the Subcommittee to address these concerns.

8. **Has Doctors Medical Center of Modesto done any studies or analyses to calculate the financial impact of HAIs on the institution?**

   a. **If so, what is the annual financial impact?**
   b. **Has Doctors Medical Center of Modesto made any effort to determine whether improved monitoring of infections would lower its costs? If so, please describe all such efforts.**

DMC has not conducted any independent studies or analyses to assess the costs associated with HAIs at the facility. DMC believes that sufficient literature is available to support the position that HAIs significantly impact hospital finances and that the implementation of appropriate monitoring processes and preventative measures are good practices that serve the best interests of both patients and the hospital.

9. **Does Doctors Medical Center of Modesto conduct facility-wide, active surveillance cultures for methicillin-resistant Staphylococcus aureus (MRSA) and/or vancomycin-resistant Enterococcus (VRE)?**

   a. **If not, please explain why not.**
   b. **If so, please describe the surveillance process and procedures.**
   c. **What are Doctors Medical Center of Modesto's rates for MRSA and VRE for calendar years 2003 and 2004?**
   d. **Please describe the barrier precautions utilized by Doctors Medical Center of Modesto for patients colonized or infected with MRSA or VRE.**

DMC actively monitors infection rates for both methicillin-resistant Staphylococcus aureus ("MRSA") and vancomycin-resistant Enterococcus ("VRE"). DMC's ICC conducts daily reviews of data collected from the prior day's positive lab cultures, admitting diagnoses, and reports of patients presenting with high temperatures. Based on this information, the ICC performs daily rounds on patient care areas and targeted record review on

patients with these potential HAIs. If a patient is found to have MRSA colonization (i.e., presence without infection) or infection, the facility's Body Substance Isolation protocol ("BSI Protocol") is immediately implemented. Pursuant to the BSI protocol, a patient with non-respiratory MRSA is given a private room if available. Otherwise, a patient with non-respiratory MRSA may share a room with another patient with MRSA or with patients who lack the following: MRSA colonization; wounds; catheters; and intubation. If a patient is suspected of or known to have respiratory MRSA, additional precautions are taken. Specifically, the patient is placed in a private room with a "STOP SIGN ALERT" on the door to the patient's room. The Stop Sign Alert instructs anyone about to enter the room to "check with nurse before entering." The nursing staff is responsible for instructing parties who wish to enter the room to wear a mask if the patient is intubated. If a patient is off ventilator, the room door may be left open. Otherwise, the door must remain closed. No fans are allowed in the patient's room. The decision whether to use additional barriers such as gloves, gowns, aprons, and eye protection is based upon anticipated contract with patient body substances. DMC's BSI Protocol is in accordance with the CDC's "Recommendations for Isolation Precautions in Hospitals."

If a patient is found to have VRE colonization or infection, DMC's Precautions for Patients with VRE protocol ("VRE Protocol") is immediately implemented. A patient with VRE colonization or infection is placed in a private room or in the same room as another patient with VRE colonization or infection with a green "STOP SIGN ALERT" on the door listing the necessary precautions to be taken. Although masks are not required upon entering the room, gloves must be worn. In addition, gowns are necessary in the following circumstances: contact with the patient or environmental surfaces is anticipated; the patient is incontinent; the patient has diarrhea; the patient has a colostomy or ileostomy; or the patient has wound drainage not contained in a dressing. DMC's VRE Protocol is in accordance with the CDC's "Recommendations for Preventing the Spread of Vancomycin Resistance."

DMC respectfully declines to provide HAI rate data to the Subcommittee. In the absence of industry standard methodologies for calculating HAI rates, DMC believes that disclosure of HAI data intended for internal use would invite public misconceptions. In addition, DMC believes that elements of the requested data are subject to peer review protection. DMC is open to discussions with the Subcommittee to address these concerns and is willing to work to find an acceptable manner in which HAI rate data may be provided.

TAB 11

Tenet **memo**

Date: May 20, 2005

To: SVPs, Hospital CEOs, CNOs, COOs, DCQIs, Infection Control Practitioners, Regional Compliance Officers, Hospital Compliance Officers, Clinical Quality Department, Regional Counsel, Regulatory Counsel

From: Reynold Jennings
Chief Operating Officer

Jennifer Daley, M.D., F.A.C.P.
SVP, Clinical Quality
Chief Medical Officer
Chairperson, Tenet Patient Safety Committee

cc: Patient Safety Committee

Subject: **Model Infection Control Program Plan**

The attached Model Infection Control Program Plan has been created as a **framework** to assist Tenet hospitals in the development of their Infection Control Program. This policy was developed by the Patient Safety Committee with input from additional internal and external parties including a representative sample of Tenet hospitals prior to finalization. The document must be adapted and edited to assure it accurately describes your program. Please note that any text in the plan that appears in **[brackets] and blue/bold font requires the insertion of provisions that are specific to your hospital.**

This plan encompasses: (1) the 2005 **regulatory requirements** from the Centers for Medicare and Medicaid (CMS) Conditions of Participation (CoP) and the 2005 Joint Commission on Accreditation of Healthcare Organization (JCAHO) Standards for Practice, (2) the **position statements** for the infrastructure and essential activities of infection control and epidemiology in hospitals from the Society of Healthcare and Epidemiology (SHEA) and the Association of Professionals in Infection Control and Epidemiology (APIC) – A Consensus Panel Report, and (3) input we have received from infectious disease physicians who practice in our hospitals and Tenet Infection Control Practitioners. Because this model plan is primarily based on CMS and JCAHO requirements, each hospital is responsible for ensuring that its infection control plan meets all of the elements set forth in the model plan.

We recognize that hospitals may have an existing policy. If this is the case, please conduct a comparison and modify your existing policy to include all components of this

model. The policy should be sent to the appropriate committees, including the Medical Staff, and departments for approval and adoption.

Please contact your Regional Counsel if you have questions about implementing this model plan in accordance with your Medical Staff Bylaws and state law. If you believe that aspects of the model plan are not workable for your hospital, please contact Cheryl Kirchner in the Clinical Quality Department via telephone at 469-893-2398 or via email at cheryl.kirchner@tenethealth.com.

Whenever possible, adoption of this policy in its entirety is preferred. At a minimum, all components of this model policy should be included by the hospitals and any additions or modifications should be cleared through Regional Counsel. Any additions or modifications should be sent to the Clinical Quality Department at Tenet-Dallas to the attention of Charles Conklin for tracking purposes. Implementation of this policy should take place within 90 days of receipt.

We hope that this model plan serves as a useful tool for you as you modify your infection control plans. If you have any questions about the model plan, please do not hesitate to contact Cheryl Kirchner or either of us. Thank you in advance for your cooperation with this important policy.

Attachment: Model Infection Control Program Plan

[Insert Hospital Logo]	[Hospital Name] Patient Safety Policy	No.
	Title:	Page: 1 of 29 Deleted: 27
	HOSPITAL INFECTION CONTROL PROGRAM PLAN	Revised Date:
		Original Date:
		Hospital Governing Board Approval Date:

1. INTRODUCTION

A. This Infection Control and Prevention Plan was developed for: *[Insert name and address of this facility]*

B. This Infection Control and Prevention Plan was instituted on *[Insert date plan was instituted]*.

2. PURPOSE

A. The purpose of the Infection Control Program Plan is to identify infections and reduce the risk of disease transmission through the introduction of preventive measures. The aim of our program is to deliver safe, cost-effective care to our patients, staff, visitors, and others in the healthcare environment (with emphasis on populations at high risk of infection). The program is designed to prevent and reduce hospital associated infections and provide information and support to all staff regarding the principles and practices of Infection Control (IC) in order to support the development of a safe environment for all who enter the facility.

B. Our goals include recommendation and implementation of risk reduction practices by integrating principles of infection prevention and control into all direct and indirect standards of practice.

C. The program at **(facility's name)** is designed to provide processes for the infection prevention and control program among all departments and individuals within the organization. It supports the mission to serve, heal, and educate with a concern for the whole patient, as well as an understanding of *Commitment to Quality* and the economic environment.

3. SCOPE OF SERVICE

A. The scope of service is to minimize the morbidity, mortality, and economic burdens related to hospital-associated infections.

B. Epidemiologic data will be used to plan, implement, evaluate and improve infection control strategies. Surveillance is a critical component of the program. Prevention and control efforts will include activities such as:

- Identifying, managing, reporting, and following-up on persons with reportable and/or transmissible diseases.
- Measuring, monitoring, evaluating and reporting program effectiveness.
- Expanding activities as needed in response to unusual events or to control outbreaks of disease.
- Addressing outbreaks and epidemics and unusual activities in a timely manner.
- Ensuring that all clinical and paramedical departments alert the Infection Control Practitioner (ICP) when an unusual pathogen is isolated or suspected.
- Focusing on medical and surgical services that have a high volume of procedures and/or have a population that may be at high risk for infection.
- Complying with mandates listed under the umbrella of infection control by licensing and accrediting agencies.

4. ASSIGNMENT OF RESPONSIBILITY / PROGRAM MANAGEMENT

A. Members of the Infection Control Committee

POLICY: The Infection Control Committee [or insert other name designated by hospital] will be comprised of the following members:

- **Chairman (a physician whose credentials document knowledge of or special interest in infectious diseases) and**
- ***Representatives from: Medical Staff (to insure representation of the major services), Administration, Nursing, Surgical Services, Risk Management, Clinical Quality Improvement, Microbiology, and [insert other facility-specific services/departments as deemed appropriate].**

RATIONALE: The risk of Healthcare Acquired Infections (HAIs) exists throughout the hospital. An effective Infection Control program that can systematically identify risks and respond appropriately must involve all relevant programs and settings within the hospital.

*Note: Confirm with your Regional Counsel what your hospital's Medical Staff By-Laws require in terms of who may be a standing member of the Infection Control Committee. In some states, a majority of physicians is required to maintain the peer review protection of the deliberations of the committee.

PROCEDURE:

- Members of the Infection Control Committee *[or other name designated by hospital]* include the following members *[If consistent with state law peer review protections, include medical staff, nursing, risk management, quality improvement, surgical services, microbiology, and other direct and indirect patient care staff (including, when applicable, pharmacy, laboratory,*

administration, central supply/sterilization services, housekeeping, building maintenance/engineering, and food services, etc.) In states that require that a majority of members be physicians, representatives from the foregoing departments may not be standing members of the Committee, but may be periodically requested to report to the Committee.]:

- The Chairperson of the Infection Control Committee *[or other name designated by hospital]* is: *[Insert Title of the individual]*

B. Duties and Responsibilities of the Infection Control Committee

POLICY: The Infection Control Program is designed and approved by the Infection Control Committee *[or other name designated by hospital].* This collaborative group will provide ongoing consultation regarding all aspects of the Infection Control Program.

RATIONALE: The successful creation of an organization-wide IC program requires collaboration with all relevant components/functions. This collaboration is vital to the successful gathering and interpretation of data, design of interventions, and effective implementation of interventions. Managers within the hospital who have the power to implement plans and make decisions about interventions related to infection prevention and control participate in the IC program. While a formal committee consisting of leadership and other components is not required as evidence of this collaboration, the hospital may want to consider this option.

PROCEDURE:

The Committee defines the epidemiologically important issues, sets specific annual objectives, and modifies the Infection Prevention and Control Plan to meet those objectives.

- The Committee reviews surveillance data monitoring for trends in infections, clusters, infections due to unusual pathogens, or any occurrence of nosocomial infections that exceed the baseline levels.
- The Committee recommends corrective action(s) and approves all proposals and protocols for special infection control studies.
- The Committee reviews antibiotic susceptibility/resistance trends.
- The Committee reviews and issues reports on infection control risk assessment as required for construction/renovation projects.
- The Committee meets at least four times annually with proceedings reported to the **(facility-specific Patient Safety Committee, Medical Executive Committee and/or Governing Body).**
- The Committee, through the Chairperson, Medical Director and/or the **(title of facility's ICP)** is authorized to institute appropriate control measures or

studies when there is reasonable concern for the well-being of patients, personnel, volunteers, visitors, and/or the community.
- The Committee will review the Infection Control Policies and department-specific infection related policies at least every two (2) years, dated at the time of each review, revised as necessary and enforced.
- The Committee keeps abreast of regulatory guidelines/standards related to infection control.
- The Committee will ensure that the findings and recommendations of the Infection Control Committee are submitted to the Medical Executive Committee, the Governing Board, and facility-specific committees.
- ***[Insert other duties/responsibilities as assigned/determined by the hospital and/or reference an existing hospital policy that addresses this.]***

C. Supervision of the Infection Control Program

POLICY:
- **(Facility name) will assign responsibility for directing IC program activities to one or more individuals whose number, competency, and skill mix are determined by the goals and objectives of the IC activities.**
- **Qualifications of the individual(s) responsible for directing the IC program are determined by the risks entailed in the services provided, the hospital's patient population(s), and the complexity of the activities that will be carried out.**
- **The hospital will have continuing services of a trained hospital epidemiologist(s) and ICP(s).**

RATIONALE: The IC program requires management by an individual (or individuals) with knowledge that is appropriate to the risks identified by the hospital, as well as knowledge of the analysis of infection risks, principles of infection prevention and control, and data analysis. This individual may be employed by the hospital or the hospital may contract with this individual. The number of individuals and their qualifications are based on the hospital's size, complexity, and needs. In addition, adequate resources are needed to effectively plan and successfully implement a program of this scope.

PROCEDURE:

- Supervisory responsibility for the Infection Control and Prevention Program at **(facility's name)** has been assigned to ***[Insert the Title (or Titles if more than one ICP) of individual(s) in charge in table below].***

Title or Role at Hospital Comments	Expertise	Dates of Service Qualifications
[Insert the Title or Role of each individual]		From: *[Specify date]* to *[Specify Date]*
[Insert comments, as needed and appropriate, to	This designated person is qualified as an expert in *(check all that apply)*:	This person is qualified based on *(check all that apply)*:

justify the selection of this individual] This employee is: ☐ Full Time ☐ Part Time ☐ Contracted	☐ Infection control ☐ Occupational health ☐ Engineering ☐ Other: *[Specify]*	☐ Ongoing education ☐ Training ☐ Experience ☐ Certification (such as that offered by the Certification Board for Infection Control (CBIC)) ☐ Other: *[Specify]*
[Insert the Title or Role of each individual]		From: *[Specify date]* to *[Specify Date]*
[Insert comments, as needed and appropriate, to justify the selection of this individual] This employee is: ☐ Full Time ☐ Part Time ☐ Contracted	This designated person is qualified as an expert in *(check all that apply)*: ☐ Infection control ☐ Occupational health ☐ Engineering ☐ Other: *[Specify]*	This person is qualified based on *(check all that apply)*: ☐ Ongoing education ☐ Training ☐ Experience ☐ Certification (such as that offered by the Certification Board for Infection Control (CBIC)) ☐ Other: *[Specify]*

- The designated person(s) has (have) been given the authority to implement and enforce the Infection Control and Prevention Program policies, coordinate all infection prevention and control within the hospital and facilitate **ongoing** monitoring of the effectiveness of prevention and/or control activities and interventions.
- The designated persons will ensure **continuous services** (24 hours a day / 7 days a week / 365 days a year) for infection control and prevention programs.
- The designated person(s) will report to: *[Insert the Title of the individual(s)]*
- Comments: *[Insert comments, as needed and appropriate, to justify the selection of the above named individual(s). Justification should address the reasons for selecting the number of individuals, including size, program scope, patient population, etc. as outlined in Policy.]*

D. Maintenance of Qualifications for Infection Control Program Leadership

POLICY: The Infection Control Practitioner (or title of facility's ICP) will stay abreast of new developments in infection control and maintain qualification status.

PROCEDURE:

- The **(title of facility's ICP)** will maintain competency in all essential elements of the job through professional organizations and offerings from the Education and Learning Department.
- The **(title of facility's ICP)** will maintain membership in infection control associations **(may have facility-specific outside organizations, i.e., Florida Association for Infection Control and Epidemiology and Florida Professionals in Infection Control).**
- The **(title of facility's ICP)** will attend one (1) educational seminar related to infection prevention and control per year. **(This is a facility-specific determination based on resources).**

E. Allocation of Resources for the Infection Control Program.

POLICY: Hospital leaders will allocate resources for the infection control program and provide systems to support infection prevention and control activities.

PROCEDURE:

- Hospital leaders will review on an ongoing basis (but no less frequently than annually) the effectiveness of the hospital's infection prevention and control activities and report their findings to the integrated patient safety program.
  - ☐ Date Effectiveness Reviewed: *[Specify date]*
  - ☐ Effectiveness Reviewed by the following individual(s) and/or group(s): *[Specify Titles of individual(s) and/or group(s)]*
  - ☐ Date Submitted to *[Insert hospital-specific name of integrated patient safety program]*: *[Specify date]*
  - ☐ *[Insert relevant comments and/or reference any policies related to this topic]*

- Systems to access information will be provided to support infection prevention and control activities. *[Insert relevant comments and/or reference any policies related to this topic]*

- When applicable, laboratory support will be provided to support infection prevention and control activities. *[Insert relevant comments and/or reference any policies related to this topic]*

- Equipment and supplies will be provided to support infection prevention and control activities. *[Insert relevant comments and/or reference any policies related to this topic]*

- Infection control personnel will have appropriate access to medical or other relevant records and to staff members who can provide information on the adequacy of the institution's compliance with regard to regulations, standards and guidelines. *[Insert relevant comments and/or reference any policies related to this topic]*

F. Shared Responsibilities for the Infection Control Program

POLICY: The prevention and control of infections is a shared responsibility among all clinical and non-clinical people in the hospital.

PROCEDURE:

- **Medical Staff Responsibilities:** The Medical Staff provides expertise from their individual respective areas and disciplines in conjunction with the members of the Infection Control Committee to help manage the hospital

infection surveillance, prevention, and control program. *[Insert additional responsibilities and/or reference any policies related to this topic]*

- **Department-Specific Responsibilities:** The Department Directors or their designees are responsible for monitoring employees and assuring compliance with infection control policies and procedures. Responsibilities include, but are not limited to:
    - Ensuring current infection control policies and procedures are available in all patient care areas/departments.
    - Revising and updating departmental IC policies and procedures in collaboration with the Infection Control Department.
    - Ensuring proper patient care practices and product safety are maintained within the department.
    - For primary nursing care areas, the Department Directors will ensure proper line day collection for invasive devices (urinary catheters, central lines, and ventilators) and monitor use for medical necessity in ICU, NICU, and the Medical-Surgical areas and medical necessity for insertion in ED.
    - Coordinating with the ICP to present educational programs on prevention and control of infections.
    - *[Insert additional responsibilities and/or reference any policies related to this topic]*

- **Healthcare Worker Responsibilities:** All healthcare workers of the organization will:
    - Adhere to hand hygiene guidelines.
    - Adhere to the Program for the control of infections.
    - Participate in the annual review of infection control activities within their departments.
    - Complete the Annual Review (may be lecture and/or self-study packet).
    - Participate fully in the Employee Health/Occupational Health program.
    - Notify the Infection Control Practitioner of infection related issues.
    - *[Insert additional responsibilities and/or reference any policies related to this topic]*

5. RISK ASSESSMENT AND PERIODIC REASSESSMENT

POLICY:

- **The comprehensive risk analysis for our hospital will include an assessment of the geography, environment, services provided and population served; the available infection prevention and control data; and the care, treatment and services provided by this facility.**
- **The Infection Control Program is ongoing and is reviewed and revised at least annually.**

- **Surveillance activities will be used to identify risks pertaining to patients, staff, volunteers, and student/trainees and, as warranted, visitors.**

RATIONALE: A hospital's risks of infection will vary based on the hospital's geographic location, the community environment, services provided, and the characteristics and behaviors of the population served. As risks change over time—sometimes rapidly—risk assessment must be an ongoing process.

PROCEDURE:

A. Baseline (initial) risk assessment:

- A careful assessment of the risk for infections has been conducted for *[Specify if risk assessment is for the entire facility, areas within this facility and/or occupational groups within this facility].*
- The risk assessment was conducted by: *[Insert Title(s) of qualified person].*
- The baseline risk assessment was based on: *[Specify geography, environment, services provided and population served; the available infection prevention and control data; and the care, treatment and services provided by this facility].*
    - Licensed Beds, Setting, Employees: **(Facility's name)** is an **(acute care)** hospital consisting of _____ licensed beds located in an **(urban)** setting with approximately _____ employees.
    - The annual population includes approximately:
      ____ Number of inpatients
      ____ Number of outpatients
      ____ Number of surgeries per year
      ____ Number of home health visits
      ____ Number of ED visits
      ____ Number of other services as provided by the facility
    - The services provided at this hospital include:

Service	Target Population	Available for (Date Range)
[Insert names of services provided]	*[Specify target population for each service provided]*	*[Specify date]* to *[Specify Date]*

[In this table, emphasize the presence of patient populations (OB, neonatal, pediatrics, long term care, spinal cord injury, burns, and various types of transplant) that are related to infection control needs.]

    - The available infection prevention and control data includes:

Data	Source Systems / Databases	Available for (Date Range)
Count of all hospital-acquired Infections	☐ QRS ☐ eIC / eCARE	*[Specify date]* to *[Specify Date]*
	☐ other: *[Specify]*	*[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]*
Rates of infection for device-associated infections	☐ QRS ☐ eIC / eCARE ☐ other: *[Specify]*	*[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]*
Rates of infection for non-device-associated infections	☐ QRS ☐ eIC / eCARE ☐ other: *[Specify]*	*[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]*
List of people currently/previously in the hospital with communicable infections.	☐ QRS ☐ eIC / eCARE ☐ other: *[Specify]*	*[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]*
List of people currently/previously in the hospital with infections that must be reported to public health agencies	☐ QRS ☐ eIC / eCARE ☐ other: *[Specify]*	*[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]* *[Specify date]* to *[Specify Date]*
[Insert other available data]		

- Risk factors are identified and interventions are implemented to decrease the incidence of infections. Specific risk factors shall include the monitoring of:
  - Invasive devices
  - Compliance with surgical antibiotic prophylaxis
  - New and emerging infectious diseases as well as antimicrobial resistant pathogens
  - Compliance with infection control policies and procedures
  - **(Facility may add additional risk factors specific to their organization)**

B. Periodic risk assessments:

- At a minimum, a reassessment of risk will be conducted annually, covering the period from: *[Specify date]* to *[Specify date]*.

- A reassessment will be conducted whenever risks are significantly changed. Unscheduled reassessments occurred this year because:

☐ There were changes in the scope of the program ☐ There were changes in the results of the risk analysis	*[Specify date]*

☐ There were changes in the emerging and re-emerging problems in the health care community that potentially affect the hospital (for example, highly infectious agents).	*[Specify date]*
☐ There were changes in the success or failure of interventions for preventing and controlling infection,	*[Specify date]*
☐ In response to concerns raised by leadership and others within the hospital,	*[Specify date]*
☐ There was an evolution of relevant infection prevention and control guidelines that was based on evidence or, in the absence of evidence, expert consensus	*[Specify date]* *[Specify date]*

- Comments: *[Insert comments as needed/appropriate]*

6. PRIORITIES AND GOALS

POLICY:

- **Based on the risks identified through our comprehensive risk analysis efforts, the IC Program (or insert title of IC Committee) will set priorities and goals for preventing the development of HAIs within the hospital. The priorities and goals will change as new information becomes available from risk analysis.**
- **Priorities and goals are based on the risks and include (but are not limited to) limiting unprotected exposures, enhancement of hand hygiene and minimizing the risk associated with procedures, medical equipment and medical devices.**

RATIONALE: The risks of HAIs within a hospital are many, while resources are limited. An effective IC program requires a thoughtful prioritization of the most important risks to be addressed. Priorities and goals related to the identified risks guide the choice and design of strategies for infection prevention and control in a hospital. These priorities and goals provide a framework for evaluating the strategies.

PROCEDURE:

(Facility Name) has identified the following priority areas for which we will limit exposure to infections by implementing specific prevention measures as defined in related policies and procedures:

Revise the 'Goal Statements' (A, B, C, D, etc.) as you deem appropriate to match your facility's actual goals.

A. Prevent and/or Reduce the Risk of Infections: The first goal is to provide an effective, ongoing program that prevents or reduces the risk of infection for

patients, staff and visitors through continuous improvement of the functions and processes involved in the prevention of infection that includes:

- Identifying and preventing the occurrences of healthcare-associated infections by pursuing sound infection control practices such as aseptic technique, environmental sanitation, standard precautions, and other isolation of patients as needed and monitoring the appropriate use of antibiotics and other antimicrobials.
- Providing education on infection control principles to patients, staff and visitors.
- Maintaining a systematic program of surveillance and reporting of state-mandated infections internally and to public health agencies.
- Assisting in the evaluation of infection-related products and equipment.
- Complying with current standards, guidelines, and applicable local, state and federal regulations, and accrediting agency standards.
- Communicating identified problems and recommendations to the appropriate individuals, committees and/or departments.

B. Limit the Spread and/or Occurrence of Infections: The second goal is to promote actions that are designed to limit the spread and/or prevent the occurrence of hospital-acquired or home-health acquired infections.

- The primary goal is to identify and reduce risks of acquiring and transmitting infections among patients, staff, contract workers, physicians, (house staff, if applicable), students, volunteers, and visitors.
- The secondary goal is to prevent the spread of infections from patients to healthcare workers by enforcing sound infection prevention practices, providing immunization services for hepatitis B and influenza, and reducing potential exposures to blood and body fluids by minimizing unprotected sharps and splash.

C. Minimize the Morbidity, Mortality and Economic Burdens Associated with Infections: The third goal is to minimize the morbidity, mortality, and economic burdens associated with infection through prevention and control efforts in the well and ill populations. Achieving this goal involves:

- Recommending and implementing corrective actions based on records, data, and reports of infection or infection potential among patients, staff and visitors.
- Maintaining an effective Employee Health program to prevent exposure and to identify communicable diseases.
- Considering epidemiologically significant issues endemic to the populations served by **(facility name)** and implementation of risk reduction strategies to high-risk patients.
- Performing Infection Control Risk Assessments with all renovation/construction performed in or at the facility.

D. Maintain Open-line Communications (Infection Control, Risk Management, and Performance Improvement): The fourth goal is to maintain

open-line communications between Infection Control, Risk Management and Performance Improvement by:

- Communicating identified problems and recommendations to the appropriate individuals, committees and/or departments.
- The (title of facility's ICP) maintains active committee participation, such as the Infection Control Committee, (facility specific list of committees) and any other ad hoc committees as designated by standards or Administration.
- See attached flow-map/algorithm for communication and accountability. Figure 1: Communication Plan and Accountability Loop. *[Attach a flow-map/algorithm to show communication plan and accountability loop.]*

E. *[Insert other goals as identified through your risk assessment]*

7. STRATEGIES TO MEET GOALS

POLICY:

- **Performance improvement guidelines (policies and procedures) are established to address all aspects of infection prevention and control using sound, scientifically valid, epidemiologic principles.**
- **The specific program activities may vary from year to year based on at least annual review of: Patient demographics, Services offered, Number and type of procedures stratified for high/low volume, high/low risk, and problem prone areas, Type of contract services utilized, practicality and cost**
- **The policies and procedures should be scientifically-based toward infection prevention and improved outcomes.**

RATIONALE: The hospital plans and implements interventions to address the IC issues that it finds important based on prioritized risks and associated surveillance data.

PROCEDURE:

A. Policy and Program Development

- Infection Control principles are incorporated into department-specific infection control policies.
- Department-specific policies are evaluated by Infection Control on a regular basis to ensure the adherence to infection control guidelines.
- The facility-specific Infection Control Program Plan will be evaluated and adjusted, as appropriate, every year.
- The effectiveness of the infection control program is evaluated annually by the Infection Control Committee. The report will be forwarded to the Medical Executive Committee and to the Governing Board.

B. Strategies to meet the goals of (facility's name)'s Infection Control and Prevention Program include the following:

Revise the 'Strategies' as you deem appropriate to match your facility's actual goals / program. Also, if you reference prevention standards or guidelines, state that the guidelines were used to guide the development of procedures or that you adopted IA recommendations.

1) Hand-hygiene program
- See Hospital Policy for *[Hand Hygiene – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy.]*
- The CDC Guidelines for Hand Hygiene in Healthcare Settings – 2002 were used to guide the development of procedures for the Hand Hygiene program.
- *[If not already included in the policy, insert any other program features, training requirements, etc. as appropriate]*

2) Storage, cleaning, disinfection, sterilization and/or disposal of supplies and equipment
- See Hospital Policy for *[Exposure to Procedures, Medical Equipment and Medical Devices – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy.]*
- *[If not already included in the policy, insert any other program features, training requirements, etc. as appropriate. Also ensure ICP participates on Product Evaluation Sub-Committee to ensure infection related products and equipment support safe and sound practices and principles and that the ICP responds to notification of a recalled item(s) specific to infection related issues.]*

3) Appropriate reuse of single use equipment (when appropriate)
- See Hospital Policy for *[Reprocessing – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy.]*
- This hospital has adopted the American Association of Nurse Anesthesia Reuse of Needles Policy (that states there should be no reuse of needles)
- *[If not already included in the policy, insert any other program features, training requirements, etc. as appropriate]*

4) Personal protective equipment
- See Hospital Policy for *[PPE – Insert hospital-specific policy name. Be sure to address who is to use it, when they are to use it, when they are trained, how you measure whether or not they are trained and whether or not they are actually using it.]*
- *[If not already included in the policy, insert any other program features, training requirements, etc. as appropriate]*

- See Hospital Policy for *[Unprotected Exposures – Insert hospital-specific policy name – If you plan to include this policy here.]*
- See Hospital Policy for *[Isolation procedures and requirements for infected or immunosuppressed patients – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy.]*
- The CDC Guidelines for Isolation Precautions – 1994 were used to guide the development of procedures for Isolation Precautions.

5) Program to reduce the incidence of antimicrobial resistant infections
   - See Hospital Policy for *[Preventing Antimicrobial Resistant Infections – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy. Address how you measure antibiotic use, hand hygiene, and any other factors that may influence the outcome]*
   - *[If not already included in the policy, insert any other program features, training requirements, etc. as appropriate]*

6) Programs to prevent hospital-acquired device-associated infections (namely central venous catheter-associated infections, urinary catheter-associated infections and ventilator-associated infections).
   - The CDC Prevention Guidelines were used to guide the development of procedures for the following:

   - Preventing Healthcare-Associated Pneumonia - 2003
   - Intravascular Device-Related Infections - 2002
   - Catheter-Associated Urinary Tract Infections – 1981
   - Also see the hospital policies for these targeted areas *[Insert hospital-specific policy names. Be sure to address how implementation is done and measured in the policy.]*

7) A program to prevent surgical site infections.
   - See Hospital Policy for *[Preventing SSI Infections – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy.]*
   - The CDC Guidelines for Prevention of Surgical Site Infections – 1999 were used to guide the development of procedures for preventing Surgical Site Infections.

8) Employee Health/Occupational Health Program: The Employee Health/Occupational Health (EH/OH) program involves interventions for reducing the risk of infection transmission, including recommendations for immunizations and testing for immunity. The ICP will collaborate with EH/OH in promoting employee and patient safety.
   - See the Hospital Policy for *[the Employee Heath/Occupational Health Program.]*

- The program will include screening for health issues, childhood illness/immunization; tuberculosis screening; immunization for hepatitis B and influenza; evaluation of post-exposure assessment to blood/body fluid exposures and/or other communicable diseases.
    - ~~*[Reference any existing policies/procedures related to this item]*~~
- When indicated, the program will also include monitoring of employee illnesses in order to identify potential relationships among employee illness, patient infectious processes and/or environmental health factors.
- The infection control program will review and approve all policies and procedures developed in the employee health program that relate to the transmission of infections in the hospital. Together, the ICP and EH/OH staff will develop, implement, and annually review and update the OSHA Bloodborne Pathogens Exposure Control Plan, Tuberculosis Control Plan, and Safety Sharps Program.
- The infection control personnel will be available to the employee health program for consultation regarding infectious disease concerns.
- At the time of employment, all facility personnel will be evaluated by the employee health program for conditions relating to communicable diseases.

  The evaluation includes the following:
  - ☐ Medical history, including immunization status and assessment for conditions that may predispose personnel to acquiring or transmitting communicable diseases;
  - ☐ Tuberculosis skin testing;
  - ☐ Serologic screening for vaccine preventable diseases, if indicated;
  - ☐ Such medical examinations as are indicated by the above.
- Appropriate employees or other healthcare workers will have periodic medical evaluations to assess for new conditions related to infectious diseases that may have an impact on patient care, the employee, or other healthcare workers, which should include review of immunization and tuberculosis skin-test status, if appropriate.
    - *[List which employees will have medical evaluations]*
    - *[Insert schedule for evaluations and what is evaluated]*
    - (Facility name) will maintain confidential medical records on all healthcare workers. [Insert how confidentiality is maintained.]
    - The employee health program will have the capability to track employee immunization and tuberculosis skin-test status. [Insert how this will be done.]
- Employees will be offered appropriate immunizations for communicable diseases.
    - Immunizations will be based on regulatory requirements and Advisory Committee on Immunization Practices recommendations for healthcare workers.
- The employee health program will develop policies and procedures for the evaluation of ill employees, including assessment of disease communicability, indications for work restrictions, and management of

employees who have been exposed to infectious diseases, including post-exposure prophylaxis and work restrictions.
    - See [insert name hospital-specific policy/procedure(s)]
- The CDC Guidelines were used to guide the development of procedures for the Healthcare Worker Safety Guidelines
    - Management of Occupational Exposures to Hep B, Hep C, and HIV and Recommendations for Postexposure Prophylaxis - 2001
    - Infection Control in Healthcare Personnel - 1998

9) Animal exposures
- See Hospital Policy for *[Animal Exposure – Insert hospital-specific policy name. Be sure to address how implementation is done and measured in the policy.]*

10) *[Insert other programs as identified by your facility]*

C. Program Compliance
- To verify compliance with the program, (the Facility's ICP title) shall conduct periodic infection control rounds with follow-up required by the Department Director.
- The Department Director or designee will conduct direct observation of appearances and practices in their specific clinical areas.

8. MANAGING CRITICAL DATA AND INFORMATION

- **POLICY:**
- **There will be an active program for the prevention, control and investigation of infections and communicable diseases that includes a hospital-wide program. Surveillance data will be analyzed appropriately and used to monitor and improve infection control and healthcare outcomes.**
- **Unless there is an unavoidable technical issue, the hospital will use an automated software system to manage infection control data.**

PROCEDURE:

A. Surveillance and Monitoring:
1) Surveillance is performed as an enhancement and/or component of the facility's Clinical Quality and Risk Prevention initiatives. It includes (but is not limited to):
- Monitoring high volume/high risk; low volume/high-risk and surgical prophylaxis.
- Evaluating new programs as well as renovation or construction in conjunction with the hospital's Facilities Management Department and the Environment of Care (EOC) team.

- Compiling and analyzing surveillance data, presenting findings and making recommendations to the Infection Control Committee and other departments and medical service chiefs as appropriate.
- Using baseline surveillance data to determine if an outbreak is occurring.
- Investigating trends of infections, clusters, and unusual infections.
- Conducting or facilitating infection control rounds or focus reviews.
- [Insert the identification and description of any other problem or event to be studied. Selection of specific events to be monitored should be guided by validated, nationally available benchmarks appropriately adjusted for patient risks, so that meaningful comparisons can be made.]

2) Surveillance Methodology

Sources for infection identification include:
- Microbiology records
- Reports from Information Systems including patient census/diagnosis
- Routine Chart reviews
- Post-discharge surveillance following surgical procedures
- Staff reports of suspect/known infections or infection control issues
- Device-associated infections (i.e., Line day usage for urinary catheters, central line catheters and ventilator day use facility-wide).
- Employee Health reports reflecting epidemiological significant employee infections
- Public Health reporting of state-mandated reportable infections
- Regular review of surveillance data
- [Insert any other data sources at your facility and/or modify list above.]

Infection Definitions:
- This facility will use the definitions for devices as defined in Horan TC, Emori TG. Definitions of key terms used in the NNIS System. *American Journal of Infection Control* 1997;25(2):112-6. *[Be sure to update this reference when/if new information becomes available.]*
- Nosocomial infections are identified using the CDC definitions for hospital-acquired infections, home care-acquired infections and long term care-acquired infections.

Data Collection Personnel
- [Insert the Titles of the people involved in the collection of infection prevention and control data. For hospitals using the QRS/eCARE Infection Control Surveillance System, Case Managers or other designated people may be involved in the collection of device day denominator data and/or the Surgical Infection Prevention data.]

Data Collection Methods
- [Insert the data collection methods instituted at your facility.]

Rate calculations:

- Infection rates are calculated using formulas accepted by the Association for Professionals in Infection Control and Epidemiology (APIC) and the Centers for Disease and Control and Prevention (CDC). See attached examples in Table 1: Example Calculations.
- Infection rates will be compared to internal and external benchmarks.
- [Please describe/list the clinical performance and assessment indicators used to support external comparative measurements. These should meet the criteria delineated by SHEA and APIC in *The Quality Indicator Study Group. An approach to the evaluation of quality indicators for outcome of care in hospitalized patients, with a focus on nosocomial infection indicators.* Infect Control Hosp Epidemiol 1995;16:308-316.). Specifically, these indicators and their analysis must address the following parameters:
    - Relation to outcome or process
    - Ability to measure variation in quality
    - Definition of numerators and denominators
    - Reliability, completeness, and feasibility of data collection
    - Appropriate risk adjustment
    - Comparability of populations; severity and case-mix adjustments for external comparison
    - Training required for indicator implementation
    - Applicable benchmarks of standards of care]
- [Please describe any details regarding the selection of the methods of measurement, including statistical tools and risk stratifications.]

3) The occurrence and follow-up of infections/communicable diseases among patients, staff and visitors will be documented by the Infection Control Practitioner (or facility specific title) and reported to the (name of facility's committee). See also Figure 1: Communication Plan and Accountability Loop.

B. Environmental Assessment/Surveillance: Environmental Assessment/Surveillance is performed in conjunction with the Environment of Care (EOC) group and includes the following:

1) Verifying compliance with the IC program, the facility's ICP will conduct periodic infection control rounds with follow-up required by the surveyed department.
2) Ensuring clean equipment and supplies are stored separately from soiled ones.
3) Ensuring linens are kept covered during transport and storage.
    - Soiled laundry areas should be kept under negative pressure to clean areas.
4) Ensuring sterile supplies are stored in a manner as to prevent contamination or damage to the packaging.
    - Fluids are to be stored on lower shelves to prevent spillage on patient care supplies.

5) Reviewing the sterilization parameters for all patient care items processed within the facility to assure standards are met.
   - Review the temperature, humidity, and air pressure relationships in all reprocessing areas.
   - ~~Review the documentation of sterile processing in all areas including the~~ Central Sterile, Surgery and Gastroenterology Labs to ensure all sterilization done in the facility meets the same standards.
   - Evaluate the surgical department's review and report of the summary of all flash sterilization by instrument type to determine if adequate supplies are being maintained.
   - Assist in the implementation of the hospital's internal product recall program
   - Assist in the evaluation of sterilization failures, reporting findings to the Infection Control Committee, Medical Staff, Risk Management, Patient Safety Director, attending physician, and patient care manager of area involved.
   - Unused single-use device (SUD) may be reprocessed by an external company (Used single-use devices will not be reprocessed by the facility.)
6) Monitoring microbiology of treated water and dialysate according to state and federal standards
7) Evaluating of patients or employees with infections or diseases from environmental organisms, e.g., Legionella, aspergillosis.
8) Routine sampling of the environment, air, surfaces, water, food, etc., is discouraged unless a related infection control issue is identified
9) Performing Infection Control Risk Assessments (ICRA) prior to renovation, construction, or planned interruption of the utility system within the patient care environment.
   - The ICRAs are to be approved by the appropriate committees, which may include, but are not limited to: EOC, Safety, ICC.
   - Rounds of the construction/renovation site are conducted to evaluate compliance with ICRA requirements. The ICP will have the authority to stop any project that is in substantial non-compliance with the requirements.
   - Any time there is construction or renovation, the ICP will be consulted prior to final design.
10) Monitoring Atmospheric Guidelines
   - Evaluate the use of negative pressure environments in the care of patients with airborne diseases.
   - Evaluate the use of positive pressure environments in the care of the immunocompromised patient.
   - The CDC Guidelines were used to guide the development of procedures for
     - Environmental Infection Control in Healthcare Facilities – 2003
     - Hospital Construction

9. INTERVENING DIRECTLY TO PREVENT TRANSMISSION OF INFECTIOUS DISEASES

POLICY:

- **(Facility name) will have the capacity to identify the occurrence of outbreaks or clusters of infectious diseases.**
- **(Facility name) will have access to the services of personnel trained and experienced in conducting outbreak investigations.**
- **When an outbreak occurs, the infection control team will have resources and authority to ensure a comprehensive and timely investigation and the implementation of appropriate control measures.**

PROCEDURE:

A. Review Microbiology Results: Infection control personnel will review microbiology records regularly to identify unusual clusters or a greater-than-usual incidence of certain species or strains of microorganisms.

- Date last reviewed: [Specify Date]

B. Monitor Baseline Surveillance Data: Baseline surveillance data will be used to determine if an outbreak is occurring.

- See policies and procedures related to surveillance as outlined in this document (Section 8: Managing Critical Data and Information).

C. Regularly Contact Non-Surveillance Areas: In patient areas of the hospital in which active prospective surveillance is not conducted, infection control programs will maintain regular contact with clinical, medical, and nursing staff in order to ascertain the occurrence of disease clusters or outbreaks, to assist in maintenance and monitoring of infection control procedures, and to provide consultation as required.

D. Day-to-Day Management of the Infection Control Program: (title of facility's ICP) and/or designee is responsible for the day-to-day management of the infection control program with guidance and input from the Medical Director of the Infection Control Program. Responsibilities will include (but may not be limited to):

- The ICP may institute appropriate precaution procedures and order cultures (if within licensing purview).
- When ICP actions are taken, the ICP will notify the physician responsible for the patient's care.
- ICP actions will be justified and documented in the medical record.
- When the case involves a non-compliant issue with front line staff, the Chief Nursing Officer, the **(title of facility's ICP)** of Human Resources Department, Patient Safety Committee, Risk Management, and/or an Administrative designee will be notified by the ICP. (These people may also be involved in determining appropriate action.)

- The ICP will maintain close communication with nursing departments, surgical services, clinical support services, laboratory, and all departments throughout the facility regarding patients with infections and those at greatest risk of healthcare-associated infections and epidemiological issues within the community.
- The ICP will share nosocomial infection information with Risk Management and Performance Improvement/Quality Department.
    - Information sharing may occur via Occurrence Reporting protocol, Infection Control Committee reports, and/or verbal communication on an ongoing basis.
    - The ICP will discuss process deviations with Risk Management and/or Performance Improvement in a timely manner.

10. EDUCATION AND TRAINING OF HEALTHCARE WORKERS

POLICY:
(Facility name) will provide ongoing educational programs in infection prevention and control to healthcare workers.

- **Infection control personnel with knowledge of epidemiology and infectious diseases will be active participants in the planning and implementation of the educational programs.**
- **Educational programs will be evaluated periodically for effectiveness, and attendance should be monitored.**
- **The goal of the educational programs is to meet the needs of the group or department for which they are given and to provide learning experiences for people with a wide range of educational backgrounds and work responsibilities.**

PROCEDURE:
The **(title of facility's ICP)**:

- Serves as a consultant to physicians, personnel, patients, volunteers, students and/or visitors regarding risks and risk reduction measures associated with disease transmission and benefits of control measures.
- Provides informal education and serves as a consultant to the staff during routine patient/facility rounding.
- Participates in new employee orientation programs by conducting a class in infection control principles and practices and area-specific in-services when requested. Infection Control principles and practices are also presented in the facility's annual review. [Provide any additional information that describes how this program is designed to meet needs of employees.]
- Contributes regularly to hospital annual education plan with both planned and just-in-time education offerings.
- Educational programs will be evaluated periodically for effectiveness and attendance. [Insert any policy/procedure related to this topic and/or describe how the programs are evaluated and monitored.]

11. REPORTING SYSTEMS AND OVERALL EVALUATION PLAN

POLICY:
The hospital shall have systems for reporting identified infections to the following:

- **The appropriate staff within the hospital**
- **Federal, state, and local public health authorities in accordance with law and regulation**
- **Accrediting bodies (Sentinel Event Reporting, Surgical Infection Prevention, National Patient Safety Goals)**
- **The referring or receiving organization when a patient was transferred or referred and the presence of an HAI was not known at the time of referral**

RATIONALE: The risk of Healthcare-Associated Infections exists throughout the hospital. An effective IC program that can systematically identify risks and respond appropriately must involve all relevant programs and settings within the hospital.

PROCEDURE:

A. Infection Classification and Intense Analysis: All Infections will be classified and a list of nosocomial infections maintained. [The log is not limited only to nosocomial infections. All incidents of infection and communicable disease must be included in the log. The log documents infections and communicable diseases of patients and all staff (patient care, non-patient care, employees, contract staff and volunteers). This would include incidents of post-operative infections in inpatients who are discharged soon after surgery or outpatients who received outpatient surgery.]

All identified cases of unanticipated death or major permanent loss of function associated with a healthcare-associated infection shall be managed as sentinel events. [The intent is to manage any unanticipated death or major permanent loss of function as a sentinel event, even if the patient acquires a nosocomial infection, not simply because the patient has acquired an infection.]

1) All positive cultures will be reviewed and classified as either:

No - Community Acquired - Organisms present or incubating at the time of admission; Includes Community-acquired (non-healthcare related) and Community-acquired (health care related) infections

No - Not Followed

- Includes cultures that will not be followed for surveillance
- Includes repeat cultures / cultures isolated previously
- Includes Infections related to prior hospitalizations

- Includes Normal Flora
- Includes Redundant Cultures – same patient, same culture – don't want to count multiple times or multiple admissions for the same condition or readmission or for a previously identified nosocomial infection. Chronic.

No - Contamination - Includes contamination (e.g., urine with a mixed culture, low colony counts in blood or sputum, etc.)

No - Nosocomial Colonization – Organisms present but not causing an infection from a normally non- sterile site.

Yes – Nosocomial Infection - All Nosocomial Infections (both device-associated and not device- associated) are defined, in general, as organisms not present or incubating at the time of admission and acquired due to, because of, or during hospitalization.

Yes – Secondary Nosocomial Infection – Infection is secondary to a pre-existing medical condition
(i.e., admission with perforated bowel and subsequent positive blood cultures with GNRs). If marked (indicating yes), a comment box will appear to identify associated primary site of infection.

2) In cooperation with the Quality and Risk Departments, the **(title of facility's ICP)** will participate in a root cause analysis of any infection that results in unanticipated death or permanent loss of function.

- An intense assessment may be done for infections as determined by the facility as being epidemiologically significant.

B. Public Health Reporting:

- In conjunction with the Laboratory personnel, the **(title of facility's ICP)** reports reportable diseases/conditions to the public health authorities.
- The occurrence and follow-up of infections/communicable diseases among patients, staff, and visitors will be documented and reported to the Public Health Department and **(name of facility's committee).**

12. EMERGENCY MANAGEMENT

POLICY: As part of emergency management activities, (facility's name) will be prepared to respond to an influx, or the risk of an influx, of infectious patients.

RATIONALE: The health care organization is an important resource for the continued functioning of a community. An organization's ability to deliver services is threatened when it is ill-prepared to respond to an epidemic or infections likely to require expanded or extended care capabilities over a prolonged period of time. Therefore, it is important for an organization to plan how to prevent the

introduction of the infection into the organization, how to quickly recognize that this type of infection has been introduced, and/or how to contain the spread of the infection if it is introduced.

PROCEDURE: See Hospital Policy for [Emergency Management – Insert hospital-specific policy name. The planned response may include a broad range of options including the temporary halting of services and/or admissions, delaying transfer or discharge, limiting visitors within an organization, or fully activating the organization's emergency management plan. The actual response depends upon issues such as the extent to which the community is affected by the spread of the infection, the types of services offered, and the capabilities of the organization. Be sure to address the following specifics in your policy/procedure:

1. The organization plans its response to an influx or risk of an influx of infectious patients.

2. The organization has a plan for managing an ongoing influx of potentially infectious patients/residents/clients over an extended period of time.

3. The organization:

- Determines how it will keep abreast of current information about the emergence of epidemics or new infections that may result in the organization activating its response
- Determines how it will disseminate critical information to staff and other key practitioners
- Identifies resources in the community (through local, state, and/or federal public health systems) for obtaining additional information.]

FIGURE 1: Communication Plan and Accountability Loop
(Each facility to modify this diagram, or one similar, to reflect the actual communication plan)

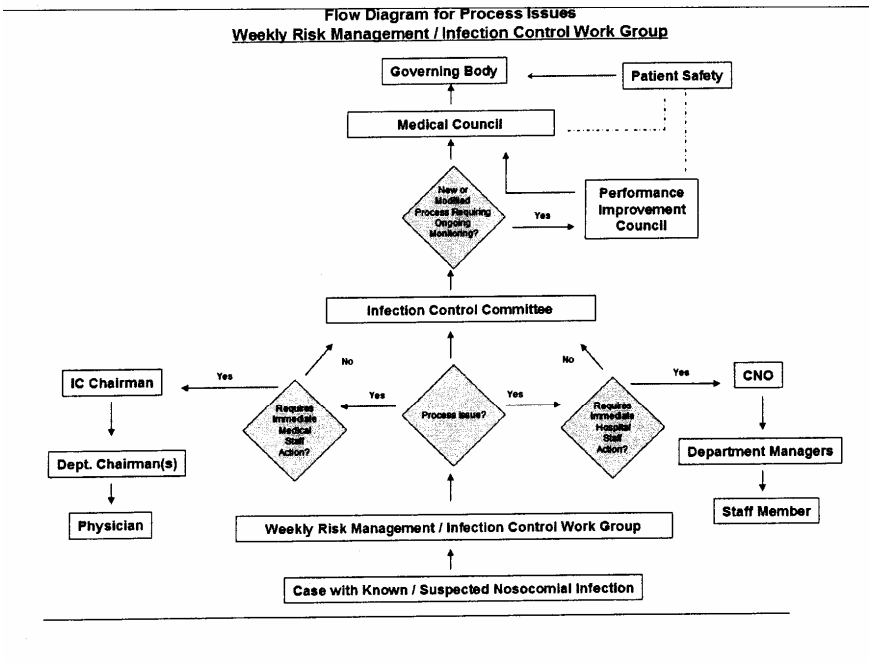

TABLE 1: Example Calculations

The formulas below are **examples** of data that can be presented as part of an infection control program. **[Each facility should review these examples, and select the rate calculations that will add value to their infection control program.]**

Infection	Rate Calculation
Device-related infections associated with urinary catheters, intravascular devices, and ventilator-associated pneumonias	# device-related nosocomial infections x 1000 # of device days
Surgical site infections	# of nosocomial surgical site infections # of patients with specific surgical procedure x 100
Reportable diseases	Number of patients with the reportable diseases
House-wide Infection Rates	# of nosocomial infections # of discharges + Transfers out x 100 OR # of nosocomial infections # of admissions and transfers in x 100
Service Rates: Infections that are associated with specific medical/surgical services	# of nosocomial infections # of discharges + Transfers out x 100 OR # of nosocomial infections # of admissions and transfers in x 100
Nursing Rates: Infections that are associated with specific nursing areas	# of nosocomial infections # of discharges + Transfers out x 100 OR # of nosocomial infections # of admissions and transfers in x 100
Infection Rates per Patient Days	# of nosocomial infections # of patient care days x 1000

TAB 12

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November 30, 2005

VIA HAND DELIVERY

Mr. Andrew Snowdon
U.S. House of Representatives
Committee on Energy and Commerce
H2-316 Ford House Office Building
Washington, D.C. 20515

Re: New York Presbyterian Hospital's Response to the September 21, 2005 Letter Request

Dear Mr. Snowdon:

This letter serves to respond to the questions set forth in the September 21, 2005 letter from Congressman Joe Barton, Chairman of the House Energy and Commerce Committee, and Congressman Ed Whitfield, Chairman of the Subcommittee on Oversight and Investigations. The questions and New York Presbyterian Hospital's ("NYPH") responses are set forth below.

Request 1: *Does NYPH monitor HAI rates?*

a. *If not, please explain why not?*

b. *If so, does NYPH monitor all HAIs or does it conduct targeted surveillance of specific high risk departments, procedures, or types of infection?*

c. *If NYPH does targeted surveillance, please identify the specific type of infection, departments and/or procedures monitored.*

d. *Please provide the rates for HAIs monitored by NYPH for calendar years 2003 and 2004.*

Response: NYPH monitors HAI rates by conducting targeted surveillance of specific types of infections. The infections monitored by NYPH are as follows: (1) Central venous catheter bloodstream infections in the Intensive Care Unit ("ICU"); (2) Surgical site infections in select populations; (3) Epidemiologically significant resistant organisms, such as methicillin-resistant staphylococcus aureus ("MRSA") and vancomyein-resistant enterococcus ("VRE"); (4) Rotavirus infections; and (5) RSV infections. NYPH will conduct targeted surveillance of a

department if, for example, an abnormally high infection rate or cluster of infections is identified in that department.

The 2003 and 2004 rates for the HAIs monitored by NYPH are attached at NYPH-HAI 000001 through NYPH-HAI 000013.

Request 2: *To the extent NYPH does monitor HAI rates, does it report such rates?*

a. If not, please explain why not?

b. If so, how and when are these rates reported?

c. Does NYPH voluntarily report HAI rates to the CDC's National Nosocomial Infections Surveillance system or National Healthcare Safety Network?

d. Please describe any barriers that NYPH has identified to collecting data that could be publicly reported.

e. Please describe any risks to NYPH (real or perceived) associated with publicly reporting HAIs.

f. How can information on HAIs be better reported to consumers?

Response: NYPH does not currently report its HAI rates externally, as there is no requirement to report such rates in effect at this time. Although New York State has enacted Public Health Law § 2819, which requires New York hospitals to monitor, track and report specified HAI to the Department of Health, this law has not yet been implemented. NYPH does report the identification of communicable diseases in hospitalized patients to the New York City Department of Health and Mental Hygiene, as required by state law. NYPH also reports clusters of nosocomial infections to the New York State Department of Health's Bureau of Communicable Disease Control, as required by state law.

NYPH does not voluntarily report HAI rates to the CDC's National Nosocomial Infections Surveillance system or National Healthcare Safety Network. The biggest risk associated with the public reporting of HAI rates is misinterpretation of the data. NYPH notes that since there are currently no standards for hospitals to collect HAI data, each hospital or hospital system employs a different methodology. This makes it difficult, if not impossible, to make a meaningful comparison between hospitals. This difficulty is compounded by the fact that hospitals have varying patient mixes, and treat patients with varying acuity levels. NYPH, for example, is an academic medical center and tertiary hospital that treats high risk patients that would not ordinarily be seen or treated at a community hospital. Without an adjustment for acuity and patient mix, it is not meaningful to compare HAI rates at academic medical centers and other tertiary hospitals to the rates at a community hospital.

Unadjusted rates may cause a patient to stray away from certain facilities, despite the fact that the facilities have more experience and are better equipped to treat the patient's condition.

Another risk associated with publicly reporting HAI rates is potential loss of patient revenues at facilities with higher infection rates. These facilities may also experience decreasing reimbursements from third party payors, as reimbursement rates are becoming increasingly tied to outcomes.

In order for HAI rates to drive educated decision making, such rates must be adjusted for acuity level, patient mix, and other considerations. Moreover, consumers must be reminded that HAI rates are not to be viewed in isolation. HAI rates are only one of a myriad of factors to be used in deciding where to receive care. Other factors include acuity level of the facility, types of services provided, and level of expertise in given areas.

Request 3: *Are NYPH's reported HAI rates adjusted to account for a patient's underlying risk of infection?*

Response: As noted in response to Request 1, NYPH does not currently report HAI rates.

Request 4: *Please provide a detailed written description of NYPH's case-finding methods for identifying and tracking HAIs.*

a. Have these methods changed during the past five years? If so, please explain.

b. Does NYPH conduct any type of post-discharge surveillance? If so, please describe.

Response: NYPH's identification of HAI is microbiologically driven. The Department of Epidemiology reviews positive cultures for specified infections. NYPH's Department of Epidemiology will then determine whether the infection was hospital-acquired by reviewing the patient's chart, and assessing whether the patient meets the criteria for the hospital-acquired infection at issue. The criteria for each of the HAIs monitored by NYPH are set forth in the Infection Control Quality Assessment and Improvement Plan of 2005. (*See* NYPH-HAI 000014 through NYPH-HAI 000019).

For example, with regard to blood stream infections, the Department of Epidemiology reviews every positive blood culture on a daily basis. The Department of Epidemiology then reviews the patient's chart to determine whether he or she meets the criteria for a hospital-acquired central venous catheter bloodstream infection ("CVC-BSI"). To be considered a CVC-BSI, the infection must develop within 48 hours or more after being admitted to an Intensive Care Unit ("ICU"), or within 48 hours after discharge from an ICU, and a central line must have been used during the 48 hour period before development of the CVC-BSI. In addition, one of the following criteria must also be met:

- Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures and organisms cultured from blood are not related to an infection at another site.

- Criterion 2: Patient has at least one of the following signs or symptoms: fever, chills, hypothermia or hypotension, and at least on of the following: (a) common skin contaminant is cultured from two or more blood cultures drawn on separate occasions; or (b) common skin contaminant is cultured from at least one blood culture and the physician institutes appropriate antimicrobial therapy.

- Criterion 3: Patient less than 1 year of age has at least one of the following signs or symptoms: temperature instability, apnea, or bradycardia and at least one of the following: (a) common skin contaminant is cultured from two or more blood cultures drawn on separate occasions; (b) common skin contaminant is cultured from at least one blood culture and the physician institutes appropriate antimicrobial therapy; or (c) the same organism is cultured from both blood and cerebrospinal fluid ("CSF") when there has been no prior central nervous system ("CNS") surgery or devices (i.e., shunts).

NYPH's methods for identifying and tracking HAIs have evolved with the changing health care environment. Many surgeries are now performed in an ambulatory setting. Those patients receiving inpatient surgery have much shorter hospitals stays than in years past. As a result, NYPH has narrowed the category of surgical infections that it monitors. In addition, NYPH now attempts to track post-operative surgical site infections occurring following certain ambulatory surgeries. NYPH sends a letter to the physicians after each herniography or laparoscopic cholecystectomy that is performed asking the physician whether an infection developed. NYPH does not conduct other post-discharge surveillance.

Request 5: *Does NYPH have dedicated infection prevention and control personnel and/or specific technology for monitoring HAI data?*

a. If so, please describe the number of full-time infection prevention and control personnel employed by NYPH and the types of technology used to monitor HAI data.

b. What additional resources would NYPH need to monitor HAI data more thoroughly?

Response: NYPH currently employs four physicians, ten nurses and two administrative assistants who are dedicated to infection prevention and control. These staff members are housed in NYPH's Department of Epidemiology. NYPH utilizes a hospital-created software program to maintain and process data relating to HAIs. In addition, NYPH's Department of Informatics is in the process of developing a system with data mining capability. This system, which is called the Epidemiology Decision Support System, will allow infection prevention and control staff to generate queries that extract relevant information from various hospital systems. For example, once completed, this program will allow NYPH to identify all patients with positive blood culture results in the Cardiac ICU during a specified time frame, and will generate a report regarding the same.

NYPH's goal is to achieve real-time surveillance of HAI. In order to achieve this goal, NYPH would need increased external funding. Increased external funding would allow NYPH to update the technology it uses to identify and track HAIs, and to improve its data mining capability. Moreover, increased funding would allow NYPH to hire additional personnel, including additional lab support personnel for molecular typing.

Request 6: *What was NYPH's total budget for detecting, monitoring, and reporting HAI's in calendar years 2003 and 2004? Projected budgets for 2005 and 2006?*

Response: NYPH's budget for the Department of Epidemiology, which is largely responsible for identifying and tracking HAIs, is set forth below. Although other departments, such as Lab and Nursing, participate in the process, NYPH does not track their costs as a budget item. Therefore, NYPH is unable to provide the total budget for the years in question.

Year	Department of Epidemiology Budget
2003	$927,288
2004	$943,588
2005 (Projected)*	$1,000,000
2006 (Projected)	$1,800,000

* The actual expenditure from January 1, 2005 through October 31, 2005 was $875,319.

Request 7: *Does NYPH monitor any "process measures" associated with HAI's including, but not limited to: adherence rates of hand washing, central-line insertion practices and surgical antimicrobial prophylaxis; and coverage rates of influenza vaccination for healthcare personnel and patients?*

a. *If not, please explain why not?*

b. *If so, please describe such process measures and provide the adherence rates.*

Response: NYPH does monitor certain process measures associated with HAIs. NYPH monitors hand hygiene through a direct observation program. Hand hygiene is a term that applies to the use of alcohol-based hand sanitizers and hand washing with soap and water. Nurses in each department are trained to observe the hand hygiene of the health care professionals working in the department. The nurses document their findings and submit reports

to NYPH's Quality Assurance Department. NYPH's hand hygiene compliance rates for April 2005 through August 2005 are attached at NYPH-HAI 000020 through NYPH-HAI 000021. NYPH also monitors influenza vaccination rates. NYPH's Department of Occupational Health tracks the number of staff who receive the vaccine. In the fall/winter of 2004-2005, the vaccination rate for NYPH staff was 32%. Due to the national shortage of influenza vaccinations, the vaccine was initially only give to NYPH staff with patient direct contact. At the end of the season, when it was determined that there was a surplus of influenza vaccines, NYPH opened up the eligibility to all staff. The 32% figure does not include staff who received flu shots from sources outside of the institution.

Request 8: *Has NYPH done any studies or analyses to calculate the financial impact of HAI's on the institution?*

a. *If so, what is the annual financial impact?*

b. *Has NYPH made any effort to determine whether improved monitoring of infections would lower its costs? If so, please describe all such efforts.*

Response: NYPH has not performed any studies or analyses to calculate the financial impact of HAIs on the institution. Similarly, NYPH has not performed any studies or analysis on whether improved monitoring of infections would lower costs. The goal of NYPH's infection and control program is not to reduce costs to the institution, rather the goal is to ensure quality health care for its patients.

Request 9: *Does NYPH conduct facility-wide, active surveillance cultures for methicillin-resistant staphylococcus aureus (MRSA) and/or vancomyein-resistant enterococcus (VRE)?*

a. *If not, please explain why not?*

b. *If so, please describe the surveillance process and procedures.*

c. *What are NYPH's rates for MRSA and VRE for calendar years 2003 and 2004?*

d. *Please describe the barrier precautions utilized by NYPH for patients colonized or infected with MRSA or VRE.*

Response: NYPH conducts facility-wide surveillance for methicillin-resistant staphylococcus aureus ("MRSA") and vancomyein-resistant enterococcus ("VRE"). NYPH routinely monitors all bacterial cultures for the presence of MRSA and VRE. If MRSA or VRE is detected, the Department of Epidemiology will review the patient's chart to determine whether the infection was hospital-acquired. NYPH's rates for MRSA and VRE for 2003 and 2004 are attached at NYPH-HAI 000022.

Upon identification of a patient with MRSA or VRE, the Department of Epidemiology will notify the patient's floor. All patients infected with MRSA or VRE are placed on contact precautions. Patients are placed in isolation, and a green sign is placed on the patient's door to alert staff of the precautions to be taken with the patient. All staff who have contact with the patient must sanitize hands upon entering and leaving the patient's room, and must wear protective attire (i.e., mask, gown and gloves), which are to be removed prior to leaving the patient's room. To the extent possible, all patient care equipment is dedicated to the single patient. If equipment cannot be dedicated to the patient, it must be cleaned with a hospital-approved detergent-disinfectant before reuse.

* * *

Please feel free to contact me at (202) 637-2169 if you have any questions.

Sincerely,

Stuart S. Kurlander/KRM

Stuart S. Kurlander
of LATHAM & WATKINS LLP

Enclosures

cc: New York Presbyterian Hospital

TAB 13

MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, Ohio 44109-1998

216 778-7800

MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, OH 44109

October 10, 2005

Joseph Barton
Edward Whitfield
Chairmen, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Honorable Barton and Honorable Whitfield:

Please see attached document in response to your request on September 21, 2005 for information on how MetroHealth Medical Center detects, monitors, and reports health-care associated infections. Please contact my office with any further questions.

Sincerely,

J. Hanrahan

Jennifer Hanrahan D.O.
Chairperson, Infection Control Committee
MetroHealth Medical Center
2500 MetroHealth Drive
office: (216)778-7828

1. **Does MetroHealth Medical Center monitor HAI rates?** *Yes*

   (a) **If not, please explain why?** *Not applicable*

   (b) **If so, does MetroHealth Medical Center monitor all HAI' or does it conduct targeted surveillance of specific high-risk departments, procedures, or types of infection?** *MHMC does targeted surveillance of high-risk areas and procedures.*

   (c) **If MetroHealth Medical Center does targeted surveillance, please identify the specific types of infection, departments, and/or procedures monitored.** *Routinely monitor the following types of infections*

   - *HAI blood stream infections per 1000 patient days – all inpatients*
   - *HAI Clostridium per 1000 patient days – all inpatients*
   - *HAI central line blood stream infections per 1000 central line days – all intensive care unit patients*
   - *HAI ventilator associated pneumonia per 1000 ventilator days – all intensive care unit patients*
   - *Surgical site infections for selective surgical procedures stratified by NNIS risk index*
   - *HAI C-section wound infections – all obstetric patients undergoing a C-section*
   - *Necrotizing enterocolitis in infants in our neonatal intensive care unit*
   - *HAI gastroenteritis – all pediatric inpatients*

   (d) **Please provide the rates for HAI are monitored by MetroHealth Medical Center for calendar years 2003 and 2004.** *Unable to provide at this time.*

2. **To the extent that MetroHealth Medical Center does monitor HAI rates, does it report such rates?** *We report rates internally. Currently there is no requirement to report, nor is there agency collecting uniform, standardized information from all hospitals in Ohio.*

   (a) **If not, please explain why?** *As above*

   (b) **If so, how and when are these rates reported?** *Not applicable.*

   (c) **Does MetroHealth Medical Center voluntarily report HAI rates to the CDC's National Nosocomial Infections Surveillance system or National Healthcare Safety Network?** *No*

(d) **Please describe any barriers that MetroHealth Medical Center has identified to collecting data that could be publicly reported.** *The main problems at present are lack of standard definitions for some HAI's such as C. difficile colitis and difficulty in interpreting clinical symptoms and radiographic findings for other types of infections such as pneumonia.*

(e) **Please describe any risks to MetroHealth Medical Center (real or perceived) associated with publicly reporting HAI's.** *There would be large risks in potential negative public perception. One of the problems is that we are a large trauma center, and care for very sick patients. It is often difficult to accurately compare ourselves to other institutions because degree of illness is not adequately captured in National Nosocomial Infections Surveillance (NNIS). For example, surgical intensive care units (ICU) with a large proportion of trauma patients will have higher rates of HAI's. Currently NNIS uses an 80% trauma patient occupancy to define a trauma ICU. Even though most of our surgical ICU patients are trauma patients, we must compare ourselves to a general surgical ICU. This means that we are not accurately capturing the degree of risk. In other words, we are comparing ourselves to a suburban hospital without any trauma patients, when we do in fact serve a large trauma population. As stated in the Society for Healthcare Epidemiology position paper on public reporting of HAI's:*

> *"The Missouri Hospital Infection Control Act of 2004 empowers the Department of Health to collect and disseminate HAI incidence data that are "risk adjusted." Although the language in these laws may be appropriate, unfortunately, there is currently no widely agreed upon, scientifically validated method for risk adjusting HAI indicators. Available systems for assessing severity of illness, such as the Acute Physiology and Chronic Health Evaluation (APACHE) score or systems using discharge diagnoses, were designed to predict the risk of death rather than the risk of HAI acquisition and therefore are useful tools to adjust for differences in expected mortality among comparison groups. These systems, however, have not been validated to predict a patient's risk for developing a HAI.*
>
> *The Centers for Disease Control and Prevention (CDC), based on the experience with the National Nosocomial Infections Surveillance (NNIS) System, concluded that use of overall HAI rates for inter-hospital comparisons was crude, inaccurate, and potentially misleading because of the lack of scientifically validated methods of risk adjustment. Service and site-specific HAI rates (eg. HAI from the medical intensive care unit versus the surgical intensive care unit) are better, but are limited because they do not dully capture variations in patients' intrinsic and extrinsic risks for HAI."*

Additionally, the mechanisms for surveillance differ from organization to organization. We feel that we have a very comprehensive system for surveillance which exceeds that of many other organizations. As a result, we may in fact identify infections that may not have been identified at other organizations.

(f) **How can information on HAI's be better reported to consumers?** *There needs to be consumer education, and there needs to be standard application of definitions and standardized surveillance mechanism. Prior to requiring public reporting, there should be distribution of uniform definitions to all healthcare agencies, rather than relying on the assumption that entities are using standard definitions. Some definitions need to be revised prior to public reporting, such as example given above.*

3. **Are MetroHealth Medical Center's reported HAI rates adjusted to account for patient's underlying risk of infection? If not, please explain why not? If so, please describe all such adjustments.** *Yes, they are adjusted according to guidelines set forth by NNIS for risk stratification. Description available at: http://www.cdc.gov/ncidod/hip/SURVEILL/NNIS.HTM*

4. **Please provide a detailed written description of MetroHealth Medical Center's case-finding methods for identifying and tracking HAI's.** *Continuous nosocomial infection review is done by the Infection Control staff. Quality control mechanisms that help insure that patients with a nosocomial infection are appropriately identified include:*
    - *Published CDC definitions are used for nosocomial infection surveillance*
    - *The Infection Control Specialist (ICS) reviews the daily summary of positive bacterial cultures.*
    - *The ICS reviews the preliminary and final autopsy reports.*
    - *The ICS communicates freely with nursing unit and physician staffs to help identify patients with nosocomial infections who may not have been identified by other means.*
    - *The ICS attends Infectious Disease rounds as an adjunct to the identification process.*
    - *The ICS conducts post-discharge reviews of the medical records of all or a sample of patients who underwent selected surgical procedures to determine the presence of a nosocomial infection that was not previously recognized or that developed after discharge.*
    - *The ICS routinely reviews the medical record for every patient in an intensive care unit or step down units for more than five days.*

- *The ICS reviews the records/medical information for patients with certain diagnostic codes in an attempt to identify any patients with nosocomial infections that were not previously recognized.*
- *Any nosocomial infection identified after discharge is included in nosocomial infection statistics, as applicable.*
- *Patients who are readmitted to the hospital soon after discharge are surveyed via our normal surveillance activities. Any infection that can be related to the previous admission is counted as a nosocomial infection.*
- *Rates of infection are calculated as indicated (e.g. by infection site, by patient location, by clinical department, by NNIS risk stratification method for surgical site infections, etc.)*
- *The data is compared to previously known and/or NNIS data when available and are analyzed to determine infection potential and possible common source problems.*
- *Data related to nosocomial infections and patient risk factors are entered into the Infection Control Module of MIDAS (software utilized by MetroHealth).*
- *Data is analyzed and shared with the Infection Control Committee and distributed to appropriate departments/personnel.*

(a) **Have these methods changed during the past five years? If so, please explain?** *No*

(b) **Does MetroHealth Medical Center conduct any type of post-discharge surveillance? If so, please describe.** *Post-discharge surveillance is conducted for C. difficile colitis and for surgical site infections.*

5. **Does MetroHealth Medical Center have dedicated infection prevention and control personnel and/or specific technology for monitoring HAI data?** *Yes.*

(a) **If so, please describe the number of full-time infection prevention and control personnel employed by MetorHealth Medical Center and the type(s) of technology used to monitor HAI data.** *There are currently 3.4 FTEs for surveillance activities although there are additional supports provided to infection control which assists these staff members in performing their jobs. For example, there are data support staff within the Quality Management Department, who create reports from the computer system which assists in the data analysis. Chart review and computerized medical records are used for monitoring infections. In addition, a number of computer systems are used to collect data, such as microbiology lab reports, etc.*

(b) **What additional resources would MetroHealth Medical Center need to monitor HAI data more thoroughly?** *There is software available that would allow enhanced surveillance, by allowing more complete data collection than is currently possible. It is time-consuming to manually extract the data from various sources. One example of this is the manner in which information on device days is collected. Currently, nurses indicate daily on a form whether patients are on ventilators or have central catheters. This data is then sent to Infection Control and has to be manually entered into a database. This process is time-consuming and leaves potential for error. It would be preferable to be able to abstract information electronically. Software is available that can perform this function, but the barrier is that it is expensive.*

6. **What was MetroHealth Medical Center's total budget for detecting, monitoring, and reporting HAI's in calendar years 2003 and 2004? What are the projected budgets for calendar years 2005 and 2006?** *Infection control resources are budgeted as a part of the MetroHealth Medical Center's Quality Management budget. The total Quality Management budget was $1,274,183 and $1,293,217 for the years 2003 and 2004 respectively. The salaries for the staff members doing surveillance during these same years were approximately $154,760 and $160,950, respectively. The project total budget for the entire department in 2005 and 2006 is $1,231,814 and $1,384,771, respectively. The salaries for the staff doing surveillance during these same years are projected to be $164,268 and $187,205, respectively.*

7. **Does MetroHealth Medical Center monitor and "process measures" associated with HAI's, including, but not limited to: adherence rates of hand washing, central-line insertion practices, and surgical antimicrobial prophylaxis; and coverage rates of influenza vaccination for healthcare personnel and patients?** *MHMC monitors hand hygiene rates, surgical antimicrobial prophylaxis and influenza vaccination rates for staff.*

   (a) **If not, please explain why not?** *We currently do not have a process in place to monitor central line insertion practices. However, we have implemented a standardized educational process for housestaff to ensure implementation of appropriate infection control precautions during central line insertion, and have provided education to all physicians regarding the central catheter insertion guidelines. We are monitoring influenza vaccination rates on inpatients, but not on outpatients at present. Of note, there has been a substantial shortage of vaccine for several years, and we have not had an adequate supply of influenza vaccine for all the individuals who should be vaccinated. This has been a major barrier to influenza vaccination.*

(b) If so, please describe such process measures and provide the adherence rates.

- *Hand hygiene - We began monitoring in 2002 prior to implementing alcohol-based hand hygiene product with a baseline compliance rate of approximately 45%. Ongoing monitoring since the implementation of the alcohol-based product has shown our compliance to be consistently above 90%.*
- *Surgical antimicrobial prophylaxis – We began monitoring timing of pre-surgical prophylactic antibiotics, selection of appropriate antibiotics and discontinuation of prophylactic antibiotics in 2003. Baseline results were 83%, 94% and 9%? compliance with nationally recognized standards. Data from 2005 shows compliance for these same 3 measures at 81%, 99% and 81%, respectively.*
- *Influenza vaccinations for staff – We have been monitoring this for the past 18 years and have shown a steady increase in the total doses administered to staff. During the 1987-1988 influenza season, we gave only 263 doses compared to 2060 doses during the 2004-2005 influenza season. Influenza vaccination rates for staff are monitored on the main hospital campus. Vaccinations that are provided to staff at satellite facilities have not been adequately captured, so that our reported influenza vaccination rates are an underestimate of the total doses given. We have implemented a process to monitor all influenza vaccinations given to staff this year, and anticipate having more complete data in the coming year. It should be noted that we were only able to provide vaccine to patient care employees during the 2004-2005 season due to the shortage of vaccine, and had to turn away employees who requested vaccine but did not have direct patient contact.*

8. **Has MetroHealth Medical Center done any studies or analyses to calculate the financial impact of HAI's on the institution?** *No*

(a) **If so, what is the annual financial impact?** *Unable to answer*

(b) **Has MetroHealth Medical Center made any effort to determine whether improved monitoring of infections would lower its costs? If so, please describe all such efforts.** *One of the components of an electronic surveillance method would be a baseline assessment of cost, and ongoing cost assessment. However, due to the cost of the program, we are not currently able to do this.*

9. **Does MetroHealth Medical Center conduct facility-wide, active surveillance cultures for methicillin-resistant Staphylococcus aureus (MRSA) and/or vancomycin-resistant Enterococcus (VRE)?** *No.*

   (a) **If not, please explain why?** *Currently the recommendation is to perform surveillance at the time of hospital admission for "high-risk patients" and place patients in contact isolation until results of surveillance cultures are known. This poses great difficulty in our institution as many patients are at high risk for these organisms, and given the advent of community-acquired MRSA, it is becoming impossible to predict who is at risk for MRSA colonization. In addition, there are an insufficient number of beds.*

   (b) **If so, please describe the surveillance process and procedures.** *Not applicable*

   (c) **What are MetroHealth Medical Center's rates for MRSA and VRE for calendar years 2003 and 2004?** *Not available*

   (d) **Please describe the barrier precautions utilized by MetroHealth Medical Center for patients colonized or infected with MRSA or VRE.** *For individuals with VRE, contact precautions are utilized routinely. Standard precautions are used for patients with MRSA, however, contact precautions are used for neonates with MRSA in the NICU.*

TAB 14

MHA Keystone Center for Patient Safety & Quality

Bringing health care providers together with information, resources and collaborative opportunities to bridge the quality chasm

News Release

FOR IMMEDIATE RELEASE
October 13, 2005

Call: Kevin Downey: (517) 410-0903 (cell on site)
Sherry Mirasola (517) 323-3443 (office)

Two-Year Project Improves Patient Safety in Michigan Hospital ICUs

More Than 120 Michigan ICUs, 70 Hospitals Participate

DEARBORN, Mich. — Michigan hospital intensive care units (ICUs) are safer today following a two-year project to reduce medical errors and improve patient safety directed by the state's hospital association and The Johns Hopkins University Quality & Safety Research Group.

Results of the project were announced today by leaders of the Michigan Health & Hospital Association's (MHA) Keystone Center for Patient Safety & Quality and patient safety experts from Johns Hopkins. *Keystone: ICU* is believed to be the largest patient safety collaborative of its kind anywhere in the world, with more than 120 Michigan ICUs and 70 Michigan hospitals participating. The results were shared at a conference for Michigan business leaders, state lawmakers and hospitals leaders. Using a predictive model and data collected from project participants between March 2004 and June 2005, the total savings in the 15-month span were:

- **Patient Lives Saved - 1,578***
- **Hospital Days Saved - 81,020***
- **Health Care Dollars Saved - $165,534,736***

"As a result of Keystone: ICU, medical errors are being avoided, and lives and health care costs are being saved," said MHA President Spencer Johnson. "Improving health care safety at the bedside benefits all patients and the governments, employers and workers that pay for health care services. Michigan hospitals are proud to be at the forefront of patient safety and health care quality improvement initiatives."

MORE

MHA HEALTH FOUNDATION

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Lansing, Michigan 48917
(517) 323-3443
Fax (517) 323-0946
www.mha.org

Keystone: ICU is already changing the benchmarks of health care quality, dramatically reducing complications once regarded as nearly impossible to eliminate. Central intravenous (IV) lines are a major source of infections in ICUs that harm patients and increase lengths of stay, which drive up costs. Hospitals participating in Keystone: ICU have reduced central IV line infections by nearly 50 percent. Prior to MHA Keystone, Michigan's rate of central line infections ranked average in the nation. Today, Michigan's performance ranks among the best in the nation. Of the 127 participating ICUs, 68 have reported zero bloodstream infections or ventilator-associated pneumonias for six months or more. Overall ventilator-associated pneumonia rates in the Keystone: ICU project continue to decrease as well. Each prevented infection reduces costs, reduces the time a patient must stay in the ICU and often saves a life.

The MHA Keystone Center for Patient Safety & Quality was created in March 2003 as a 501(c)(3) division of the MHA Health Foundation. MHA Keystone brings together hospitals, national experts and best practice evidence to improve patient safety by addressing the quality of health care delivery at the bedside. In addition to Keystone: ICU, the Keystone Center is working on projects to improve stroke care and boost the number of organ donations made in Michigan hospitals.

The two primary leaders of the MHA Keystone Center and its ICU project are Chris Goeschel, RN MPA MPS, who serves as Keystone's executive director, and Peter Pronovost, MD, PhD a practicing anesthesiologist and critical care physician, lecturer, and internationally known patient safety researcher and leader from the Johns Hopkins University.

MHA Keystone Center is exploring ways to improve safety and reduce errors in other health care delivery settings, and will be expanding work with the Johns Hopkins Quality and Safety Research Group in a new "Partners in Possibility" initiative during 2006. Corporate sponsors are being invited to join with the MHA Keystone Center in these important initiatives.

For more information, please visit www.MHAKeystoneCenter.org.

** These impact estimates are based on projections from the Johns Hopkins Opportunity Calculator. This model applies estimates of the prevention of deaths and decreased hospital stay as extrapolated from published empirical studies. The estimated dollar savings is based on an average cost of a hospital day and an ICU day in Michigan from a sample of Michigan hospitals.*

###

MHA Keystone Center
for Patient Safety
& Quality

Bringing health care providers together with information, resources and collaborative opportunities to bridge the quality chasm

MHA Keystone: ICU

The Challenge
More than 5 million people are treated each year in U.S. hospital intensive care units (ICUs). Care delivered in ICUs costs about $180 billion a year, which represents almost 30 percent of total annual acute care spending. Improving the delivery of care and reducing medical errors in ICUs can improve patient outcomes and improve financial performance.

The Response: Michigan Health & Hospital Association (MHA) Keystone
MHA Keystone, with patient safety experts from Johns Hopkins University, launched Keystone: ICU in October 2003 with a matching grant from the Agency for Healthcare Research and Quality.

Keystone: ICU provides evidence-based, "best-practice" interventions to participating hospitals aimed at making ICU care safer, improving the quality of care, enhancing the culture of safety and staff satisfaction, and eliminating unnecessary or avoidable costs.

Keystone: ICU has been an overwhelming success. It now represents the largest regional partnership of ICUs ever assembled in a single initiative — more than 125 ICUs are now participating.

In most participating hospitals, the Keystone: ICU implementation team includes a senior executive (vice president or above), an ICU director, ICU nurse manager, ICU physician, ICU nurse, pharmacist and a department administrator. Each team commits to collecting required data, attending two meetings annually, and participating in project conference calls. Each team also agrees to implement the interventions as presented and to share what they learn with other teams. During the first two years of Keystone: ICU, the interventions included:

- **Intervention 1**: Implement Comprehensive Unit-based Safety Program
- **Intervention 2**: Implement Daily Goals Sheet
- **Intervention 3**: Eliminate Bloodstream Infections (BSI)
- **Intervention 4**: Eliminate Ventilator-associated Pneumonia (VAP)
- **Intervention 5:** Implement and evaluate an intervention to reduce ICU mortality
- **Intervention 6:** Evaluate characteristics of ICU teams and senior leaders that are associated with successful improvements in patient outcomes

MHA Keystone manages the project, focusing particularly on strengthening relationships and forging new ones between hospital leadership and ICU teams. Dedicated project Web space, weekly conference calls that are recorded and provided back to each team, e-mail rapid response times, data support and report development, shared tools and consistent encouragement to share what is being learned all help ICU team members understand the importance of their work and Keystone's commitment to supporting them.

MHA HEALTH FOUNDATION

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www.mha.org

The Results to Date
Keystone: ICU participating hospitals have achieved significant and measurable clinical improvements. Keystone: ICU is saving lives by improving patient safety and reducing medical errors in intensive care units.

Keystone: ICU Milestones

- 127 ICUs — 122 in Michigan and five in other states — are participating in Keystone: ICU.
- Of the 127 participating ICUs, 68 have reported zero bloodstream infections or ventilator associated pneumonias for six months or more.
- Overall catheter-related bloodstream infections in the Keystone: ICU project were cut in half between March and December 2004.
- Overall ventilator-associated pneumonia rates in the Keystone: ICU project continue to decrease as well.
- As announced in October 2005, using a predictive model and data collected from ICU project participants between March 2004 and June 2005, the total savings in the 15-month span were:
    - **Patient Lives Saved - 1,578***
    - **Hospital Days Saved - 81,020***
    - **Health Care Dollars Saved - $165,534,736***

** These impact estimates are based on projections from the Johns Hopkins Opportunity Calculator. This model applies estimates of the prevention of deaths and decreased hospital stay as extrapolated from published empirical studies. The estimated dollar savings is based on an average cost of a hospital day and an ICU day in Michigan from a sample of Michigan hospitals.*

Other Important Outcomes

- MHA Keystone has expanded the vision of what constitutes important hospital and health system advocacy and policy efforts. Michigan legislators have welcomed presentations about Keystone. Nationally, Keystone: ICU stands out as an important example of innovative improvement that can be sparked by modest federal funding.
- Blue Cross Blue Shield of Michigan (BCBSM) provides incentives to hospitals that achieve certain quality and safety thresholds. Hospital participation in Keystone: ICU was so significant that BCBSM agreed to nearly $10 million in financial incentives for hospital participation in 2004.
- MHA Keystone has identified a new role for state hospital associations, and other state hospital associations are taking notice. As a neutral convener and project leader, the association can truly lead local implementation of evidence-based health care improvements. The biggest winners are patients.

To learn more, please visit www.MHAKeystoneCenter.org.

TAB 15

Title of Project: Statewide efforts to improve care in intensive care units

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Organization: The Johns Hopkins University School of Medicine
Quality and Safety Research Group

Michigan Health & Hospital Association

Project Dates: 10/01/03 through 09/30/05

Federal Project Officer: Marge Keyes

This project was supported by the US Agency for Healthcare Research and Quality, grant number. 5UC1HS014246-02

ABSTRACT

Purpose: To achieve quantifiable improvements in intensive care unit (ICU) quality and safety in Michigan.
Scope: The project had three specific aims for improving clinical and cultural outcomes. Participants included 127 ICU teams from 77 hospitals.
Methods: This prospective cohort study used a collaborative model led by the Johns Hopkins University (JHU) and Michigan Health & Hospital Association (MHA). The project involved statewide implementation of improvement interventions using tools and methods developed and refined at JHU. ICU teams collected and submitted data and facilitated project interventions. MHA provided project management and oversight. Primary outcome measures were safety culture scores using the Safety Attitudes Questionnaire (SAQ), catheter-related blood stream infection (CRBSI) and ventilator associated pneumonia (VAP) rates, and adherence to evidence-based interventions (EBI) for ventilated patients.
Results: During year one, aggregate SAQ scores improved in five domains: safety climate 20%; teamwork climate 11%; perceptions of management 16%; working conditions 13% and job satisfaction 6%. The median CRBSI rate decreased from 2.8 at baseline to 0 at 0–3, 4–6, and 7–9 months post-intervention ($P \leq 0.003$). Preliminary data suggest aggregate VAP rates decreased from 5.32 at baseline to 3.52 after 12 months. Compliance with EBI increased from 86% to 92%. We implemented a structured safety program in Michigan that resulted in significant improvements in safety culture, use of EBI and reduction or elimination of CRBSI and VAP. Broad implementation of this program could realize significant improvements in patient safety nationwide. Our model of partnership between researchers and state hospital associations may provide a mechanism for large-scale improvements in safety.

Keywords: collaborative, patient safety, culture, catheter related blood stream infection, ventilator-associated pneumonia, keystone

Purpose

The overall objective of the study was to improve the safety of ICU care in Michigan. The specific objectives were to have 80% of staff in each ICU report a positive safety culture; eliminate catheter-related blood stream infections (CRBSIs) and ventilator-associated pneumonias (VAP); and ensure that evidence-based interventions were being used for at least 90% of ventilator days in each ICU. The specific aims follow:

Table 1: Specific Aims, Hypotheses and Goals of MHA Keystone ICU Project

Specific Aim	Hypothesis	Intervention & Process
To implement and evaluate the impact of the Comprehensive Unit-based Safety Program (CUSP).	The CUSP will lead to measurable improvements in patient safety and safety culture.	**Comprehensive Unit-Based Safety Program (CUSP)** 1. Safety Culture Assessment (SAQ) 2. Science of Safety Educational Training 3. Staff Identify Safety Issues 4. Senior Executive Partnership 5. Learn from one defect per month and implement teamwork tools 6. Reassess Safety Culture (SAQ)
To implement and evaluate the effect of a communication tool in ICUs.	The use of targeted interventions will lead to significant improvements in culture of safety	**Daily Goals** 1. intensivist-lead interdisciplinary daily rounds* 2. use of a daily goals sheet to communicate and prioritize work
To implement and evaluate the effect of an intervention to reduce or eliminate catheter related blood stream infections.	With this intervention catheter related blood stream infections will be eliminated or markedly reduced.	**Catheter Related Blood Stream Infection (CRBSI)** 1. Staff education on infection control practices 2. Create central line cart with equipment needed for central line insertion** 3. Use of a check list to ensure compliance with appropriate procedures** 4. Institute a policy that nurses assist in central line insertion and can stop non-emergent procedures that violate guidelines 5. Ask providers daily whether a central line can be removed 6. Provide feedback to staff on catheter related blood stream infection rates
To implement and evaluate the effect of an intervention to improve the care of mechanically ventilated patients.	With this intervention ventilator associated pneumonia, duration of mechanical ventilation and ICU length of stay will be reduced.	**Ventilator Bundle** 1. Elevate the head of bed to at least 30 degrees, unless contra-indicated 2. Provide peptic ulcer and venous thrombosis prophylaxis 3. Appropriately sedate patients 4. Test daily if patients can be extubated. 5. Control glucose values ≤110 mg/dl.

* Hospitals without intensivist staffing are encouraged to identify a physician champion or unit director to lead interdisciplinary rounds.

** Based on evidence-based guidelines for central line insertion

Scope

The need to improve quality and safety in healthcare is widely acknowledged. (1-3) In 1999, the Institute of Medicine (IOM) created a compelling case for patient safety in its report *To Err is Human.*(4) This report sparked a dialogue that continues to advance, although consensus on patient safety goals, priorities, methods, and measures for safety initiatives are slow to emerge.(4) The IOM provided a strategy for health system redesign in a follow-up report, *Crossing the Quality Chasm*, yet evidence of improvement is still limited.(5-7) Large scale improvements in patient safety are needed, but nowhere in sight.(8;9) To achieve improvements in quality and safety on a large-scale requires a balance between scientific rigor and feasibility. In this project we developed and implemented a large-scale patient safety effort focused on intensive care units (ICUs) located or headquartered in Michigan. Year one included 108 intensive care units from 72 hospitals. 127 ICU teams from 77 hospitals participated in year two. Characteristics of participating hospitals and ICUs are provided in Table 2. A list of participating hospitals is found in Appendix A.

Table 2. Characteristics of participating hospitals and ICUs

Hospital Characteristics (N=77)	**N (%)**
Hospital setting	
Rural	20 (27%)
Urban	57 (73%)
Teaching Status	
Teaching	41 (53%)
Nonteaching	36 (47%)
Number of hospitals bed	
< 100	16 (21%)
100-400	46 (60%)
> 400	15 (19%)
ICU Characteristics (N=127)	
ICU Type	
Medical	81 (64%)
Medical-surgical	23 (18%)
Surgical	23 (18%)
Median number ICU beds (range)	12 (3-52)

Methods

The project was designed as a prospective cohort study using ICU-specific historical controls as the baseline comparator for evaluating the effects of implementing patient safety interventions (i.e., a pre/post design). The project was lead by patient safety researchers from the Quality and Safety Research Group at Johns Hopkins. Project management was the responsibility of the Michigan Health and Hospital Association Keystone Center for Patient Safety and Quality. A quality improvement team in each of the intensive care units collected and submitted baseline data, and then

implemented specific quality improvement interventions in a staggered fashion (approximately every 3 months). The interventions were guided by use of toolkits which included educational materials and structured activities in support of the interventions. The specific aims did not change during the AHRQ funded years of the project (2003-2005).

To reduce bias in data collection, we developed a manual of operations that included explicit definitions for each process and outcome measure. Standardized data collection forms were developed, pilot tested, revised and distributed to ICU teams and then converted into an electronic format. We provided ICUs with monthly and quarterly reports of performance within their ICU and compared their performance to aggregate results from the other participating ICUs.

The director of the Johns Hopkins Quality and Safety Research Group (QSRG) was the principal investigator and the executive director of the Michigan Health and Hospital Association Keystone Center (MHA) was the project director. The executive director and MHA staff interacted with participating hospitals and met regularly with the QSRG. A website (www.mhakeystonecenter.org) provided participants access to educational materials, tools, reference documents, project data (with encrypted ICU identifiers) and project updates.

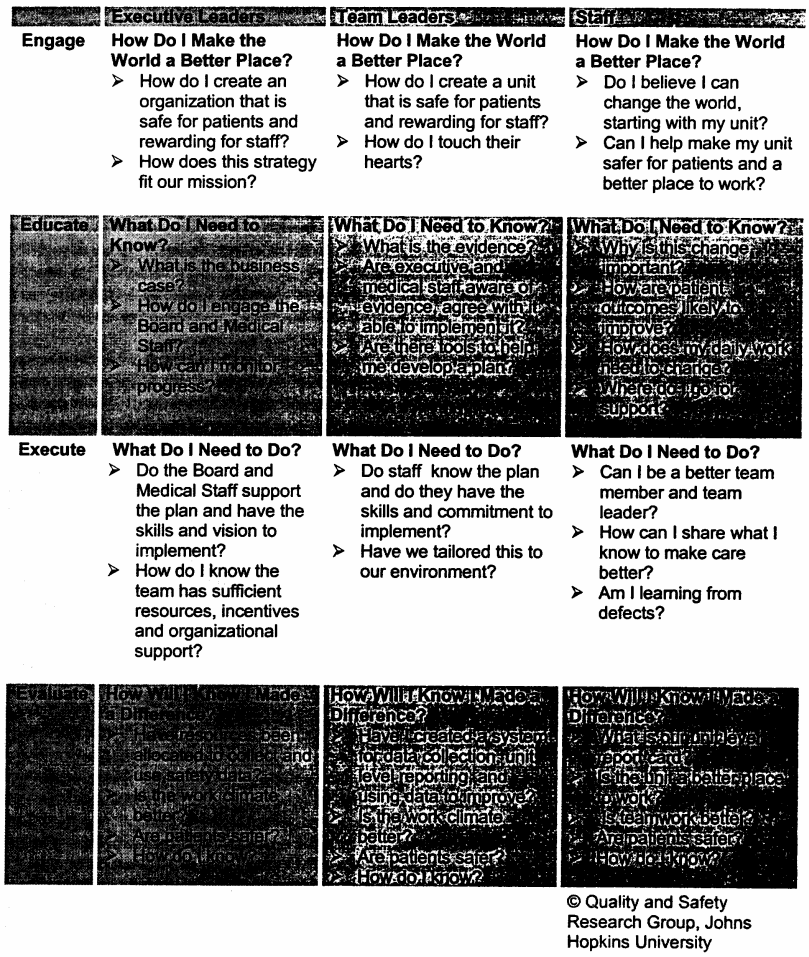
The QSRG developed the interventions, supplied supporting evidence, participated in the development and evolution of electronic data collection tools and worked with Keystone Center staff to analyze the ICU data. QSRG team members served as faculty at the biannual workshops and led monthly conference calls. To maintain interest, the principal investigator (PJP) and project director (CG) periodically sent joint letters to the CEOs of participating hospitals outlining the project's progress and challenging them with tasks to demonstrate continued support for their ICU improvement team.

Our change model for this intervention (Figure 1) was intended to integrate and implement theories related to the diffusion of innovation and behavior change.(10-13). In this model, we partnered senior hospital leaders, the ICU improvement team, and ICU staff to help ensure all stakeholders were involved in the change process. Teams were mentored on methods to facilitate local change, including identifying and resolving common barriers using theoretical and experience-based strategies.

We recognize several limitations of our study. First, we used a "pre-post" study design to measure the effect of the interventions, rather than a more robust cluster randomized trial. Our study design will limit our ability to make a causal inference regarding the interventions and outcomes. This limitation resulted from the participating ICUs requested to choose their own timing for initiation of the patient safety interventions rather than having it randomly assigned. However, since ICUs cannot implement all interventions immediately, randomization of ICUs to early versus late introduction of individual interventions may be feasible in future projects.

Second, we did not collect data on patient severity of illness to allow for adjustment in our analyses. Collecting such data was not feasible since additional staffing resources were not available. This staffing constraint is a significant issue that must be considered in all large-scale, real-world patient safety improvement projects. In addition, the inter-rater reliability of data elements in current risk-adjustment methodology is poor, even among trained data abstractors, (14) making reliability of these adjustments potentially questionable. Fortunately, in the absence of a new

Figure 1 Strategy for Leading Change



patient product-line within the ICU, severity of illness tends to change little over time.(15) Consequently, this limitation is unlikely to jeopardize the validity of our project, which focused on comparing performance within an individual ICU over time.(15)

Third, while we only included CRBSI and VAP data from hospitals that used NNIS definitions, significant variation in these definitions still exist among hospitals.(16;17) Since our goal was to reduce CRBSI and VAP rates within ICUs over time, and not to compare rates among ICUs, our results are likely valid as long as teams did not change their definitions for CRBSI and VAP during the study period.

Fourth, we did not collect data for ICU mortality, length of stay, or costs of care and we may not be able to determine whether improvements in ICU care led to reductions in these outcomes. We tried to implement a simple data collection tool to prospectively capture this data; however, data collection proved too burdensome for reliable, large-scale use. In addition, this data was not available from administrative database sources in Michigan.

Despite these limitations, this study has several notable strengths. It focused on improving culture, processes of care and clinical outcomes in an entire state. The culture change may improve the effectiveness and sustainability of the safety improvements. In addition, this project includes rigorous data collection and presents a model that could be replicated in other states, health systems or countries. Finally, the project provides an opportunity to improve the science of quality improvement.

Results

The project team is actively involved in data cleaning activities and a number of manuscripts are in the preliminary phases. Thus, our results are in the analysis phase and not yet ready to be reported. We expect over the coming months to submit a number of manuscripts reporting the results of this project. At this time we are able to report on the baseline measures and tentative interim analyses of CRBSI and VAP.

The clinical and cultural improvements achieved by the teams were transforming. Overall response rate for the baseline SAQ was 72% with safety and teamwork scores varying widely among ICUs and caregiver type. Only 3% of ICUs, at baseline, achieved our goal of 80% of staff reporting positive teamwork and safety culture. After 12 months culture score improvements included: safety climate 20%; teamwork climate 11%; perceptions of management 16%; working conditions 13% and job satisfaction 6%.

For participating ICUs, the mean rates (95% confidence interval), at baseline, of CRBSI and VAP were 4.2 (0 - 21.3) per 1000 catheter days and 9.28 (0 -22.2) per 1000 ventilator days respectively. The average number of ventilator days in which patients received evidence-based interventions ranged from a mean of 25% for maintaining glucose ≤ 110 mg/dl to 89% for stress ulcer prophylaxis. Analysis of the Ventilator-Associated Pneumonia data is not yet complete but preliminary data suggests aggregate rates decreased from 5.32 at baseline to 3.52 after 12 months. Compliance with the ventilator bundle increased from 86% to 92%.

The median catheter-related blood stream infection rate decreased from 2.8 at pre-intervention baseline to 0 at 0–3, 4–6, and 7–9 months post-intervention ($P \leq 0.003$). A sensitivity analysis conducted by excluding hospitals with missing data did not change this result.

These results provide preliminary evidence that the use of our evidence-based interventions and the efforts of the teams involved in the collaborative resulted in improvements in care and outcomes for patients in ICUs in the state of Michigan.

The need to improve quality and safety in health care is a widely accepted fact and imperative in the U.S. and abroad. Yet, this initiative is the first known, rigorous effort to improve ICU care throughout an entire state. In this collaborative, we included teams from 127 Michigan ICUs, made significant efforts and realized significant results that improved care for ICU patients state-wide.

There are several important lessons learned from this novel cohort study that we believe can shape future efforts to improve care in the ICU and elsewhere in the hospital. First, partnering with a hospital association provided a unique opportunity to efficiently and effectively implement a large scale patient safety collaborative. As a neutral convener, state hospital associations can bring national expertise and organization to a large cohort of hospitals to implement a focused safety project.

Second, we learned that simple and profound questions can provide a powerful framework for change. There is no set formula for system redesign, although there are many tactics shown to be effective in improving care. The key to success, however, is stakeholder engagement.(18) Through experimentation and reflection, we developed a transformation model to guide our efforts. We recognized that senior leaders, project leaders (generally ICU physician and nurse managers), and front-line staff should do the following: ***Engage*** - understand how this project makes the world a better place; ***Execute*** - understand exactly what needs to be done and ensure staff have resources to do it; and ***Evaluate*** - answer the tough question: are we safer? The interventions we implemented are evidence-based, feasible and meaningful at the bedside and for senior leaders.

We must improve the rigor with which quality improvement data are collected and standardize our approach to collaborative methods. Quality and safety improvement studies should be viewed as cohort studies and approached with the rigor of other cohort studies. (19;20) In most collaboratives, half the teams submit data, about a quarter of those improve and nearly half who improve question the validity of the data. (21) In general, the net result is improvement in a small percentage of teams. To support more rigorous data collection, we followed the methodology used in clinical trials--provided participants with a manual of operations for data collection, standardized data collection forms and developed a database for entering data. Collaborative efforts must also develop a data quality control plan and include, at a minimum methods for monitoring missing data. Further research needs to address how to deal with missing data and how to make causal inferences in quality improvement studies.

Fourth, expectations for senior leaders, team leaders and staff should be succinct. We have found that all of these groups prefer explicit, clear tasks, with instructions, rather than broad general concepts.

Fifth, these efforts require resources to--manage the collaborative, develop standardized measures, analyze data and produce team reports and develop interventions. In addition, teams need to be coached and educated throughout the project. Teams also need time to implement interventions and monitor performance.

Teams routinely reported lack of dedicated time to implement interventions given their current workload to be a significant barrier to collaborative activities. We attempted to overcome this barrier by instituting a condition for participation that physician and nurse leaders had to dedicate 20% protected effort to this project. As such, CEO's were periodically sent letters reminding them of this commitment. Finally, team leaders need training in leading change and project management. Many project leaders expressed concern that they were ill-equipped to lead this effort, particularly in garnering support from physicians.

In partnership with the Michigan Health & Hospital Association, we created a safety program targeted to senior leaders, ICU leaders and ICU caregivers that included focused interventions and measures to improve culture, improve the use of evidence-based interventions for ventilated patients and reduce CR-BSI and VAP rates. To our knowledge, this was the first state-wide project to improve ICU care. Successful implementation of this project provides a model to improve patient safety that can be broadly applied.

Table 3. Distribution of Catheter Line Days According to Hospital Characteristics

Characteristic	Catheter Line Days (%)
Teaching	117,580 (76%)
Hospital bed size	
<100	1,450 (1%)
100 – 199	9,905 (6%)
200 – 299	27,103 (18%)
300 - 399	46,295 (30%)
400 – 499	13,511 (9%)
≥500	56,396 (36%)
Region	
Upper Peninsula	3,127 (2%)
Middle	12,223 (8%)
North Central	4,362 (3%)
East Central	12,899 (8%)
West Central	12,101 (8%)
South East	86,259 (56%)
South West	17,291 (11%)
Out of state	6,398 (4%)

CRBSI = Catheter-related blood stream infection

Table 4. **Catheter-Related Blood Stream Infection Rates per 1000 Catheter Days by Time Period**

Time Period*	Total Catheter Line Days (%)**	No. of ICUs**	Median CRBSI Rate	IQR	P-value***
Pre-intervention baseline	33,857 (22%)	48	2.8	0.5 – 4.9	Reference
Peri-intervention	39,457 (25%)	74	1.7	0 – 4.5	0.10
0 – 3 months post-intervention	30,756 (20%)	68	0	0 – 2.9	0.002
4 – 6 months post-intervention	24,109 (16%)	59	0	0 – 3.3	0.002
7 – 9 months post-intervention	9,392 (6%)	24	0	0 – 2.2	0.001
Unknown	17,089 (11%)	13	1.0	0 – 2.3	0.047

CRBSI = catheter-related blood stream infections, ICUs = intensive care units, IQR = inter-quartile range

* The time periods used for analysis of CRBSI rates, according to when the CRBSI intervention was implemented by ICUs, are described in Table 1.

** The number of catheter days and participating ICUs decreased in later time periods for two reasons: (1) not all ICUs provided complete data for all time periods, and (2) staggered implementation of the CRBSI intervention resulted in a lower number of ICUs available to provide data during the later periods. For example, an ICU which implemented the intervention immediately upon study initiation could not provide data for the pre-intervention baseline time period.

KEYSTONE: ICU Participating Hospitals
2005

Aleda E. Lutz VAMC
Battle Creek Health System
Bay Regional Medical Center
Beaumont Hospital-Royal Oak
Beaumont Hospital-Troy
Borgess Medical Center
Botsford General Hospital
Bronson Healthcare Group
Central Michigan Community Hospital
Chelsea Community Hospital
Community Health Center of Branch County
Covenant HealthCare
Crittenton Hospital Medical Center
Dickinson County Hospital System
Foote Health System
Garden City Hospital
Genesys Regional Medical Center
Gerber Memorial Health Services
Gratiot Community Hospital
Hackley Hospital
Harper University Hospital
Henry Ford Bi-County Hospital
Henry Ford Health System
Henry Ford Wyandotte Riverside Hospital
Holland Community Hospital
Huron Medical Center
Huron Valley Sinai Hospital
Ingham Regional Medical Center
Lakeland Hospital
Lapeer Regional Hospital
Marquette General Health System
McLaren Regional Medical Center
Memorial Healthcare
Mercy General Health Partners
Mercy Hospital Cadillac
Mercy Hospital Grayling
Mercy Medical Center Clinton
Mercy Medical Center-Des Moines
Mercy Medical Center-Sioux City
Mercy Memorial Hospital
Metropolitan Hospital
MidMichigan Medical Center
Mt. Clemens General Hospital
Munson Medical Center
North Oakland Medical Center
Northern Michigan Hospital
Oakwood Annapolis Hospital
Oakwood Heritage Hospital
Oakwood Hospital & Medical Center
Oakwood South Shore Medical Center
POH Medical Center
Port Huron Hospital
Providence Hospital & Medical Centers
St. Agnes Medical Center
St. John Detroit Riverview Hospital
St. John Hospital & Medical Center
St. John Macomb Hospital
St. John Oakland Hospital
St. John Health-River District Hospital
St. Joseph Mercy Hospital
St. Joseph Health System-Tawas City
St. Joseph Mercy Oakland
St. Joseph Regional Medical Center-South Bend
St. Joseph's Mercy of Macomb
St. Mary Mercy Livonia
St. Mary's Mercy Medical Center
St. Mary's of Michigan
Sinai-Grace Hospital
Sparrow Health System
Spectrum Health
Spectrum Health United Memorial
Sturgis Hospital
Three Rivers Area Hospital
Univ. of Michigan Hospitals & Health Centers
War Memorial Hospital
West Branch Regional Medical Center
West Shore Medical Center

List of Publications and Products

Published Papers

Pronovost PJ, Goeschel G. Improving ICU care: It takes a team. *Healthcare Executive*. 2005 Mar/Apr. 14-22.

Pronovost PJ, Goeschel G. A novel collaborative model to improve ICU care in Michigan. *ICU Management* 2006 (in press).

Papers Submitted and under review.

Pronovost PJ, Berenholtz SM, Goeschel G, et al. Improving patient safety in Michigan intensive care units. *JI Crit Care*

Sexton JB, Lyon J, Berenholtz SM, et al. Assessing and improving safety climate in a statewide sample of ICUs. *JAMA*

Pronovost PJ, Needham DM, Berenholtz SM, et al. A multi-faceted intervention to reduce catheter-related blood stream infections in Michigan intensive care units. *NEJM*

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TAB 16

Representing approximately 30 percent of acute care costs or $180 billion annually, intensive care is one of the largest and most expensive components of U.S. healthcare. More than five million people are admitted to ICUs annually, and studies suggest that nearly every one of those patients admitted to an ICU suffers a potentially life-threatening adverse event. Healthcare leaders should ask themselves: How often do we harm patients? How often do patients receive the interventions they should receive? How well have we improved our culture of safety?

Improving ICU Care: It Takes a Team

by Peter Pronovost, M.D., Ph.D., and Chris Goeschel, R.N.

In late 2003, patient safety experts at The Johns Hopkins University partnered with the Michigan Health & Hospital Association Keystone Center for Patient Safety & Quality on *Keystone ICU*, a two-year project involving 72 hospitals. The project focuses on implementing field-tested best practices to reduce the risk of medical errors and enhance patient protections in the ICU.

Thus far, demonstrated impacts of *Keystone ICU* include a strengthened sense of teamwork among executives and physicians all the way to the bedside, better outcomes for patients, and enhanced communication among caregivers. Taken together, these translate into an improved culture of safety. The best part is, the model and interventions lend themselves to replication by those with the will and the courage to embrace major change on behalf of safer ICU care. So, how do you get there?

A Five-Step Approach

Each participating organization has a team assigned to the project, composed of—at a minimum—a physician leader, nurse leader, staff nurse, pharmacist, and senior executive. The teamwork is focused on patients, evidence, and a dedication to improvement based on collecting meaningful data and sharing project-related successes and challenges. Our experience suggests that there is unique potential for successful patient safety initiatives where organizers bring clinical experts together with healthcare providers that have a shared locus of affiliation—for example, a state hospital association, a safety coalition, or a large health system. The affiliating organization serves as the neutral facilitator of the learning process. A willingness to excuse lack of performance because of variation in group demographics seems less likely to occur if participants are aligned in ways beyond the collaborative itself. Indeed, we have found that the teams bring each other along.

Teams are improving ICU culture, learning from errors, ensuring that patients are receiving evidence-based intervention, and reducing harm through a framework that focuses on five structured interventions and the use of standardized data collection tools. The teams will also monitor ICU mortality and length of stay. Two of the interventions focus on staff education, training, and improved team communication. The three subsequent activities are centered on specific clinical targets. The five areas of concentration are:

1. Develop a comprehensive patient safety program that includes a Web-based error-reporting system.
2. Implement the use of specialists who coordinate ICU care and a checklist approach to daily rounds that encourages communication among multiple caregivers.
3. Attempt to eliminate bloodstream infections.
4. Attempt to eliminate ventilator-associated pneumonia by ensuring patients on breathing machines receive evidence-based intervention.
5. Ensure patients with severe infections receive evidence-based intervention.

As the first step, or intervention, patient safety programs were developed. Each of the other four interventions are being added one at a

time, every three to six months (see page 18).

The process employed to keep teams moving through the hard work of transformational change is built on continuous nurturing of valued relationships. The hospital teams, Keystone Center staff, and Hopkins safety specialists meet face-to-face at least twice a year. Keystone Center and Hopkins host monthly conference calls that are rich in content and provide ample opportunity for Q&A. Keystone Center also sponsors conference calls at least twice a month that are focused on "coaching" via shared experiences. A participant Web site contains tools, reference documents, and blinded data, and a bulletin board is used for hospital-to-hospital conversations. An electronic newsletter every other month shares stories "from the trenches," brings a message from the project leaders, and answers frequently asked questions. Keystone Center project staff visit participating sites to meet with teams and see *Keystone ICU* in action. Keystone Center and Hopkins project leaders send written *Keystone ICU* updates and requests for assistance directly to hospital CEOs and medical staff leaders based on identified need. In essence, the project is treated like any other critical strategic initiative.

The Executive's Role on the Team

We recognized that senior leader support is essential for improving quality of care. That's why each team was assigned a senior leader who agreed to "adopt the unit." The principal investigator and project director send CEOs bimonthly letters asking them to do specific interventions. These interventions are framed by literature review and review of the work of the *Keystone ICU* teams, including perceived barriers to success. The letters delineate specific executive activities and a suggested time frame for implementation and response.

We believe that executives are absolutely committed to improving safety. Asking executives to address and report back on a specific issue within an identified time frame—while providing them with the rationale for the request and suggesting mechanisms to address the issue—demonstrates respect for demands on executive time but does not minimize their accountability for quality and safety. The ICU project leader at the unit level is copied on the letter and asked to coordinate with the executive on completion of the activity.

This method of engaging executives and their team leaders using targeted letters was initially introduced to expedite the use of chlorhexidine, a solution used to clean the skin during insertion of central venous catheters (see page 20). The method was viewed positively by both the executives and the teams. Clear direction, backed by clinical evidence and communication to each executive leader and ICU team leader, resulted in a rapid transformation of the standard of care. Impressed by the outcome when senior leaders and ICU leaders were contacted to address the chlorhexidine challenge, we responded in a similar fashion to evidence revealing team confusion about how to **maintain** active engagement of their executive in *Keystone ICU*. A second targeted letter was sent requesting that CEOs meet monthly with their ICU team, review clinical data on a regular basis, invite the ICU team to present *Keystone ICU* at a board or leadership meeting, and write a story about the team's extraordinary commitment and efforts in their internal newsletter. Each of these requests has been similarly successful.

Beyond tangible results, on project conference calls teams are reporting a new sense of support from executive leadership. Executives assert improved communication with ICU physicians, frontline staff, and managers, and a better appreciation for work accomplished at the bedside. Many units report a significant improvement in ICU culture and safety attitudes. *Keystone ICU* executives can say that ICU staff perceptions of patient safety are better today than when the project began.

The executives uniformly report that this program has been informative and rewarding. Nearly all report

The Interventions

Keystone ICU teams begin by implementing the Comprehensive Unit-based Safety Program and establishing expectations for improved communication and staffing in the ICU. These interventions provide a framework to improve culture and learn from errors. Next, the teams work on interventions to decrease catheter-related bloodstream infections, ventilator-associated pneumonias, and mortality in severe sepsis. These interventions are based on a patient safety program developed by patient safety leaders at Johns Hopkins, which demonstrated dramatic improvements in quality, safety, and staff satisfaction. As a result of the interventions, patient outcomes improved and ICU length of stay decreased. This freed up bed capacity and allowed increased admissions to the ICU.

1. Implement Comprehensive Unit-Based Safety Program.

Goal: Implement and evaluate the impact of the CUSP.

Hypothesis: The CUSP will help teams learn from mistakes and improve the safety climate.

Implementation

1. Evaluate culture of safety.
2. Educate on the sciences of safety.
3. Identify preventable errors. Determine how the next patient might be harmed.
4. Assign a senior executive to adopt team.
5. Learn from one preventable error per month.
6. Re-evaluate culture.

2. Implement Daily Goals Sheet and Other Communication Tools.

Goal: Implement and evaluate the effect of an intervention to improve communication and staffing in ICUs.

Hypothesis: The use of targeted interventions will lead to significant improvements in ICU mortality and length of stay.

Implementation

1. Have intensivists* lead interdisciplinary rounds.
2. Use Daily Goals Sheets with clear and explicit expectations to guide care.
3. Implement teamwork training and communication strategies.

3. Eliminate Bloodstream Infections (BSI) through the BSI Bundle.

Goal: Implement and evaluate the effect of an intervention to reduce or eliminate catheter-related bloodstream infections in ICUs.

Hypothesis: With this intervention, catheter-related bloodstream infections can be reduced or eliminated.

Implementation

1. Educate staff on bloodstream infection control practices.
2. Create a central-line cart that contains all equipment needed to comply with evidence-based guidelines for central-line insertion.
3. Institute a policy that requires nurses to assist in central-line insertion.
4. Require use of a checklist to ensure compliance with evidence-based guidelines for central-line insertion.
5. Provide regular feedback to staff on infection rates.

4. Eliminate Ventilator-Associated Pneumonia through the Vent Bundle.

Goal: Implement and evaluate the effect of an intervention in improving the care of ventilated patients in ICUs.

Hypothesis: With this intervention, ventilator-associated pneumonia, duration of mechanical ventilation, and length of ICU stay will be reduced or eliminated.

Implementation

1. Elevate the head of the bed.
2. Provide peptic ulcer and venous thrombosis prophylaxis to ventilated patients.
3. Appropriately sedate ventilated patients.
4. Test daily if patients can be extubated.
5. Use continuous subglottic suctioning.
6. Implement mouth care and oral decontamination.

5. Reduce Mortality in Severe Sepsis with the Sepsis Bundle.

Goal: Implement and evaluate an intervention to reduce mortality in patients with severe sepsis.

Hypothesis: With this focused intervention, mortality can be reduced in patients with severe sepsis and septic shock.

Implementation

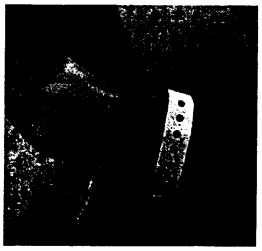
1. Ensure rapid initiation of appropriate antibiotics.
2. Ensure use of steroids in patients with septic shock.
3. Provide activated protein C that meets hospital-specific guidelines.
4. Remove unnecessary antibiotics at day four.

* In cases where intensivists are not available, have a physician champion or unit director lead interdisciplinary rounds.

—PP/CG

The Chlorhexidine Story

Evidence suggests that using chlorhexidine to clean the skin prior to placing a central venous catheter can cut the risk of catheter-related bloodstream infections in half with minimal, if any, increase in costs. Yet it is infrequently used.



This defect, like all defects, involves system properties. The capacity to reduce catheter-related bloodstream infections by adhering to evidence-based practice is predicated by administrative and clinical *system* parameters. Using chlorhexidine hinges on the product being available in the hospital and in central-line kits. Availability is contingent upon procuring the product, an administrative function and also a system property.

Procurement rooted in evidence-based evaluation, rather than merely front-end costs or habit, describes an administrative system structured to minimize defects. Likewise, ICU protocols that mandate adherence to standardized, evidence-based techniques (such as sterilizing with chlorhexidine before line insertion, rather than accepting personal provider preference) represents a clinical system designed to reduce defects. We speculated that a focused and coordinated awareness campaign about chlorhexidine use among a group of motivated clinical and administrative leaders could improve system properties and quickly result in a tipping point for the availability and use of chlorhexidine for central-line insertions in *Keystone ICU* hospitals. The potential impact: a dramatic decrease in bloodstream infection rates from central-line placement.

To accomplish this, we targeted ICU clinical leaders participating in the project and hospital chief executive officers. During a project meeting with participating teams, we presented the evidence regarding chlorhexidine. Teams were then asked to work with their supply purchasers and infection control staff to ensure that chlorhexidine is included in their central-line kits, ICUs, and other clinical units for skin sterilization. The target implementation date was explicitly stated as "within six weeks." Hospital CEOs were sent a letter requesting the same chlorhexidine intervention in the six-week time frame.

The results have been astounding. Twenty-eight hospitals (39 percent) had no chlorhexidine in their facility at the time of our request, yet 18 (64 percent) of these hospitals were able to stock it in their hospital, ICU, and central-line kits within the targeted time frame. The remaining facilities had mixed availability of the product at the time the request was made. Their efforts involved rapid expansion of availability and use. Within six weeks, 56 hospitals (78 percent) reported stocking chlorhexidine in their hospital, 46 hospitals (64 percent) had it available in their ICUs, and 43 hospitals (60 percent) had chlorhexidine in their central line insertion kits.

In addition, every hospital CEO except one committed to meeting all three expectations and demonstrated that they had begun the conversion process within six weeks. One small facility with a limited number of central-line insertions each year could not justify the line kit expense. However, it now stocks chlorhexidine, wrote a central-line insertion protocol that requires use of chlorhexidine for skin cleansing, and monitors adherence to the new protocol with each central-line insertion. Teams continue to report when they have completed phasing in chlorhexidine. Teams also report that the chlorhexidine central-line protocol is spreading to other high-intensity settings where central lines are placed, such as surgery and emergency departments. *Keystone ICU* executives can say that this system defect has been eliminated in their ICUs and is being eliminated throughout their hospitals.

—PP/CG

Reprinted from
Healthcare Executive
MAR/APR 2005

Improving ICU Care: It Takes a Team

identifying and mitigating hazards in the ICU—generally with no or low-cost solutions. The monthly meeting with teams allows senior leaders to get closer to their customers, and surface and mitigate system problems that would otherwise have been invisible. Our experience with *Keystone ICU* demonstrates that senior leaders are uniformly aware of the patient safety problem and are generally committed to improving safety yet nearly universally lack clarity on exactly what they can do to improve patient safety. In *Keystone ICU*, we provided clarity; senior leaders responded.

The Results

After six months of data collection, 22 Michigan ICUs dropped catheter-related bloodstream infection rates to zero. Aggregate rates plummeted from above the 25th National Nosocomial Infection Surveillance System percentile, to below the 10th percentile. Ventilator-associated pneumonias declined in equally dramatic fashion. Re-measure of the culture won't occur until one year into the project, but anecdotally teams are reporting an amazing change in the work environment. The level of participation on conference calls and attendance at workshops suggests the enthusiasm is consistent and genuine. Medical staff champions and hospital administrators are equally enthusiastic about their shared efforts to strategically address patient safety and their shared commitment to the principle that harm is untenable.

These leaders are beginning to develop answers to questions: How often do we harm patients? How often do patients receive the interventions they should receive? How often do we learn from defects? How well have we improved our culture of safety? They are putting in place systems so that they can confidently answer these questions: Is my hospital safer today than it was yesterday? How do I know?

The science of safety is evolving, and the need for clear and feasible evidence-based interventions that improve patient outcomes deserves national attention and additional research funding. The path toward a safer future, however, is before us now. We believe the five interventions developed at Johns Hopkins and implemented now in more than 100 ICUs as part of *Keystone ICU* allow any hospital with an ICU to join us on that path.

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MR. WHITFIELD. Dr. Cardo, how long have you actually been the Chief of Healthcare Quality at the Centers for Disease Control?

DR. CARDO. I have worked in the field of prevention of healthcare-associated infections since 1984. I have been at CDC for 13 years in that division, and I have been the director of the division for the last two years.

MR. WHITFIELD. So a big part of your career has been devoted to preventing infections, I take it?

DR. CARDO. Yes.

MR. WHITFIELD. Just how serious is healthcare-acquired infections within the totality of our healthcare system in America today?

DR. CARDO. We know there are several problems in our healthcare system, but healthcare-associated infections are a very important problem. And as it was said before, it is a problem that more needs to be done in order to prevent more infections. So it is not just a big problem, but a problem that deserves more attention so more action can be done and more infections can be prevented.

MR. WHITFIELD. And do you have any way today to determine what the, say, hospital-acquired infection rate is in any hospital in the U.S.? If I come to you and I say what are the infection rates for patients undergoing surgery at George Washington Hospital in Washington, D.C., can you answer that question?

DR. CARDO. No, I cannot answer that question. At CDC, we have voluntary surveillance system that includes 300 hospitals, most of them medium or large-sized hospitals, and we are now in the process of expanding that to any healthcare facility in the United States.

MR. WHITFIELD. So--

DR. CARDO. The system has assurance of confidentiality, so as CDC, we cannot provide the rate of a specific hospital, but we are changing the system in a way that if a State wants to get access to that information, it is going to be possible.

MR. WHITFIELD. But you are saying because of Federal laws relating to the patient's privacy, that you are prohibited from providing information, even if a hospital did have a high infection rate? Is that correct?

DR. CARDO. That is correct.

MR. WHITFIELD. But you are taking steps to change that. Now, do you have the authority to do that from a regulatory standpoint?

DR. CARDO. What we are changing is the way that the information can be shared. So we would not be the one providing that information in case you call us, but the hospital can give this authority to other groups, like a State. If we work with Missouri or Virginia and they want to use our system so hospitals can report their information, the State can get access to that information. So we are really moving towards a way to facilitate sharing that information.

MR. WHITFIELD. But how does it infringe on a patient's right of privacy to obtain an infection rate for a hospital if you are not giving any information about a particular patient?

DR. CARDO. It is not just a patient's right. The 308(d) assurance of confidentiality gives assurance not just for the patient, but also for the hospitals.

MR. WHITFIELD. So the hospital has privacy protection as well?

DR. CARDO. Exactly.

MR. WHITFIELD. And what is the section that provides that protection?

DR. CARDO. I remember this. It is 308(d).

MR. WHITFIELD. 308(d), okay.

DR. CARDO. I can provide you more information later if you need.

MR. WHITFIELD. But the NNIS system is the voluntary system, is that correct?

DR. CARDO. Correct.

MR. WHITFIELD. But now you are moving to this National Healthcare Safety Network?

DR. CARDO. Correct.

MR. WHITFIELD. And what is the difference in those two?

DR. CARDO. The difference is that, as you heard before, things are changing and we are learning from that, so it is an improvement of what we had before. It is a web-based system. It is a system that any healthcare facility in the United States can use to collect information on infection rates. We also include information in what is called process, that is, how the clinicians are following the recommendations that should be used to prevent those infections. And we are working with the States and other healthcare organizations so if they want, they can work with their hospitals and they can share the data among those hospitals, like we did with Pittsburgh Regional Healthcare Initiative, and finally, we are also being ready for the use of the electronic data for hospitals that may have that available that could facilitate the detection and monitoring of those infections.

MR. WHITFIELD. You know, the testimony that we have heard today is that between 1.7 and two million people acquire these infections every year, and we have heard figures of 9,000 people dying a year, or 99,000 people dying a year, which is quite a large figure. The Centers for Disease Control, have you all determined or been able to determine or is it your responsibility to determine what is the primary cause of these types of infections?

DR. CARDO. In looking at the information that we get from hospitals, it is very important, because not only are we determining the primary cause of those infections, but also we learn in ways that we can prevent those infections, because that is our primary goal. Our primary goal is to prevent those infections. So we know that the most frequent types of infections, like bloodstream infections, urinary tract infections,

pneumonias, and surgical site infections, and we also know the type of bacteria that cause those infections. So it is not just a way to monitor, but a way to learn from that and make a difference in terms of providing that information and using information for action in the local levels so they can prevent those infections.

MR. WHITFIELD. Do you feel like the time is right for national standards relating to this issue, or do you recommend we adopt national standards, or do you feel like you are trying to adopt national standards, or should we wait for more States to adopt standards? What should we do?

DR. CARDO. The time is now for us to act.

MR. WHITFIELD. The time is now?

DR. CARDO. For us to act and prevent more infections. I think we are ready to respond, and we have started in the way to look at national standards. We still need to learn more in terms of what should be the national standards for all hospitals in the United States, especially when we consider that most of what we have learned is from large and medium-sized hospitals, and there are many hospitals that are small-sized hospitals.

But this should not be a reason for us not to do anything, and in terms of public reporting, HICPAC, CDC, and professional organizations, we published a guideline that has been used by States so they can start something, and we are also working with the National Quality Forum to move towards national standards in the consensus process can be used. But we are working very closely with all the States that want to do something about it, so we can at least have some common standards or some common language that we are going to follow. One concern is if we start using different definitions and different ways of collecting information, in the future it will be very difficult to assess the impact of everything that we are doing right now.

MR. WHITFIELD. Now, do you have any enforcement mechanism against hospitals at all?

DR. CARDO. We don't.

MR. WHITFIELD. Do not?

DR. CARDO. We do not. So the way we do, we work with partners and we work also with our colleagues in CMS. We work very closely also with the Joint Commission and we work with partners that can do things that we cannot. We don't have any regulatory--

MR. WHITFIELD. So it is all a partnership basis and the Joint Commission and so forth?

DR. CARDO. Yes.

MR. WHITFIELD. And do you feel like the partners that you have, the groups that you are working with, do they view this as a significant issue

as well, or do they think that there are other more serious issues that they need to deal with?

DR. CARDO. I think the good news is that we are not the only ones now who think that it is an important issue. In the past, it was CDC and the professional organizations directly involved in the prevention of healthcare-associated infections. We see that now the partnership has expanded. We have the public, we have the purchasers, and then we also have CMS being very involved in the issues, and we are working very close together. We have the Joint Commission, and the fact that we are here today and we see so many people talking about the problem and how to solve it shows that I think there is a commitment now on several levels to make a difference.

MR. WHITFIELD. And do you have a task force that deals explicitly with hospital-acquired infections or healthcare-associated infections?

DR. CARDO. Our whole division works with that, and we also have an advisory committee that is called HICPAC. It is an advisory committee to the Secretary of HHS and to CDC that has experts as part of that committee to help advise and move forward. In that committee, we have, again, the results from all the different partners that are directly or indirectly involved in the prevention of infections.

MR. WHITFIELD. Well, my time is expired. I will recognize Mr. Stupak for 10 minutes.

MR. STUPAK. Thank you.

Doctor, in your testimony, you refer--and the words have been used a lot here today—healthcare-associated infections, yet all of your statistics that you refer to refer to infections acquired in hospitals. So isn't really healthcare associated infections misleading and confusing to the public?

DR. CARDO. Thank you for giving me the opportunity to clarify that. As you mentioned before, nosocomial was a very confusing word, so we tried to move away from that because every time we said we are trying to prevent nosocomial infections, people say, what? So we really saw the importance of changing that. Then hospital-acquired infections was the terminology; however, now procedures are not just done in hospitals, they are done in healthcare. So we are seeing similar problems in long-term care, ambulatory care, so if you look at the data I provided, I said healthcare-associated infections, but in U.S. hospitals--

MR. STUPAK. Right, but are you collecting statistics for the long-term care facilities?

DR. CARDO. We are now starting the process of--

MR. STUPAK. So you are just starting?

DR. CARDO. But again, it is not just collecting statistics, but also looking at ways to improve prevention of infections in those settings.

MR. STUPAK. Well, let us talk about that because CDC has been collecting this information for 35 years, since 1970 you stated, right?

DR. CARDO. Yes, CDC started with a few hospitals.

MR. STUPAK. So for 35 years, and when you are talking about national standards, you said the time to act is now. Then you said, but we need to learn more. So does that mean we are not going to do anything? In response to the Chairman on national standards you said the time to act is now, but we need to learn more. So we don't do anything until we learn more? That is not the way it should go. It has been 35 years.

DR. CARDO. Again, thank you for the opportunity. Thirty-five years of collecting information, that has been extremely important, to even define what needs to be done, so groups like were mentioned before, Keystone and Pennsylvania, groups that we are working very closely with to see how those recommendations can be implemented and prevent infections.

Today we are focusing on the collection of information, but it is really a dynamic process and we work very close in terms of having not just collection of data, but recommendations and evaluations so we can make a difference. My reference in terms of we need to learn a little bit more is related to the development of national standards, and I think the experience we are seeing in some of the States can be very helpful for us to learn how to best implement the public reporting. That is the only thing I was referring to. I am sorry if I misled you.

MR. STUPAK. No, you are not misleading me. You have been doing this for 35 years. You worked with a small group of hospitals, about 10 percent of all the hospitals in the United States. During that time, hospital stays have become dramatically shorter, yet infection rates continue to go up. It would appear that CDC's efforts have not been very effective beyond the hospitals in your network, which is less than 10 percent. I mean, I would think that while you are collecting this information, what you just said, you are making recommendations. Since hospital stays are shorter, infection rates should be going down, but as we see, they are going up. So while you are collecting information, I don't see how you have been effective in reducing it. And I say that respectfully, but everyone is saying this is a national crisis, but I don't see where CDC has taken that underneath the same type of approach, other than collecting information.

DR. CARDO. Congressman, again, thank you for mentioning that so I can clarify that in addition to collecting information, we also have a very active program in terms of having recommendations. Those recommendations are the ones that are being implemented in Pennsylvania and Keystone, and again, the good news is although at the

national level, we may not be seeing a lot of progress, we are very happy to see that our work on a regional basis with several groups has really made a difference in terms of preventing infections.

We took the risk a few years ago of working with those in Pennsylvania, adopting the elimination of preventable infections, and that was very important in terms of showing some of the results you are going to--

MR. STUPAK. Sure, they are testifying later, and I will ask them about that.

But in the Keystone, wasn't that through Johns Hopkins University? Keystone was through Johns Hopkins, it wasn't through CDC.

DR. CARDO. The recommendations being used in the Keystone are recommendations published in the CDC guidelines and Johns Hopkins--

MR. STUPAK. Did you make these CDC guidelines available to all hospitals?

DR. CARDO. Yes, sir.

MR. STUPAK. Okay. You indicated that you had this website, and I think it is called NHSN, right, that was launched in 2005? It is a secure Internet-based system that builds on work relationships and surveillance standards developed by the NNIS. Does the public have a right to access that information for public information as to the infection rates of these hospitals?

DR. CARDO. The public has the right of assessing in aggregate fashion.

MR. STUPAK. No, NHSN.

DR. CARDO. NHSN is not a web--it is a web-based system--

MR. STUPAK. Okay.

DR. CARDO. --and we do have a website that provides information in--

MR. STUPAK. To the general public?

DR. CARDO. --how to prevent infections and everything.

MR. STUPAK. No, as to how my hospital is doing. If I want to look up my hospital, can I go to your website and find out how my hospital is doing on infection rates?

DR. CARDO. No, you cannot.

MR. STUPAK. So you collect information for 35 years and the only ones who know about it are hospitals, not the public, right?

DR. CARDO. We--

MR. STUPAK. Let me ask you this. On enforcement, don't you have a right to enforce as to hospital's infection rates, which would be something that would be serious, underneath Section 1864(c) of the Medicare/Medicaid Act, to survey and accredit hospitals participating in Medicare, and if there are allegations that suggest the existence of

significant deficiencies, such as infection, can't you withhold their accreditation for Medicare and Medicaid payments?

DR. CARDO. CMS can, and that is the reason we work with CMS.

MR. STUPAK. Well, earlier you said CMS is one of your partners here, so wouldn't that be an enforcement mechanism if you really want to drive down infection rates?

DR. CARDO. Working with CMS so they can do that, and that is what we have been doing.

MR. STUPAK. You have been doing that?

DR. CARDO. That is what I mentioned initially. The work--

MR. STUPAK. Have you ever--

DR. CARDO. --with CMS--let me rephrase. We work very closely with CMS, so the standards that CMS enforces can be used to better prevent infections.

MR. STUPAK. Okay, but has CDC worked with CMS and threatened to withhold Medicare and Medicaid payments to a hospital that had high infection rates? Have you ever done that?

DR. CARDO. We are working with CMS in the budget reconciliation bill--

MR. STUPAK. Sure, but my question is, have you ever used Sections 1864(c) to threaten a hospital to clean up its infections rates or you would withhold payments under Medicare and Medicaid?

DR. CARDO. Not as CDC.

MR. STUPAK. Okay. There seems to be some debate whether the Pittsburgh Initiative and some of the other groups have put in place very specific evidence-based practices that dramatically reduce hospital-acquired infections. We are going to hear from those folks next. But there does not seem to be debate over whether these practices work or do not work, in fact, they work quite well. Why hasn't CDC and then your partners there, the Center for Medicaid and Medicare Services, demand that these programs be instituted now at every hospital getting Federal money? I mean, you talked about Pittsburgh and we talked about Keystone here today, and you said they are good programs, so why haven't you required every hospital getting Federal money to institute these practices?

DR. CARDO. And that is the reason we are trying more and more to improve our relationships with the ones that have such authority, such as CMS and Joint Commission, so those things in the future could be done.

MR. STUPAK. So after today, you will start doing that?

DR. CARDO. No, sir, we have been trying.

MR. STUPAK. That is 35 years, though, I mean, when are you going to start trying, really start?

DR. CARDO. We are learning from the process and we have improved it, and we have been trying even more. And I think the fact that we are here today talking about it shows the knowledge and importance for the United States, not just for CDC. So I hope the fact that we are here today can even motivate other groups who have the prevention of infections as a priority.

MR. STUPAK. What do we have to do to motivate CDC to do it? I mean, seriously, I am not trying to be flippant here, but hospital stays are shorter, infection rates are up. You testified it is a dramatic thing. You have talked about other initiatives that work. We've got Mr. Murphy over here proposing that we withhold Federal payments to hospitals that don't lower their infection rates. I believe you already have that authority under Section 1864(c), so the Murphy legislation may not be necessary. And 35 years that CDC has been looking at it, and I don't see any dramatic or I don't see even a recommendation from CDC to tell hospitals, clean it up or we will enforce it. I won't be here 35 years later asking you the same questions, but--

DR. CARDO. We have had several recommendations, and we are very strong in our recommendations that prevention should be a priority and what hospitals should be doing. I agree that there is a gap between what hospitals should be doing and what exactly is happening, and that is the reason we are working with partners that have that as a priority, like the ones that were mentioned before, to show that if things are done the way they should be done, we can prevent infections and save lives. And I think this is the success of the CDC work and with all the partners engaged into this effort.

CMS is the enforcement authority with regard to hospitals, and I would be more than happy to get an answer for you from CMS and provide it for the record, because we don't want to talk on their behalf. I can say what we are doing at CDC, but I would be more than happy to get--

MR. STUPAK. The last line of your testimony says "CDC is strategically positioned to continue to provide leadership in this area." We would just like you to start and get these recommendations in and cut down on the infection rates.

DR. CARDO. I agree. Thank you.

MR. WHITFIELD. Dr. Burgess, you are recognized for 10 minutes.

MR. BURGESS. Thank you, Mr. Chairman. Dr. Cardo, thank you for being with our committee today.

Now, we keep hearing a figure of 90,000 deaths caused by in-hospital infection. Have we just developed some really strong bugs out there, or are there other factors involved here?

DR. CARDO. Ninety-thousand deaths are associated with the infections, not all caused by the infections, but you are correct that most of the infections we see now are caused by multi-drug resistant organisms. Some of them are very difficult to treat. In addition to that, some of the patients who get infections are sicker, so it sometimes also contributes to that.

MR. BURGESS. So not all the patients fit the prototype of the otherwise healthy 14-year-old boy who broke his arm on a sled; some are going to be patients with co-morbid conditions, some, in fact, receiving heroic therapy at the end of life on ventilators for long periods of time and that sort of thing? Is that a correct assumption on my part?

DR. CARDO. It is a correct assumption.

MR. BURGESS. Okay. What percentage of the hospital-acquired infections would you say would be caused from the overuse of antibiotics?

DR. CARDO. What we see is the increase, as I said, in resistance and not just in the staphylococcus like the MRSA, but also in the gram negative bacteria. And we see infections caused by multi-resistant gram negative bacteria, and most of them were related because of the transmission of infections from patient to patient, like hand hygiene, but also because of the misuse and the overuse of antibiotics.

Another problem that we are seeing as a result of the overuse of antibiotics is like the emergence of dclostridium difficile infections. They are killing more than they used to do before, and they are also affecting more people in the hospitals than they did before.

MR. BURGESS. That would be postrating dificilic infections?

DR. CARDO. Yes, so not only the problem in terms of transmitting those infections from one person to another, but the overall misuse of antibiotics really plays an important role and makes things even worse.

MR. BURGESS. Yeah, I can remember years ago the pediatrician at our hospital told us that they were primarily using cantomicin in the nursery, and they were saving genomicin because they didn't want to overuse it. The rest of us weren't saving genomicin, we were using it hand over fist. So I don't know what the pediatricians were saving it for, and I have always wondered about that.

But let me ask you this. If part of the problem is overuse and over-prescription of antibiotics by the physician, by the provider community, what do you think would happen to antibiotic use with Mr. Stupak's suggestion of withholding Medicare and Medicaid payments to hospitals where patients acquire a hospital infection? Don't you think that is going to put people in a position where they will be a little quicker on the trigger with starting the antibiotics in the IV?

DR. CARDO. I think if we prevent infections to start with, we don't need to treat the infections. I just wanted to say that because I think it is a very important message. Many times we focus on the management of antimicrobial use, and we may go in the wrong direction. I think if we prevent infection, we don't even have the antimicrobial resistance problem to deal with.

MR. BURGESS. But let me--for just a second, because if I am a surgeon or I am a physician practicing in a hospital and I do an operation and I think, oh, golly. If I get a darn post-op infection, they are going to nick me for half of my surgical fee on this, so I am just going to go ahead and start triple drug therapy at the time of surgery, rather than let the patient run a fever.

DR. CARDO. And that is when it may be a potential problem, but we also work with the institutions so they can have systems to monitor appropriate use of antibiotics, so you won't have that as an unintended consequence of the pay per performance or pay per reporting issue.

MR. BURGESS. Well, really it gets down to collecting the data and the proper use and dissemination of that data, and sometimes it does take 35 years to acquire some of the information that we have to receive.

But like most good physicians, one spinal cord synapse will generally do, don't generally need a lot of cortical input. If I don't want my patient to get an infection and I don't want to get nicked from a Medicare or Medicaid payment, I am going to start the antibiotics. I think that is just normal human behavior, and doctors are not exempt from that.

Let me just ask you a question, because we are going to run short of time. The collecting of information that can--we don't know if the statement you have in your record--and I apologize for being out of the room while you gave your testimony, but the statement is "We don't know yet if public reporting will reduce the number of infections, but we do support the collection of information." Now, we are going to hear from some epidemiologists later on and I will bet they tell us to measure is to manage, and I don't know that I will disagree with that statement, but since public reporting has been shown to be effective--well, I guess to get back to what Mr. Stupak was asking, when you identify a hospital with high rates, do you share that with the Joint Commission of Accreditation of Hospitals?

DR. CARDO. No, what we do, we call the hospital and we really work with the hospital so infections can be prevented. We cannot share that information with other institutions, but--

MR. BURGESS. Why is that?

DR. CARDO. It is because of the CDC authority. We don't have authority to do that, but we work--and I just want to mention that

monitoring--when we say collect information, it is not just collecting rates. All the information that has been collected in all these years has evolved and we have learned more and more, and lots of the recommendations that we have now are really based on what we learned from information that has been collected. We are not recommending collection of information just for collection of information, and we think it is very important, even with this movement for public reporting. And I go back to the comment that was said before, that not only are we looking at rates, but we also look at how hospitals are doing in terms of adherence to the recommendations that we know can reduce infections.

And so again, CDC is a public health agency, and we have limited authority, different than other agencies in terms of sharing information or sharing the identity of either a specific hospital or a patient.

MR. BURGESS. But if authority to share information with other agencies or other organizations, I don't know, perhaps that is something we could provide you. The silo effect there bothers me. If you have that data readily at hand, as a practitioner at a hospital that has such a problem, if my administration hasn't made me aware of it, I would very much appreciate someone making me aware of it, even if it was the CDC.

Let me go on, because I am going to run out of time here. I am a big believer in transparency, and I think, as far as our healthcare system, one of the real benefits we can give the patients is increased transparency. But I also recognize that there is a dark side to transparency. Opacity has value in some venues. What would be your opinion about the concerns you have about public reporting? Is there a downside to having these reports up and available to the public on the Internet?

DR. CARDO. At this point, we believe that public reporting can be a tool to really improve prevention, and when we talk about the hospitals that report data to our voluntary system, we believe that probably not all the hospitals are doing the same thing and following the same standards. So it could be a very good motivation for hospitals to really have more commitment and more priorities in terms of preventing infections.

MR. BURGESS. So there is no down side to the hospitals--

DR. CARDO. The down side is if we don't do it right, we may mislead people, and so I think several things were mentioned here before, and they are not just how to provide information, but provide information that is meaningful. And if we want to compare hospitals, we need to have some risk adjustment that can really compare hospitals that perform different procedures or have different types of patient populations.

So I think the main thing is we need to make sure that the information that is going to be shared is helpful and we are not

misleading. It should be information that can be used again for prevention.

MR. BURGESS. What is your opinion, not necessarily official CDC opinion, but what is your opinion of the top three things that a hospital or healthcare provider can do to prevent infections?

DR. CARDO. For hospitals, the first thing that they need to do is to have prevention as a priority for them, and to make that as a priority for every healthcare provider that works in that institution. I think that what we are seeing with several collaborations is the no tolerance, no excuse for not doing what is right, and can you really change--it is a cultural change. I think in the past we said that most of the infections were not preventable. Now, what we need to look at is each infection is potentially preventable unless proven otherwise. And when you change that, you really change the motivation that your providers, your clinicians, everyone in the institution will have in terms of following all the recommendations that we know can prevent infections. And we have seen in collaborations in Pittsburgh, in Michigan, in several groups, that when they do that, they see a major improvement in the decrease in infections.

So I think that is the main strategy. It is just do the right thing all the time, no exceptions. But leadership is a very important point to get it done.

MR. BURGESS. May I just ask one brief follow-up to that? Are there other institutional settings, such as jails, college dormitories, Army barracks where multiple antibiotic resistant bacteria are a problem?

DR. CARDO. Yes, probably all the ones that you mentioned. And we see problems in terms, again, inappropriate use of antibiotics and also transmission of those infections.

MR. BURGESS. And are you working with those institutions--

DR. CARDO. Yes.

MR. BURGESS. --as hard as you are with your hospitals? Thank you.

MR. WHITFIELD. Yes, I just have a couple of other questions.

We hear a lot about antibiotic resistant bacteria. You had mentioned it, a number of other people had mentioned it, and it is my understanding that in Europe, particularly in northern European countries, that they have been able to get their MRSA infections down to almost zero by doing active surveillance cultures of all high risk patients. And I was wondering, what is your opinion of that?

DR. CARDO. Screening patients when they are hospitalized and then isolating patients is an effective way of decreasing infections, but it is not the only way. You do need to have a comprehensive approach. I think the major issue is that you need to have people following

recommendations, like, washing their hands and following the appropriate recommendations to prevent infections all the time.

So we have some facilities in the United States that are screening patients and being successful, and others are being successful even without doing that. The main issue is to have healthcare providers following a recommendation to prevent transmission of infections all the time, because MRSA is one problem. We also see that some of the hospitals in Europe, now they are having problems with other bacteria with multi-drug resistance. So I think we need to address the problem in a more comprehensive way and really make sure that we are doing our best all the time.

MR. WHITFIELD. This is the last question. The National Quality Forum recently announced that it would be endorsing national reporting standards for healthcare acquired infections, as well as a standardized method for collecting, reporting the data. Will CDC have any involvement in that project?

DR. CARDO. Yes, we do.

MR. WHITFIELD. Okay.

DR. CARDO. We have been involved since the beginning--

MR. WHITFIELD. Okay.

DR. CARDO. --and we have helped them to draft, with other groups, what the proposals should be, and we have members of CDC participating in all the different committees. And we are also providing all the standards that we have at CDC to see if they should be the standards that are going to be considered as national standards.

MR. WHITFIELD. Does anyone have any additional questions?

MR. STUPAK. No.

MR. WHITFIELD. Okay. Well, Dr. Cardo, thank you very much for being with us today. We appreciate your testimony and hope that you will continue to maintain focus on this issue, and we look forward to working with you as we move forward.

DR. CARDO. Thank you very much for the opportunity for looking at this issue.

MR. WHITFIELD. At this time, we will call the third panel forward, and I will introduce the third panel at this time.

Mr. Marc Volavka, who is Executive Director of the Pennsylvania Health Care Cost Containment Council; we have Dr. Richard P. Shannon, who is the Chair of the Department of Medicine at the Allegheny General Hospital; we have Ms. Chris Goeschel, who is the Executive Director of the Keystone Center for Patient Safety and Quality; we have Dr. Robert Haley, Southwestern Medical School, University of Texas Southwestern Medical Center; we have Dr. Jennifer Daley, who is Senior Vice President and Chief Medical Officer of Tenet

Healthcare; we have Dr. Scott Hammer who is Chief of the Division of Infectious Diseases at the New York Presbyterian Hospital/Columbia University Medical Center; and we have Dr. Jennifer Hanrahan, who is the Chairperson of the Infection Control Committee at the MetroHealth Medical Center.

Those of you who are members of the third panel, thank you very much for being with us today. We appreciate your patience. We certainly look forward to your testimony, because you have a vast period of experience and you are on the front lines of this issue, and we really do value your input.

As you heard me discuss earlier, any time we do an oversight hearing we like to have the witnesses testify under oath. Do any of you have any difficulty testifying under oath today? And I am assuming you do not have an attorney with you today. So if you would stand--oh, you do have a legal attorney, okay. Is he going to be testifying or--okay. If you would stand and raise your right hands, I will swear you in.

[Witnesses sworn.]

MR. WHITFIELD. Thank you very much.

Dr. Hammer, it is always good to have your attorney with you, so we are glad for that.

Okay, at this time we will recognize Ms. Goeschel for your five-minute opening statement.

STATEMENTS OF CHRIS GOESCHEL, RN, MPA, MPS, EXECUTIVE DIRECTOR, MHA KEYSTONE CENTER FOR PATIENT SAFETY AND QUALITY; DR. ROBERT WARE HALEY, DIVISION OF EPIDEMIOLOGY, SOUTHWESTERN MEDICAL SCHOOL, UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER; MARC VOLAVKA, EXECUTIVE DIRECTOR, PENNSYLVANIA HEALTH CARE COST CONTAINMENT COUNCIL; DR. RICHARD P. SHANNON, CHAIR, DEPARTMENT OF MEDICINE, ALLEGHENY GENERAL HOSPITAL; DR. SCOTT HAMMER, CHIEF, DIVISION OF INFECTIOUS DISEASES, NEW YORK PRESBYTERIAN HOSPITAL/COLUMBIA UNIVERSITY MEDICAL CENTER; DR. JENNIFER HANRAHAN, CHAIRPERSON, INFECTION CONTROL COMMITTEE, METROHEALTH MEDICAL CENTER; AND DR. JENNIFER DALEY, SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, TENET HEALTHCARE CORP.

MS. GOESCHEL. Thank you, Mr. Chairman and members of the committee. Good afternoon. My name is Chris Goeschel and I am the Executive Director of the MHA Keystone Center for Patient Safety and Quality, which is a division of the Michigan Health and Hospital Association.

In 1999, the landmark Institute report, "To Error is Human" suggested that at least 44,000 people die annually in U.S. hospitals from preventable medical error. The report challenged healthcare providers to design safer healthcare systems and suggested that most errors do not result from individual recklessness, but instead are caused by faulty systems, processes, and mistakes. The MHA concluded that if the Institute of Medicine was correct, surely healthcare providers have the capacity to fix the system problems and eliminate preventable errors.

Early in 2003, the Association established the Keystone Center, whose job it is to help all Michigan hospitals translate evidence into practice. Standard strategies for our projects include creating will, building relationships, partnering with experts, using our collective voice, and being courageous. The Keystone ICU project, which I am going to talk to you about today, has nothing to do with public reporting and everything to do with eliminating hospital healthcare-associated infections. The Keystone ICU project is a collaborative project between the MHA Keystone Center, 77 hospitals, 127 intensive care units, and the quality and safety research group at Johns Hopkins University.

In October of 2003, we received critical initial funding from the Agency for Healthcare Research and Quality as one of 13 projects awarded a patient safety matching grant. The $1 million that Michigan received over two years was matched by over $14 million in cash and in-kind contributions by Michigan hospitals that participated in the project. Dr. Peter Pronovost from the Johns Hopkins University is the principal investigator for the project, and I am the director.

Our goals when we began Keystone ICU included to have 80 percent of staff in each ICU report positive safety culture, to eliminate catheter-related bloodstream infections, and ventilator associated pneumonia, and to ensure that evidence-based therapies were provided for patients on respirators. All Michigan hospitals with ICUs were invited to participate in the project. Each team was required to have a senior executive as a member of the team, and on a periodic basis, Dr. Pronovost and I sent letters to those senior executives encouraging their continued support and giving them specific tasks to demonstrate their engagement with this project.

We could not have accomplished what has happened in Michigan without our expert partners. The Johns Hopkins Quality and Safety Research Group developed the interventions that we used in the ICU

project, they supplied the supporting empiric evidence, they participated in the development and evolution of electronic data collection tools, and worked with us to analyze the data that we were looking at. Dr. Pronovost and his colleagues on the research team served as faculty at biannual workshops, led monthly conference calls with our teams, and to this day, we have weekly conference calls with those 127 intensive care units.

Part of the success of our project, we believe, is bound in the fact that we use standardized data collection. We developed measures based on CDC definitions, data collection tools that allowed every hospital participating throughout the project to be collecting the same evidence the same way, and report it on a regular basis. We gave them feedback on monthly and quarterly bases, we compared their results to aggregate State-wide improvements, and every single week we talked with them to figure out how the teams that were doing the best were accomplishing what they did.

What have we accomplished? Using a predictive model that is based on the empiric evidence and actual data collected in our project, during the first 15 months of Keystone ICU, we suggest that the ICU teams saved over 1,500 lives, 80,000 ICU days, and in excess of $165 million. By the end of the 15 months' worth of data collection that was part of the AHRQ funded project, those numbers looked at almost 1,578 lives, $175 million, and 84,000 patients' days. It is not insignificant to understand that Michigan hospitals are now paying for the opportunity to continue this important work.

Importantly, in the State of Michigan for over a year, the median bloodstream infection rate in those 127 ICUs is zero, none, nada. When we started, we were a little over the NNIS mean. We are now at zero. A bloodstream infection from a central IV catheter in one of our ICUs is a rare event and it is treated as such. It is investigated thoroughly.

How did we get there? We looked at changing the culture. Hospitals are complex networks of information, interests, and competing priorities, and changing culture is incredibly challenging work. Our explicit goal was to improve the ICU care for patients in every single hospital. We encouraged teams to share what they were learning, and they were amazingly candid in doing so. We discovered early in our project that the brightest and most motivated clinicians, even when they were presented with the evidence for changing practice, encountered obstacles that required new understanding and new skills, and so we created a change model that involved engagement, telling the stories, and creating the imperative for change. Education, providing the evidence to support the system redesign that we are asking for. Execution, providing

the materials and resources that were necessary to collect the data, and evaluation, seeing if what we were doing was really making a difference.

As we move forward today, there are a couple of key lessons that I would like to leave with you that we think have utility for the discussion that is happening here today. We think operational areas for improvement must be clearly defined and manageable. We selected the ICU because clearly one-quarter of those healthcare-associated infections that have been talked about all day, if you read the literature, those infections occur in intensive care units. If we want to go after infections, let us start where we know there are lots of them.

Clinical targets have to be equally well defined in significance in terms of the opportunity to improve, and supported by clear evidence of how to improve. We have heard today that 35 years worth of CDC data on infections hasn't changed. What we need is help in understanding how to go about eliminating the infections that data was suggesting absolutely exist. We believe in voluntary partnering. Every hospital in this State was invited to be part of this, and it was a safe environment in which to learn. We think that freedom from concern about imminent public reporting created an environment where clinicians could share openly, learn rapidly, and quickly improve care.

In Michigan, we have a long and honorable history of voluntarily reporting hospital-specific data, but for this project, we really felt it was important to get our arms around eliminating the infections. We believe that it is critically important to increase our involvement in health services research. Suggesting as the IOM did that providers could design a safer healthcare system as evidence-based assumes that there is clinical evidence on what works in the healthcare delivery, and unfortunately, the facts don't support that. As a country, we invest very little in health services research. The NIH budget last year, which is primarily dedicated to the development of better treatments for illness, was some $29 billion. The AHRQ budget, dedicated to solving delivery problems, was only $320 million. Put another way, for every dollar that Congress allocates to develop breakthrough treatments, it allocates one penny to ensure that Americans actually receive those treatments.

We believe the MHA Keystone ICU project was a powerful example of what Federal pennies can do. If additional investments were made to take what we have learned and support similar expert-led evidence-based projects throughout the country, the impact could be profound. If similar pennies were invested in funding health services research to improve delivery of surgery care or emergency care or obstetrics care, we would likely expedite the pace of measurably improved patient outcomes and save money, yet the funding stream to AHRQ remains paltry and current AHRQ research priorities are focused primarily on technology, a crucial

tool for healthcare improvement, but clearly not the only area where more research is needed.

Finally, we learned that our breathtaking results can serve as leverage for additional quality and safety initiatives. Hospital demand in Michigan is high for Keystone projects to address surgical infection prevention, and we have a project on the drawing board. Emergency department care and high-risk obstetric care are also priorities. While there are national data collection efforts in all of these areas, there are few resources to help us understand how to efficiently improve. Evidence is scarce on how we should proceed.

In conclusion, as the committee continues its work, we would encourage consideration of addressing healthcare-associated infections by focusing initially on areas where the evidence is clear and research is available on how to implement the needed changes. We favor voluntary initiatives premised on inclusiveness. We encourage additional funding for AHRQ so that research related to designing safer healthcare can be expanded. We encourage the development of funding mechanisms so that when initiatives are successful, like Keystone ICU, they can be disseminated throughout the country. We hope there will be additional research dollars allocated to support development of needed evidence on how to improve care in all high-risk, high-volume clinical settings.

Finally, we hope that the decisions regarding public reporting of infection data will reflect the complexity of identifying and attributing infections. Changing the impetus from doing good to looking good will not serve patients or the industry. The return on investment for the $1 million of AHRQ funding is clear. The Keystone ICU project is an example of the genuine improvement that can occur.

Thank you, Mr. Chairman.

[The prepared statement of Chris Goeschel follows:]

PREPARED STATEMENT OF CHRIS GOESCHEL, RN, MPA, MPS, EXECUTIVE DIRECTOR, MHA KEYSTONE CENTER FOR PATIENT SAFETY AND QUALITY

Mr. Chairman, members of the Committee and staff – good afternoon. My name is Christine Goeschel and I am the Executive Director of the Keystone Center for Patient Safety and Quality; a 501(c) (3) division of the Michigan Health and Hospital Association (MHA). The MHA is an association of 149 not-for-profit acute care hospitals in Michigan. The MHA works to promote better health within our communities; improve the quality of patient care; and improve coverage for high-quality, affordable health care services for all Michigan residents. The MHA Keystone Center is an essential vehicle for achieving the MHA mission, which is to advocate for hospitals and the patients they serve.

In 1999, the landmark Institute of Medicine report *To Err is Human* suggested that at least 44,000 people die annually in hospitals throughout the United States as a result of preventable medical errors. The report challenged health care providers to design safer delivery systems and suggested that most errors do not result from individual

recklessness, but instead are caused by faulty systems, processes and mistakes. The MHA concluded that if the Institute of Medicine was correct, surely healthcare providers have the capacity to fix system problems and eliminate preventable errors.

Michigan hospitals have a long and distinguished record of voluntarily working with the MHA and each other to address health care issues. This concern for quality and patient safety was no different. In early 2003 the association established the MHA Keystone Center for Patient Safety and Quality, to help all Michigan hospitals "translate evidence into practice." Standard strategies for project development include creating will, building relationships, partnering with experts, using our collective voice, and being courageous.

In my comments today I will describe a large and very successful voluntary effort that resulted in an unprecedented reduction in IV catheter related blood stream infections and ventilator associated pneumonias in intensive care units throughout Michigan. Then I will discuss the downstream impact of that project and the implications of the effort for health policy in Michigan. Finally, I will summarize the key lessons from our experience that we believe have broad utility.

The Michigan Keystone ICU Project

The Keystone ICU Project is a collaborative effort between the Michigan Health & Hospital Association (MHA)-Keystone Center for Patient Safety & Quality, 77 hospitals, and 127 individual intensive care units and the Johns Hopkins Quality and Safety Research Group (QSRG). In October 2003 we received critical initial funding from the U.S. Agency for Healthcare Research and Quality (AHRQ) as one of 13 projects awarded a patient safety matching grant. The one million dollars of funding we received over two years was matched by over 14 million dollars in cash and in-kind contributions from the MHA and the hospital participants. Dr. Peter Pronovost from The Johns Hopkins University is the principle investigator for the project and I am the MHA project director. The ICU improvement project received Institutional Review Board approval by the Johns Hopkins University School of Medicine.

Project Goals

The overall objective of the project is to improve ICU care in Michigan. The specific goals are to have 80% of staff in each ICU report a positive safety culture; to eliminate catheter-related blood stream infections (CRBSIs) and pneumonia associated with being on a breathing machine (ventilator) (VAP); and to ensure that evidence-based therapies for patients on ventilators are being used consistently and appropriately in each ICU.

Enlisting Hospital Participation

All Michigan hospitals with ICUs were invited to participate during the grant application process in June, 2003. Each hospital was required to assemble an ICU improvement team, and provide the MHA Keystone Center with a list of team members and a written commitment to the project signed by a hospital senior executive. At a minimum, the ICU improvement team included a senior executive, the ICU director and nurse manager, an ICU physician and nurse, and often a department administrator. Hospital senior executives were asked to ensure that the ICU physician and nurse would commit 20% of their time to the project. In addition, each team committed to implementing the specific patient safety interventions, collecting and submitting the required data in a timely manner, attending the biannual 1.5 day conferences and participating in monthly conference calls.

Importance of Experts

The Johns Hopkins Quality and Safety Research Group, as the expert partner, developed the interventions used in the ICU project, supplied supporting empiric evidence, participated in the development and evolution of electronic data collection tools and worked with MHA Keystone Center staff to analyze the ICU data. Dr. Peter Pronovost and his research team served as faculty at the biannual workshops and led the monthly conference calls. As a means to reinforce senior executive involvement, the principal investigator and I periodically sent letters to the CEOs of participating hospitals outlining the project's progress and challenging them with tasks to demonstrate continued support for their ICU improvement team. We created a manual of operations which included explicit definitions for each process and outcome measure. Standardized data collection forms were developed, pilot tested, revised and distributed to ICU teams and then converted into an electronic format. We provided ICUs with monthly and quarterly reports of performance within their ICU and compared their performance to aggregate results from the other participating ICUs.

Resources to achieve the goals

MHA Keystone staff and I interacted with participating hospitals via e-mail, phone calls and face to face visits. In the early months of the project it was not unusual to receive over 1500 emails a week. We committed to answering e-mails within a business day to keep the hospitals engaged in the work of change. I also met regularly with the Johns Hopkins University research group. A website (www.mhakeystonecenter.org) was created to provide participants access to educational materials, implementation tools, reference documents, project data (with encrypted ICU identifiers) and project updates. I provided updates to the MHA Board on a regular basis, and ICU teams were asked to provide project reports to their local management teams and senior leadership groups.

Mid-Project Results

Using a predictive model based on empiric evidence and actual data collected from project participants, the first 15 months of **the project resulted in savings of 1558 lives, over 80,000 ICU patient days, and in excess of $165 million dollars.** By the end of the 18 months of data collection that were part of the AHRQ funded project, the predictive model suggests that teams saved 1,574 lives, over 84,000 ICU days and over $175 million dollars. Infections from central IV catheters plummeted. **The median CR-BSI rate in participating ICU's has now been at zero for almost a year**. Ventilator associated pneumonia rates in the ICU's have been cut by 40%. **Forty six ICU's have gone for over six months with no ventilator associated pneumonias. Fifty seven ICU's have gone for over six months with no blood stream infections from IV catheters** .The culture of safety and teamwork as measured by the most psychometrically sound instrument in the field (and reflecting the perceptions of nearly 7,000 ICU doctors and nurses) has improved by a statistically significant margin, but still has a ways to go.

Facilitating Culture Change

Culture, simply defined is "the way we do things around here." Hospitals are complex networks of information, interests and competing priorities and changing culture is incredibly challenging work.. Since our explicit goal was to improve ICU care for the patients in every participating hospital, teams were encouraged to share their experiences and provide social support to each other. They were amazingly candid in doing so. We discovered early in our MHA Keystone ICU project that the brightest and most motivated clinicians, even when presented with evidence for changing practice, encountered obstacles that required new understanding and new skills.

We developed a change model designed to help teams navigate the system obstacles they encountered. Our model involves ***engagement*** (creating the imperative for change), ***education*** (providing the evidence supporting the system redesign being asked for),

execution (providing the materials and resources required to redesign work and ensure patients receive evidence-based interventions), and ***evaluation*** (perform rigorous data collection and analysis to determine if patient safety and clinical outcomes are improved).

What We Learned

There are several important lessons from this study that we believe are important for our interest today in understanding ways to eliminate health care associated infections and maximize the usefulness of reporting mechanisms.

1. **Operational areas for improvement must be clearly defined and manageable**. ICU was a target for us because it represents one of the most expensive and complex settings in health care, yet typically involves a limited set of clinicians with whom to facilitate the work of change. The science of safety is new; our interest in making measurable improvements demands reasonable steps.

2. **Clinical targets must be equally well defined, significant in terms of the opportunity to improve, and supported by clear evidence on how to improve**. CDC definitions for catheter related blood stream infection are clear and widely accepted. Definitions for ventilator associated pneumonia are less clear, but the range is well defined and again, well accepted by industry infection control experts. In our case, Dr. Pronovost and his research team at Johns Hopkins experts had developed tools to facilitate broad and rapid improvement.

3. **Voluntary partnering,** with an emphasis on achieving improvement in all organizations, facilitated development of a virtual learning community. The experts brought rigorous data collection methods and measurement, tools to improve care based on the measurement, and empiric evidence supporting the changes which would have been inefficient, perhaps even impossible to pursue one organization at a time. The MHA Keystone Center was a trusted, local, neutral convener. This link efficiently and effectively allowed unprecedented improvement in record breaking time, across a diverse group of ICU's.

4. **Freedom from concern about imminent public reporting creates an environment where clinicians can share openly, learn rapidly and quickly improve care**. Because the focus of the project was and is to improve care for patients, everything else became a secondary issue. Teams did not waste time explaining away less than stellar performance; rather, time was spent determining how to improve care by tapping the learning community: that is, the 126 other ICU's working on the same initiatives, using the same standardized definitions, same data collection methodologies and same tools for improvement. Michigan has a long history of voluntary public reporting of hospital specific parameters of care, always structured in a way to support consumer use. Yet, the Keystone ICU project leaders agreed that public reporting could have changed the focus from "doing good" to "looking good". Measuring and improving infection rates is clinically complicated. It would be difficult to present infection information to consumers in a way that reflects appropriate consideration in individual decision making. Instead, the focus continues to be to make the best evidence based care possible for every individual receiving ICU services in a participating hospital.

5. **Increased investment in health services research is a critical component of improving healthcare delivery.** Suggesting that providers can design a safer healthcare system that is evidence-based assumes there is plentiful evidence on "what works" in health care delivery. Unfortunately, facts don't support that assumption. As a country we invest very little in health services research. The National Institutes of Health (NIH) budget last year (primarily dedicated to development of better treatments for illness) was some $29 billion dollars. The AHRQ budget (dedicated to solving delivery problems) was only $320 million dollars. As Dr. Steven H. Woolf from the Virginia Commonwealth University stated so poignantly in his January 8, 2006 editorial in the Washington Post: "*for every dollar congress allocates to develop breakthrough*

treatments, it allocates one penny to ensure that Americans actually receive those treatments". We believe MHA Keystone ICU is a powerful example of what federal pennies can do. National estimates are that there are nearly 75,000 central line infections in ICU's each year, and some 14,000-28,000 deaths. If additional investments were made to take what we have learned and support similar expert led, evidence-based projects throughout the country, the impact could be profound. If similar pennies were invested in funding health services research to improve delivery of surgery care or emergency department care or obstetrics care, we would likely expedite the pace of measurably improved patient outcomes and save money. Yet the funding stream to AHRQ remains paltry, and current AHRQ research priorities are focused primarily on technology: a crucial tool for healthcare improvement, but clearly not the only area where more research is needed.

6. **Payers may support quality and safety improvement efforts that are evidence based, involve large cohorts of hospitals and are data driven using rigorous methods for data definition and collection**. Blue Cross Blue Shield of Michigan (BCBSM), the largest insurer in the state, recognized early the importance of the MHA Keystone ICU project. They had a pre-existing quality program in which hospitals could earn an incentive payment for achievement of specific quality improvement goals. MHA Keystone ICU was incorporated into this plan for 2004 and 2005.

Finally, we learned that **these breathtaking results can serve as the leverage for additional quality and safety initiatives.** State-wide initiatives are underway to improve stroke care and organ donation rates and a Keystone project aimed at eliminating healthcare associated infections is in the planning stages. Health policy committees of the Michigan legislature have heard presentations on our work and are enthusiastic about the efficiency and effectiveness of our voluntary effort. Hospital demand is high for Keystone projects to address surgical infection prevention, emergency department care and high-risk obstetric care. While there are national data collection efforts in many of these areas, there are few resources to help hospitals efficiently improve. Evidence is scarce regarding how to proceed.

In conclusion, as the committee continues its work, we would encourage consideration of addressing healthcare associated infections focusing initially on areas where evidence is clear and research is available on how to implement needed changes. We favor voluntary initiatives premised on inclusiveness. We encourage additional funding for AHRQ, so that research related to designing safer healthcare can be expanded. We encourage development of funding mechanisms so that when initiatives are successful, they can be disseminated throughout the industry. We hope there will be additional research dollars allocated to support development of needed evidence on how to improve care in high-risk, high volume clinical settings. Finally we hope that any decisions regarding public reporting of infection data will reflect the complexity of identifying and attributing infections, and the limited evidence on how to prevent them. Changing the impetus from doing good to looking good will not serve patients or the industry. The return on investment for the $1 million of AHRQ funding is clear. The Keystone ICU project is an example of the genuine improvement that can occur when hospitals are supported, given expert guidance, firm targets for improvement and an opportunity to learn together. We encourage further investments of this type, where the focus can be learning how to improve delivery of care and patient outcomes.

MR. WHITFIELD. Thank you. Dr. Haley, you are recognized for 5 minutes for your opening statement.

DR. HALEY. Thank you, Mr. Chairman.

I want to say, I am a convert to public reporting of infection rates. I started my career at the CDC over 30 years ago in the hospital infections

branch, doing research on this problem. At that time, it was a problem that we knew very little about. There weren't systematic definitions, there was no measurement. What we found, and I think this is a lesson for us in why we are going to do public reporting, we found that when we investigated epidemics in hospitals, we would go into a hospital and we would immediately meet resistance, particularly if we used the words "hospital-acquired" or "healthcare-acquired" and so we made up the name nosocomial to reduce the sensitivity of the doctors and the nurses and the administrators in the hospital so that they would let us in and let us help. We found that when we measured their infection rates, suddenly the resistance melted away. They saw that their rates were high, higher than they thought, and immediately people would ask, as in the Keystone project, what can we do now? But you see, the ingredients in Keystone and in all these other individual instances we are going to hear about, they are going to talk about how we took these actions and the infection rate fell. Well, how did you know the infection rate fell? It is because you had a measurement first, and the measurement then gets people interested that you can get them together and incent them to take these actions. They intervene with things they should have been doing anyway, but they didn't because they weren't measuring. You measure, they intervene, the rates go down, and you save lives and we see that over and over and over again.

We actually did a study back in the '70s and '80s where we took a random sample of U.S. hospitals, several hundred hospitals. We looked at 300,000 patients and we looked at hospitals that were doing measurement, hospitals that were not doing measurement, hospitals that were doing intensive control efforts without measurement or with measurement, and then we measured their infection rates over five years with an independent system. We found that in order to reduce the infection rates consistently over a number of years, the vital elements were you had to have measurement and you had to have control-intervention activity. You had to have both. If you lacked either one, you had no impact. That is basically still the only major controlled study that has looked at the effectiveness of any kind of quality-controlled, quality-improved intervention.

I was 10 years at CDC. I then went to Parkland Hospital in Dallas about 20 years ago, served on the infection control committee there for 20 years, and now I am on the Texas Expert Panel for designing our statewide reporting system. So the key thing is, you have got to measure. To measure is to control, as we say in infection control. What gets measured gets done.

Now, what is also interesting, I just looked on Medline the other day before I came. There are 18,000 scientific papers on the problem of

hospital-acquired infections published since 1970. It is a huge amount of research. We know a lot. We know how to do this. We don't need more research to know what to do. That doesn't mean we are going to stop research, because we can continue to improve, but there is a ton of stuff known. CDC led the way all the way through this thing. APIC, the Association for Professional in Infection Control, and the Society of Hospital Epidemiologists helped lead the way.

Here is the dilemma. We know all of this, we have had good leadership. Many of our hospitals are doing just those things that you need to do to control the infections. The problem is a lot more are not doing it, have never done it, and are not going to do it until it is mandatory. That is just the way it is. Up until about a year ago, I would have said no, we don't want to make this public because then we will alienate the hospitals and they won't participate. And then Lisa McGifford and the Consumers Union came forward and started this movement among States and legislatures, and suddenly it occurred to me, you know, it has been 30 years, as Representative Stupak said, it has been 35 years and we have been waiting for the hospitals to all do it, and they didn't do it. And now the Consumers Union is leading a movement to make this public. It is time. Then we said it is time, and then we found who were our best collaborators, it was the Texas Hospital Association. It was the Hospital Association saying yeah, let us do it. Nobody was opposed to it.

The real question is how do you do it? And there is a big argument going on now. It is sort of a clandestine argument. Is it process measures or outcome measures? There is a big movement, particularly at CMS, let us measure process only because it seems easy to measure and it seems like, it is really closer to the prevention effort. I would submit to you that it is going to have no impact. Remember the big study I talked about, it is called the Scenic Project. Unless you have outcome measurement and process intervention, if you weigh out both of those, it is not going to work. If all you are going to do is measure process, you are going to have process intervention with no outcome measurement, I guarantee you there will be no--but that is the way the country is moving. I am going to predict that the National Quality Forum, that is what they are going to come down heavy on because it is easy to do, seems easy to do. The reason it seems easy to do, we have never done it very much. We know all the problems with outcome measurement because we have done it a lot.

Now, why did I really convert? Partly it is why I mentioned, but the other thing is we have been doing so much measurement in so many hospitals for so long, the sensitivity over it is gone. Hospitals are no longer concerned about their infection rates and somebody knowing

them. That sensitivity has gone away because we have done it so much, and so we are not seeing a push back by the hospitals and the hospital organizations.

Okay. Now let me point out, there are three big problems with measurement, and the devil is in the details and here they are.

For 30 years, we have learned gradually how do you do this, and there are some lessons. First of all, you can't just do something that is easy. You can't just put the numbers of infections up there on a website. You know what that is going to do? It is an easy number and the consumers would love it because it is easy to understand, but when you just look at the numbers and not the percentage rates, you are going to actually steer the patients to the worst hospitals, not to the best ones, because--and the same thing with risk adjustment--if you just show the hospitals the raw infection rates without risk adjustment, what you are going to do is end up sending them to the worst hospitals, not to the best hospitals. And also, just the issue of rates themselves--I am sorry. The completeness of measurements themselves, the hospitals that do the least effort, put the least effort into measuring their infections will detect the fewest. Their infection rates will be lowest, they will look the best, and then those rates will direct the patients to the worst hospitals, the ones that aren't trying. They are not measuring, and thus not controlling.

And so you see, as we designed this we have got to get it right and do the things that we worked out in these 18,000 articles over the last 20 years, and not just take some easy path because it looks easy and looks inviting. We have got to do the research into what really works.

Now, let me end up sort of talking about Texas. Our Texas system--

MR. WHITFIELD. Please summarize.

DR. HALEY. Yeah, that is what I am going to summarize.

Basically, in Texas we are going to take the hard road. We are going to measure the hardest things to measure, which is surgical site infection rates in a very high percentage rate of our operations, not just in a few clean ones, but most of them. It is going to be a real tough job. We are also going to measure infections in ICUs. We are going to do rates, we are going to do risk adjustment. And the Texas Department of Health, our health department, we are going to collect the data ourselves. We are not going to have our reports go to CDC because if we collect the data ourselves, we can do the quality control on it. We can get patient's names because when you have a State law mandating it, you then are free from HIPAA and a lot of the legal entanglements.

Then what are we going to do when we clean the data and get it all ready? At the end of the year we are going to ship it to CDC for the research process so they can aggregate the data. But we think that is the model and where we are going in Texas. So I think the bottom line is

measurement is important, just as process activities are important. You have got to have them both. Most hospitals are not measuring worth a darn, and we need mandatory reporting, but at this point, it should be a State activity, and as several people have said earlier, we need various States to experiment and find out what is the way to do it. And then, at that point, we need a National Quality Forum to do it. I think it is too soon to have a National Quality Forum looking at it. Certainly, you don't want Federal legislation. We want the States to experiment and learn from it.

That is my comment.

[The prepared statement of Dr. Robert Ware Haley follows:]

PREPARED STATEMENT OF DR. ROBERT WARE HALEY, MD, DIVISION OF EPIDEMIOLOGY, SOUTHWESTERN MEDICAL SCHOOL, UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

Good afternoon, members of the Subcommittee on Oversight and Investigations. I thank you for this opportunity to come before you today to discuss the critical issue of public reporting of hospital-acquired infections, also referred to as healthcare-associated infections, nosocomial infections, or simply hospital infections.

I should point out that I am a convert. For 30 years I have performed research on this problem and pushed hard for hospitals to measure their infection rates and use the information to reduce their infection risks of their patients, but not to report them publicly. But when Lisa McGiffert and the Consumer's Union started this national movement for public reporting, they created a new perspective that has caused me, like most experts in the field, to rethink my position and now to become a strong supporter of public reporting.

In 1973 right out of my medical residency, I joined the U.S. Public Health Service as an officer in the Epidemic Intelligence Service at CDC and ended up serving there for 10 years. I worked in the Hospitals Infections Branch, a small unit doing the early studies on what then was a newly emerging disease problem in hospitals, about which no one knew very much. During my 10 years there, I worked full time in research on the problem, developing definitions for the infections, methods of measuring them, and ways of using the measurements to reduce the infection risks. There I directed a national study called the SENIC Project (Study on the Efficacy of Nosocomial Infection Control), in which we studied a representative sample of U.S. hospitals to determine what approaches actually lead to reductions in hospital infection rates. In that project, we studied over 300,000 patients in several hundred hospitals all over the country and found out what works. This remains the only study ever to test whether quality improvement programs are effective.

We found that measuring the hospital infection rates and then using those rates to direct control measures led to large reductions of the infection rates over 5 years; whereas, in hospitals that did not measure infections rates, the rates either did not change or went up over the 5 year period. In other words, we proved the old saw "*what gets measured gets done*," or as we say about hospital infections, "*To measure is to control.*"

From this finding and other scientific information, CDC recommended that all hospitals voluntarily measure their infection rates to reduce them to the irreducible minimum. Subsequently, CDC and other researchers have done extensive research into how to do the measurements so as to get the biggest impact in reducing infection risks. In a computer literature search, I found over 18,000 scientific papers on the

epidemiology, prevention and control of nosocomial infections since 1970. So you can see that there has been a tremendous amount of research focused on this problem, and one of the main findings is that certain types of measurements of infection rates has a powerful impact in reducing infection risks to patients.

The good news is that, in the past couple of decades, many hospitals have adopted these recommendations and have reduced their infection rates substantially; the bad news is that another sizeable group of hospitals have not adopted this approach.

Years ago hospitals were very defensive about infection rates. We were very concerned that releasing infection rates publicly would lead to obstruction of infection rate measurements within the hospitals and paradoxically to *increasing* infection risks for patients. But over the years, as measurement became routine—and useful—in many hospitals, the defensiveness has declined. So when Lisa McGiffert and the Consumers Union began pushing for public reporting, we encountered little objection from hospitals, and instead we saw a way to get all hospitals doing the types of measurement they should have been doing all along. That's why I became a convert.

However, there still are some scientific problems with reporting hospital infection rates to the public that must be addressed in the state reporting systems. These problems are real. If not addressed, they could cause public reporting to have unintended negative consequences for patients. And these problems are what well meaning critics of public reporting cite as the basis for their opposition. Let me trace several of them.

First, there is the problem of accuracy in identifying the infections. These infections are hard to discover. An expert infection control professional must apply standardized definitions. Many infections occur after the patient goes home. If you just rely on the discharge codes assigned by a clerk in the medical records department, you will miss and make many errors. Codes depend on what has been documented, but the information is written by the physician in a way that considers important infection criteria. The effect is that hospitals that do the best job will have higher infection rates than those who give it little effort or who rely on clerks not trained in infection control, and so the publicly reported data would tend to direct patients to the more careless hospitals rather than to the careful ones who are reducing their infection rates.

Second, many consumers and advocates want very simple numbers of infections that they can understand without much thought or study. Experts are rightly concerned about this because simple numbers are misleading. Let's take a simple example: suppose one hospital in town has 25 to 30 surgical infections per month, and the second hospital has twice as many, 50 to 60 surgical infections per month. The consumers would understand these numbers easily and would decide to go to the first hospital because it has fewer surgical infections. But suppose the first hospital performed only one-quarter as many operations as the second. This would mean that the actual risk of infection after surgery would be twice as high in the first hospital. Again, the simple numbers would appear easier to understand but would lead the consumers to a much higher risk hospital. The solution to this problem is to report *rates* of infection—the number of infections divided by the number of operations, a percentage—rather than simple numbers of infections. It takes a little thought to understand a percentage instead of a number, but it gives the consumer a truer measure of the risk in different hospitals.

Third, a more subtle, but equally serious problem is with differences in the intrinsic risk of the patient mix in different hospitals. Suppose that two hospitals perform the same number of operations each month but the first hospital does mainly elective hernia operations and coronary bypass operations on stable business executives, and the other hospital is a level 3 trauma center operating on gunshot wounds to the chest and abdomen and people with fresh heart attacks. The surgical infection rates in the second hospital will be several times higher than those in the first hospital, but it is likely that the surgeons in the second hospital have better outcomes when you compare apples to apples. Again, consumers seeing simple infection rate comparisons might choose the first

hospital for their coronary bypass operation even though their chance of a complication might be far less in the second hospital. The solution to this problem is to apply what's called a *multivariate risk index* to level the playing field on the underlying risk of infection—that is to compare apples to apples. I developed the first index for this purpose, and now a modified version of this, called the NNIS (National Nosocomial Infection System) Risk Index, is used all over the world. Again, it takes a little more thought to understand, but it gives the consumer a truer measure of the risk in different hospitals.

From these examples, you can see why well meaning experts would oppose public reporting without the qualifiers I've just described. Today that opposition exists because rightly concerned consumer activists want simple information on their healthcare facilities. This information will end up misleading those very consumers, directing them to the riskiest hospitals rather than to the safest ones, rewarding the hospitals with lenient infection control programs and penalizing the most vigorous programs.

Right now a number of states are developing statewide public reporting systems and trying different approaches. I am a member of the expert panel appointed by our Texas state legislature to design our state system. We are putting together a plan that will require all Texas hospitals to perform the type of risk-adjusted infection rate measurements that will translate into reduced infection risks, and then they will upload their datasets to the Texas state health department as a byproduct of doing what will control their infection risks. We are not going to create some simplistic administrative activity that takes our infection prevention and control professionals away from productive measurement. The data, the state of Texas intends on reporting publicly will be the most meaningful information for consumers to consider in assessing the safety of different hospitals.

I understand that thirty-four other states have introduced, considered or passed bills for public reporting. Some states are planning to have their hospitals' infection prevention and control professionals submit their data to the CDC network which may or may not be reported to their state and then to the CDC. The National Quality Forum is going to develop consensus standards which may not address *how* data is collected and reported.

In Texas, we are going to handle the whole thing within our state and then provide CDC with our collective data for research purposes.

I personally am not in favor of mandating reporting of infection rates on all states until additional research and methods have been tested and proven. I think the various state legislative initiatives will provide information on what works best, and then a national consensus may take shape naturally. There is much to learn in this early stage from a diversity of state experiments.

Above all, the scientific evidence is clear. Measurement of infection rates is an essential component of controlling the infection risks in a hospital. *What gets measured gets controlled.* Sophisticated measurement approaches, including risk adjustment, can make the process valid and insightful. Overly simplistic approaches, while immediately attractive, are regressive for controlling infection risks and misleading to consumers. I see both industry leading organizations such as APIC (Association for Professionals in Infection Control and Epidemiology), SHEA (Society for Healthcare Epidemiology of America) and the Consumers Union playing constructive roles in driving this movement in a productive direction at the state level, where it should remain focused for now. I expect that the movement will eventually lead to meaningful reduction in hospital infection risks as well as to better informed consumers.

MR. WHITFIELD. Thanks, Dr. Haley, and we want all of you to be enthusiastic and keep these opening statements within 5 minutes.

Mr. Volavka, you are recognized.

MR. VOLAVKA. And I could do it real quick by saying I agree with him, with one exception, and I think we know where that is going. I think we would have some discussion on risk adjustment. But I deeply appreciate the opportunity to be here, and there is a slide presentation that should be up.

I am going to start with a riddle. When is a surgical site infection a surgical site infection, and the answer is when the hospital puts them on a bill and sends them to the third party payer to pay.

Riddle number two: When is a surgical site infection not a surgical site infection? The answer is when PHC4 is doing a public report.

I have already given you my written remarks, but there are six key points I would like to make. The first one that I think is most compelling is that hospital-acquired infections are deadly. This is data based upon Pennsylvania's collection. For every 1,000 patients who get a hospital-acquired infection, 130 die. For every 1,000 patients that do not get a hospital-acquired infection, 24 die. What that means is 104 additional deaths for every 1,000 patients. In other words, if you get an infection in the hospital, the odds that you will die during that hospitalization are 5.41 greater than if you don't. I don't like those odds. Nationally, on the basis of all underreported data, this translates to 40,000 additional deaths. That is approximately 110 people per day. If 110 people per day were dying from the bird flu, I think we would be calling that an epidemic.

Second, the cost of hospital-acquired infections is staggering. The statewide average payment, real dollars checks, for a patient hospitalized, absent an infection, in Pennsylvania, is $8,000. The average payment for a patient in Pennsylvania hospitalized with an infection is $60,600. That is a $54,000 difference, payment, real check. And this pie chart will tell you in Pennsylvania who is paying most of that bill. Medicare, 68 percent of the infections reported in Pennsylvania. The taxpayers of this country are paying this bill, and I humbly suggest that they are paying it in 49 other States as well.

The cost of hospital-acquired infections continues to place an already financially shaky healthcare system at greater jeopardy. Now, we cannot improve what we do not measure. I absolutely agree with that, and I just have to take some issue with the CDC. This is Representative Stupak's point. This is 20 years of CDC. Patient days are down, lengths of stays are down, surgical things are down. The incidences of infection is up by 36 percent. This is from the New England Journal of Medicine. Now, this same journal at the same time said in its editorial, "If collecting data in isolated hospital areas represents best practice, when two million Americans develop a hospital-acquired infection resulting in 90,000 deaths and $5 billion in costs, then best is just not good enough."

Hospital-acquired infections are preventable. With patients, payers, and providers all losing out, it is hard for me to understand why there is still so much debate surrounding this point. Hospital-acquired infections are not inevitable, nor should they be expected.

For years, there has been a so-called myth of inevitability, that is, the hospital-acquired infections are inevitable byproducts of providing hospital-based care. Too often, blaming inevitability instead of bringing some control and standards to current chaos is the norm. Hospital-acquired infections should not be about placing blame or fault. However, they also should not be about masking their existence behind statistical methodology, like infections per 1,000 line days and language like nosocomial that only the experts can understand and explain. We need to get some of the most dedicated people I have ever met, the infection control professionals, out of the data collection business and onto the floors and into the patient rooms where they can do what they are trained to do. We need to provide them with the resources to support them.

Don't let the perfect be the enemy of the good. While I believe, like the New England Journal, that the best has been problematic, I do not believe that data needs to be perfect, particularly when it comes to data collection and public reporting, we don't need pine needle detail, data perfection, or epidemiological purity to shine light on a problem. Those who argue about needing perfection before we publicly report miss both the light and the point. Sometimes sunshine is the best disinfectant.

Public reporting works. Public reporting is the first step and not the only step in measuring the extent of the problem and the effectiveness of solutions implemented. Public reporting does change behavior.

With that said, my final message today is that the States have historically been and continue to be the incubators for innovations and solutions, and as such, their role in transforming the Nation's healthcare system needs to be engaged and enlarged. In testifying before the U.S. Senate two weeks ago, Paul O'Neill said, "Unfortunately, the Federal government rarely sets performance targets at all, let alone setting them at the theoretical limit of human attainment. The result of not insisting on the elimination of fundamental problems with the performance of the healthcare system is more of the same or worse." I believe Mr. O'Neill was right. States need the flexibility and the Nation benefits when States are encouraged to experiment with solutions that may work toward the common goal, while recognizing the unique socioeconomic and political environments that vary dramatically among the 50 States.

Rather than setting a single standard on the whats and hows of data collection, what Congress can do best is establish performance targets and goals and then provide incentives the States can use. If Congress

said simply and clearly in 5 years, the goal of our healthcare delivery system should be to eliminate all hospital-acquired infections, and in 5 years, Medicare will no longer pay for any hospitalization in which a hospital-acquired infection occurs, I humbly suggest the goal of patient safety that we all share would be transformed into action virtually overnight by a hospital and physician community. There could be no more noble or compelling issue for Congress or the Nation to tackle.

Mr. Chairman, with all due credit to a former Member of this august chamber, I would like to close with the following observation. I think we all agree that this is an elephant, and I think we all agree that this is a mouse. And since Pennsylvania began its path of recording, I have been accused more than once of seeing pink elephants where none exist. But to me, this is a pink elephant, and yet those who argue for scientific purity and epidemiological perfection might challenge me and say no, that is an inference, not a fact. That could just as easily be that mouse you just showed with a glandular condition because of the metal he was eating. Well, when it comes to hospital-acquired infections, Mr. Chairman, to me, and I think to virtually every citizen of this country, it really doesn't matter if you call it a pink elephant or a mouse with a glandular condition, because on this one, the public gets it. They know hospital-acquired infections are bad. They know they don't want one. They know they don't want their family or their friends to get one, and they know that if they must be hospitalized, they would like to have information about the facilities in their area that have the lowest possible number.

They get it, Mr. Chairman, and on this issue, what they actually get is they don't want to get it. I think it is time to stop, to roll up our sleeves, stop wringing our collective hands, and start washing them.

Mr. Chairman, on behalf of the Governor and the General Assembly of Pennsylvania, my council members who set our policy in direction, and the incredibly dedicated staff of my tiny little obscure State agency, I humbly thank you for the privilege and the honor of testifying here today.

[The prepared statement of Marc Volavka follows:]

PREPARED STATEMENT OF MARC VOLAVKA, EXECUTIVE DIRECTOR, PENNSYLVANIA HEALTH CARE COST CONTAINMENT COUNCIL

- Pennsylvania began collecting data on hospital-acquired infections in January 2004. Almost every state has the capability to establish a reporting system based on Pennsylvania's model.
- The Pennsylvania Health Care Cost Containment Council (PHC4) has found that the patient safety and financial impact of hospital-acquired infections is larger than originally reported. During the first nine months of 2005,

Pennsylvania hospitals confirmed more hospital-acquired infections than for all 12 months of 2004.

- Hospital-acquired infections are deadly. You are over five times more likely to die during a hospital admission in which you acquire an infection than if you don't.
- The costs of hospital-acquired infections are staggering. Payment data suggests that, on average for commercially-insured patients, there was a $52,600 difference between hospital admissions in which the patient acquired a hospital-acquired infection and one in which the patient did not.
- Hospital-acquired infections are not inevitable, nor should they be expected. Simple and effective methods, such as hand washing, using gloves, and properly sterilizing equipment, can dramatically reduce and/or eliminate hospital-acquired infections.
- We cannot improve what we do not measure. Requiring the collection and publicly reporting of data are two steps in measuring the extent of the problem and identifying solutions.
- Don't let the perfect be the enemy of the good. When it comes to data collection and reporting on hospital-acquired infections, the data need not be perfect. In fact, we ultimately need to find ways to get infection control professionals out of the data collection business and into the business of finding and preventing hospital-acquired infections.

Mr. Chairman and Members of the Committee:

Good afternoon, my name is Marc P. Volavka, and I am the Executive Director of the Pennsylvania Health Care Cost Containment Council. I am honored to have the opportunity to address this Committee today and to talk about the importance of publicly reporting hospital-acquired infections.

Last summer, the Pennsylvania Health Care Cost Containment Council – often referred to by its acronym, PHC4 – issued a landmark report on hospital-acquired infections. Thus, Pennsylvania became the first state in the nation to put some hard figures around the incredible burden of these infections.

While we expected to receive some attention, we were, quite frankly, astounded by the firestorm of debate that tiny, four-page report caused. Since our first report, PHC4 has issued two additional briefs on hospital-acquired infections, one of which has just been released today.

Data Collection and Reporting in Pennsylvania

I thought I should begin by giving some background on Pennsylvania's data collection process. I also think it is important to set the record straight about what PHC4 did and did not report in our groundbreaking Research Brief. First and foremost, despite what some have said, we did not use "billing data" to identify hospital-acquired infections. The infections listed in our reports were identified, submitted and confirmed by Pennsylvania hospitals.

To define hospital-acquired infection, PHC4 adopted, with minor clarifications, the Centers for Disease Control and Prevention (CDC) definition: *an infection is a localized or systemic condition that 1) results from adverse reaction to the presence of an infectious agent(s) or its toxin(s) and 2) was not present or incubating at the time of admission to the hospital*. Essentially, what this means is: you didn't come in with it, and you got it in the hospital. Frankly, this is not a difficult concept to grasp.

PHC4 also adopted the CDC's 13 major site categories that define the hospital-acquired infection location, and expanded the list of 13 to include a category for multiple infections and to differentiate device related and non-device related infections. We then redefined a two-character data field (Field 21d) on the *Pennsylvania Uniform Claims and*

Billing Form, which is submitted along with administrative and billing data for each inpatient hospital admission. Hospital personnel enter one of a defined set of codes into this field when the relevant hospital-acquired infection is present. Almost every state in the nation is already positioned to use the uniform billing form in a similar manner.

In Pennsylvania, data collection began in January 2004, and hospitals were required to submit data to PHC4 on four types of hospital-acquired infections: surgical site, urinary tract, pneumonia, and bloodstream infections. The data collection requirements were gradually expanded over a period of several quarters, and as of January 2006, Pennsylvania hospitals are now required to submit data on all hospital-acquired infections.

So what did PHC4's first report on hospital-acquired infections reveal? In 2004, Pennsylvania hospitals confirmed 11,668 hospital-acquired infections. The hospital admissions in which these infections occurred were associated with an *additional* 1,510 deaths, 205,000 *extra* days of hospitalization and $2 billion in *additional* hospital charges. While these numbers are certainly shocking, what is chilling is that the figures were underreported – just the tip of the iceberg. PHC4's most recent report released today, which looks at only the first three quarters of 2005, underscores that the problem of hospital-acquired infections is larger and more costly than originally estimated. It also highlights the difficulty in getting a standard, consistent and understandable form and format to identify and collect this information.

During the first nine months of 2005, Pennsylvania hospitals confirmed and reported 14,526 hospital-acquired infections. If the reporting trend continues for fourth quarter, we will approach 20,000 identified HAI's for all of 2005.

13,711 of the 14,526 are identical to the 4 categories that were confirmed and reported in 2004 -- the 11,668 figure. The hospital admissions in which these 13,711 infections occurred were associated with an additional 1,456 deaths, 227,000 extra hospital days and $2.3 billion in additional hospital charges.

Hospital-acquired Infections Are Deadly

While I think all of this background is important, there are really six key points I would like to make today based on Pennsylvania's public reporting experience. The first, and perhaps most compelling, is that *hospital-acquired infections are deadly*.

As I previously mentioned, based on only nine months of 2005 data from Pennsylvania hospitals, the hospitalizations with hospital-acquired infections were associated with 1,456 additional deaths. Extrapolated nationally, this translates to almost 40,000 *additional* deaths annually. That's approximately 110 people per day dying nationally. If 110 people were dying daily from the Bird Flu, I think we'd be calling that an epidemic.

While I hate to throw out too many numbers because real people and real lives are at the heart of this issue, a comparison of the mortality rates of patients with and without hospital-acquired infections is also eye-opening. Of the 13,711 Pennsylvania patients with a hospital-acquired infection in first nine months of 2005, 13 percent died, compared to 2.4 percent of patients who did not contract such an infection. What that means is, you are over five times MORE likely to die during a hospitalization if you get an infection, than if you don't. Those aren't good odds.

The Costs of Hospital-acquired Infections Are Staggering

Just as hospital-acquired infections are a major patient safety issue, their financial implications are staggering, which brings me to my second point. The cost of hospital-acquired infections continues to place an already financially shaky health care system at greater jeopardy. Through insurance premiums and tax dollars, Americans are spending exorbitant amounts of money on these infections, which are, in almost all instances, preventable.

Again, based on only nine months of 2005 data, the hospital admissions in which these infections occurred were associated with $2.3 billion in additional hospital charges, just in Pennsylvania. Extrapolated nationally, the total would reach $46 billion.

As our research brief issued today identifies, Pennsylvania has also become the first state in the nation to put hard numbers around actual payments. Pennsylvania received actual payment data from third-party commercial insurers and matched it to the hospitalizations for 2004 in which the reported hospital-acquired infections occurred. In 2004, the average payment – that is the actual payment, not charge – for a hospitalization with a hospital-acquired infection was $60,678. The average payment for a hospitalization without a hospital-acquired infection was $8,078.

This data shows that, on average, there was a $52,600 payment difference between hospital admissions with and without a hospital-acquired infection. As a result, we estimate additional insurance payments to Pennsylvania hospitals from the private sector, Medicare and Medicaid at $613.7 million for the 11,668 hospital-acquired infection cases in 2004. To extrapolate for all of 2005, with the assumption that payments did not change at all (not a solid assumption) we estimate that payments made to hospitals for patients who get a hospital-acquired infection will be over $1.2 billion in Pennsylvania alone. That would be $24 billion in payments nationally. And, this is only the hospital portion of the payment. It does not include the additional physician payments, or the ongoing care many of those patients need, if they are the lucky ones who survive the infection.

This is a major concern to Pennsylvania businesses and labor unions that pay insurance premiums through the commercial market and to public sector programs. It also contradicts those who say there is no low-hanging fruit in health-care cost savings left to find.

Now, as compelling as these numbers are for the health care purchasers paying the tab, there is an equally compelling business case for hospitals to prevent hospital-acquired infections. While hospitals get paid, on average, seven times more for a patient that acquires an infection, work done by Dr. Richard Shannon, under the auspices of the Pittsburgh Regional Healthcare Initiative, and continued by others, indicates that the cost of treating these infections far exceeds the extra payment received. I believe Dr. Shannon will testify more on this point, so I will leave that to him.

Hospital-acquired Infections Are Not Inevitable

With patients, payers and providers all losing out, it is hard to understand why there is still so much debate surrounding my third point. *Hospital-acquired infections are not inevitable, nor should they be expected.* These infections can be prevented. For years, there has been this so-called myth of inevitability – that is, hospital-acquired infections are the inevitable byproducts of providing hospital-based care. This myth has persisted despite the fact that simple and effective methods, such as hand washing, using gloves and properly sterilizing equipment, can dramatically reduce the incidence of hospital-acquired infections.

Too often, blaming "inevitability", instead of identifying and correcting poor processes of care, is the norm. Hospital-acquired infections should not be about placing blame or fault, with either patients or providers. However, they also should not be about masking their existence behind statistical methodologies like "infections/1000 line days" and language like "nosocomial" that only the "experts" could understand or explain. When talking about hospitals, if you didn't come in with it, and you got it in the hospital, to me, that's a hospital-acquired infection.

The new moniker; "healthcare-associated infections", concerns me, because it has the potential to blur and soften the implications of, and the solutions for, infections acquired while hospitalized.

We Cannot Improve What We Do Not Measure

Of course, finding solutions is ultimately what we should be about. That is why PHC4 has a history of public reporting. We cannot bring attention to problems that see no light. *We cannot improve what we do not measure.*

Obviously, not all of the feedback PHC4 has received with respect to its publicly reporting hospital-acquired infections has been positive. One of the criticisms we have received is that our public reporting about this deadly issue does not help to improve care. In fact, we have heard over and over again from industry officials that *reporting* infection rates is not the same as *reducing* infections. Well, on that point, I agree. But, if you don't collect data, you can't identify the problem; and if there is no public accountability, where is the incentive to provide solutions?

After PHC4's first report was issued, one of our critics said, "There is no evidence to support the public disclosure as a means to reduce the incidence of these infections." My response to was that he was only half right.

There is no evidence to support public disclosure because *public disclosure of hospital-acquired infections has never been done – until now.*

We have also been cautioned about the potential consequences of mandatory reporting for hospital-acquired infections. It has been argued that such mandatory reporting may deflect resources from patient care and prevention, mislead stakeholders if inaccurate data is published, and cause some physicians to avoid treating sicker patients. This theme – "the unintended consequences of public reporting" – has been repeated in the recent literature on public reporting.

Let me address this issue head on.

First, while there may not be any evidence yet that public reporting DOES help reduce the incidence of hospital-acquired infections, I would humbly suggest there is ample evidence that the way we have been doing business over the past 30 plus years, which has relied heavily on private, voluntary, non-public collection and analysis of data by the CDC is NOT working.

In an article published in the *New England Journal of Medicine* in 2003 they reported that nationally between 1975 and 1995:

- The number of patient days decreased by 36.5%
- Lengths of stay decreased by 32.9%
- The number of inpatient surgical procedures decreased by 27.3%
- The number of infections decreased by 9.5%

However:

- The incidence of nosocomial infections per 1,000 bed days increased by 36.1% (*New England Journal of Medicine*, 348:7, 2003)

It was ***these*** statistics that caused the *Journal* to publish the following remarks in its editorial:

> "If collecting data in isolated hospital areas represents "best practice" when 2 million Americans develop a hospital-acquired infection, resulting in 90,000 deaths, and $5 billion in cost, then best is just not good enough." (*New England Journal of Medicine,* 348:7, 2003).

To echo the title of today's hearing, PHC4 believes that public reporting ***IS*** about saving lives and money by empowering consumers and purchasers of health care benefits. Public reporting is the first step in measuring the extent of the problem and the effectiveness of solutions implemented. Public reporting changes behavior. The best

scientific evidence of this is the most recent study done by Dr. Judith Hibbard, and published in the July/August 2005 issue of *Health Affairs*, indicating that hospitals that were publicly reported on in Wisconsin had significant quality improvement the following year – while those that were NOT publicly reported on, and that had only private feedback, or no feedback at all, showed little, if any, improvement.

And with respect to hospital-acquired infections, PHC4 believes that by providing objective, comparative data to the public, both patients and third-party payors can make more informed decisions about choosing a hospital and our hospitals themselves, with heightened awareness of the seriousness of this issue, and with the potential for public accountability, will more rapidly implement better and more contemporary infection control practices.

PHC4 works under the philosophy that the public reporting of health care data is the policy approach that saves the most lives and best stimulates quality improvement. This philosophy is, in fact, consistent with the Administration's current goal of increased health care price and quality transparency. And the case for public reporting can be made by several PHC4 achievements. For example, since PHC4 began publicly reporting patient mortality rates for Pennsylvania hospitals, these rates have dropped from significantly above the national average in 1993 to significantly below the national average in 2003. Similarly, mortality rates for coronary artery bypass graft surgery in Pennsylvania have dropped 48% in the past ten years, mirroring the years of public reporting by PHC4. And, Hannan, Chasen et al, demonstrated that in the case of the two states that had been publicly reporting on CABG mortality the longest, New York and Pennsylvania, the decrease in CABG mortality was significantly greater that that experienced across the nation at large. (*Medical Care*, 2003).

One of the other criticisms I would like to address is the rhetoric of the "meaninglessness" of our data, perhaps best articulated in an August 2005 *Governing* magazine article:

> "Put out these gross statistics and people get all alarmed, but what are they going to do with this data? If you think hospitals are going to scramble and fix it, then maybe, but I don't think that's what will happen. I think they will look at the data and call it what it is — meaningless."

Meaningless? To whom?

The following letter to the editor appeared in the July 29, 2005 issue of the *Pittsburgh Post Gazette*:

> I was interested in reading about hospitals and infections ("Alarms Raised on Hospital Infections," July 12). My husband went into one of the large hospitals in the Pittsburgh area for a heart catheterization and was told he needed open-heart surgery. I spoke with the surgeon after the operation and was told that the operation was a success. After about four days of intensive care, I saw a new bag hanging beside the bed and asked why and what for. I was told he had an infection and needed an antibiotic. I asked how did he get an infection. The reply was "Everyone thinks that hospitals are the cleanest places in the world, but they are not." My husband died on the 12th day in the intensive care unit. Remember the old saying, "The operation was a success, but the patient died"? How true."
>
> ELINOR ROGERS McGINN
> Churchill

And, on July 18, 2005, Frederick K. Miller said:

> "I am glad to see a state agency doing its job! My wife had three operations. The Dr. did not address her infection for a year after surgery. She got the infection at a local hospital. There is a low staff of nurses. I had several relatives get an infection at the same hospital. One of them died."

While I take issue with the notion that our data is meaningless, I am cognizant of the fact that the data on hospital-acquired infections needs to be improved, and made both meaningful and actionable.

And, with all due respect and deference to the CDC, what is currently viewed as the national standard for gathering information on hospital-acquired infections – the National Nosocomial Infections Surveillance System (NNIS) and the definitions and guidelines that it uses – does not meet the mark. This voluntary system has operated for over 30 years, involves data collection which is not comprehensive, consistent or comparative and, for the most part, is not publicly available.

In a study of the NNIS data collection/reporting, conducted by the Centers for Disease Control and Prevention itself, and subsequently reported in a 1998 issue of *Infection Control and Epidemiology,* three separate groups of infection control experts reviewed 1136 patient charts in order to determine the consistency, objectivity and credibility in using such a surveillance system for identifying hospital-acquired infections. After a review of the charts, results from abstracters at nine NNIS participating hospitals indicated **611** infections were present. A second group of trained reviewers evaluating those same patient charts found 474 out of those 611 infections reported were in fact, hospital-acquired infections, but also found 790 additional infections not reported by the hospital, for a total of **1264**. Finally, in a review of the charts by CDC personnel themselves, 525 out of the 611 were identified as hospital-acquired infections with an additional 340 infections not reported for a total of **865** total infections.

The study, in my eyes, demonstrates that, a voluntary, hospital-based reporting system used to monitor hospital-acquired infections and guide the prevention efforts of infection control practitioners, is neither objective, nor consistent; and brings all the biases that human judgment and diffuse guidelines produce. In today's age of technology and the ability to electronically download lab, pharmacy, and other vital clinical data, private companies like MedMined, Theradoc, Cereplex, and others have already developed software tools that in a far more automated way, detect and identify hospital-acquired infections. Just as it is with a patient's medical record and history, it's time to let the paper and pen go.

Don't Let the Perfect Be the Enemy of the Good

I believe, to its credit, that the CDC will acknowledge some of the shortcomings of the manner in which the NNIS database was collected, and the problems with very complicated and often misinterpreted definitions. While I believe it has been problematic, I do not believe that the data needs to be perfect. That is why my fifth message is that *we cannot let the perfect be the enemy of the good.* When it comes to data collection and public reporting, we do not need pine needle detail, data perfection or epidemiological purity to shine light on a problem. Those who argue about needing perfection before we publicly report, miss both the light, and the point. Sometimes, sunshine is the best disinfectant!

In fact, we need to find ways to get some of the most dedicated people I've met – the physicians in infectious disease and our infection control professionals – out of the pine needles of manual data collection, and onto the floors and into the rooms of hospitals, so they can do the job they were trained for – finding and preventing the causes of the hospital-acquired infections.

I also think I can safely say that the pattern in Pennsylvania, as well as in other states that embrace public reporting, is that once health care data gets reported, the data gets better and so do the improvement efforts.

States are the Incubators of Health Care System Innovation

With that said, my final message today is that *states have historically been, and continue to be, the incubators for innovation and solutions,* and, as such, their role in transforming the nation's health care system needs to be engaged, and enlarged. In addition to shedding light on the problem of hospital-acquired infections, Pennsylvania, and others, have led the way in other efforts to promote greater transparency in health care through collecting and reporting health care data. Florida, Maine, New York, Maryland, New Jersey, and Virginia are also laboratories of transparency, using different outcome measures and different data collection methods, but all aimed at the same goal: greater public transparency on both quality and cost.

In testifying before a U.S. Senate Committee two weeks ago, Paul H. O'Neill said:

> "Unfortunately, the federal government rarely sets performance targets at all, let alone setting them at the theoretical limit of human attainment. The result of not insisting on the elimination of fundamental problems with the performance of the healthcare system is more of the same, or worse. For example, there are clear reasons that the appalling healthcare-acquired infection rate – affecting approximately 1 in 12 people admitted to the hospital -- has been steady or increasing for decades."

I believe Mr. O'Neill was right. It's time to stop wringing our collective hands, and start washing them!

States need the flexibility, and the Nation benefits, when states are encouraged to experiment with solutions that may work toward a common goal, while recognizing the unique socio-economic and political environment that varies dramatically amount the 50 states.

Rather than setting a single standard on the "what's and "how's" of data collection, what Congress can best do is establish performance targets and goals, and then provide incentives that states can use, with flexibility, and, given their own limited resources, begin to act on reducing and eliminating hospital-acquired infections.

If Congress said simply and clearly: In five years, the goal of our health care delivery system should be to eliminate all hospital-acquired infections, and, in five years, Medicare will no longer pay for any hospitalization in which a hospital acquired infection occurs; I humbly suggest the goal of patient safety that we all share would be transformed into action virtually overnight by our hospital and physician community.

There could be no more noble or compelling issue for Congress, and our nation, to tackle.

While the public may not fully grasp the nuances of a risk adjusted mortality rate, or how to decipher HEDIS measures on appropriateness of preventive care outcomes, when it comes to hospital-acquired infections, the public "gets it"! Hospital-acquired infections are bad. They don't want one; they don't want their family or friends to get one; and they ***want to know***, should they have to be hospitalized, which hospitals in their area are doing the best to prevent them.

In fact, what the public fully "gets" is, they ***DON'T*** want to "get it".

In Pennsylvania, we're doing our best to provide usable, actionable information to see that this goal is achieved.

Mr. Chairman, on behalf of the Council members that set our priorities and agenda, and with pride in the dedicated and talented staff of PHC4, I thank you for the honor and the privilege of testifying here today.

MR. WHITFIELD. Well, thank you, Mr. Volavka.

At this time, I recognize Dr. Shannon for his 5 minutes.

DR. SHANNON. Thank you, Mr. Chairman. I will ask my colleague, Mr. Volavka, to help tee up a couple of slides I would like to share by way of illustration.

It is my goal today to convince you that hospital-acquired infections are not inevitable, but products of unreliable processes and mal-aligned incentives that reward activity, not clinical outcomes.

A major challenge to the concept of public reporting has been the theory of inevitability, the notion that a hospital-acquired infection is an inevitable consequence of complex care, and therefore an acceptable form of collateral damage in our daily battle against disease. An additional barrier, however, is the fact that we shroud this problem in epidemiologic metrics that are obscure and tend to hide the human face, thereby mitigating the harm.

As an example, we were reporting for years an average infection rate of 5.1 infections per 1,000 line days. One day, I said how many human beings is that? Five, 10, 50? There was simply no way to know. When data is presented in obscure fashions, it may be understandable to an epidemiologist, but I submit that we, and I venture to say most healthcare professionals, were totally unaware of the tragic human consequences or of our primary involvement in them. As a result, it becomes easy as a healthcare professional to dismiss such a common occurrence as unavoidable or inevitable.

We now know at Allegheny General Hospital that with respect to hospital-acquired infections, there is only one acceptable benchmark: zero. The unambiguous goal of zero that no one should contract an infection in a hospital that did not arrive with it obviates the need for a complex metric.

Now, the argument that the data needs to be normalized in order to compare hospitals of different sizes and types, simply to my mind focuses the attention on the wrong set of comparisons. Rather, I would submit the correct approach is for each hospital to benchmark against itself in its current condition and to demonstrate rapid and consistent progress toward the theoretical limit. If the public were to know that we were all getting better, it would be greatly reassured.

And to those that argue that their patients are sicker, I say please hurry, because that is all the more reason to perfect your processes, as I know of no critically ill patient that gets better when a superimposed hospital-acquired infection occurs.

But the best way for me to challenge the myth of inevitability is to illustrate how close you can come to the theoretical limit. Over the last

32 months, we have dedicated ourselves to the proposition of eliminating hospital-acquired infections using work redesign borrowed from industries such as Toyota and ALCOA, which are leaders in producing reliable products. I won't belabor the data on this first slide. It is included in the testimony and you have heard today through the Washington Post that we have been successful in reducing our line infections from 49 to 3 and our deaths from 19 to 1. What I want to tell you about these results is they have occurred at the same time that we have seen a doubling of the use of central catheters and we have seen a steady increase in the acuity of illness in our patients as measures by the Atlas severity grade. Said differently, using more catheters and caring for sicker patients are not justifications for higher numbers of infections. In our ICUs, we decided to replace the flawed theory of inevitability with the proven principles of reliability in practice.

Now, needless to say, when you define a hospital-acquired infection as inevitable, you also create the rationale for paying for it, but little is known as to whether the hospitals actually make or lose money on these cases.

[Slide.]

To explore this, we have looked at 54 central line infections from our institution, and I want to just share a few factors from them. We believe that an economic analysis must begin with an understanding of exactly how the harm occurred and specifically how it affected the patient. So I share with you the case of a 39-year-old man who came to our hospital, not with a critical illness, but with pancreatitis, an inflammation of his pancreas due to high plasma triglycerides. On the sixth hospital day, this man developed a central line-associated bloodstream infection with methacillin resistant staphylococcus aureus due to a femoral line that had been in place for four days. As a result of that bacterium, he developed multiple surgical complications requiring repeat laparoscopies to drain abscesses, he developed renal failure requiring dialysis, he needed to undergo a tracheotomy to maintain his ventilation, and 86 days after this man came to our hospital, he was discharged to a long-term care facility.

Now, I don't share this with you because I am proud of it; I share it with you because unless you understand the human consequences, there is no motive to change. Healthcare workers are not motivated by line infections per 1,000 line days, but they renounce a current condition when they understand the magnitude of the human harm expressed in such human terms, and they begin to believe they can do something about it. Next slide.

[Slide.]

Now, at Allegheny General Hospital, we have had a chance to look at the economics of such cases. In the right-hand panel, you see that we

got paid $200,000 for this care, yet it cost us $241,000 to provide it, meaning we lost from operations a full $41,000 on this case alone. Notably, the care provided as a result of the complication cost $170,000, or nearly 71 percent of the entire cost of care. In addition, I have shared for you in this slide risk adjustments that you constantly hear about. These are three different sets of patients, all age-matched, matched by their Atlas severity grade at the time of admission, and matched for their admitting diagnosis. In the left-hand panel, you can see that when we actually do it right in the pancreatitis, the payment is much less, $5,900, but so too is the cost. Yet as a hospital, we make a cool $119 on average.

Arguably, this patient was sicker, due to the initial presentation with hypertension and partial pancreatic obstruction, but in the second illustration I provide you with the common finding that our hospital is paid very well when it provides an advanced level of care, the kind of care we are expected to provide, particularly when it is surgical care. And in such complex cases, we have a very nice operating margin of $40,000.

By the third comparison, though, I show you two other patients who developed severe pancreatitis and needed to be intubated for long periods of time and required a tracheotomy. Again, our hospital is well paid, $125,000 for such complex care, even though the result is less than optimal. And the margin, $27,000 remains quite healthy. Yet in the case of my 37-year-old patient, when complex care is further complicated by a central line infection, the economic turns sharply negative with an operating margin of -$41,000. These costs do not include payments to physicians, they do not include the cost of long-term care, his ongoing dialysis, or the loss of a productive worker. Next slide.

[Slide.]

This is the average data for 54 infections. $64,000 is the payment, $91,000 is the cost. We lose $26,000 on average for every infection. $1.4 million is the operating loss per year. Only three people went home. Next slide.

[Slide.]

I am going to click through to the bottom in the interest of the Chairman's time.

We have reduced both ventilator-associated pneumonia and central line infections in our organization. This has resulted in savings that approach $2.2 million over two years. We received a $2.1 million incentive payment for the good work. That means this work alone in two ICUs netted for the hospital a new operating margin of $4.3 million. In the course, we spent $34,000 in investment, not one penny of Federal money, and we admitted 126 additional patients to our unit, and we saved 47 lives.

Mr. Chairman and members of the committee, it is quite obvious what we need to do. We do need to measure, but more importantly, we need to act. This is a win-win. It is a win for patients, it is a win for providers, it is a win for payers, and it is a win for purchasers. We need to be about it, and we need to be about it now.

Thank you.

[The prepared statement of Dr. Richard P. Shannon follows:]

PREPARED STATEMENT OF DR. RICHARD P. SHANNON, MD, CHAIR, DEPARTMENT OF MEDICINE, ALLEGHENY GENERAL HOSPITAL

Summary
Hospital Acquired Infections: The Conspiracy of Error and Waste in Healthcare

1. Hospital acquired infections in general and central line infections (CLABs) and ventilator-associated pneumonias (VAP) in particular are not inevitable consequences of complex healthcare but are indicative of unreliable processes and perverse economic incentives.

2. These infections and their consequences can be reduced through work standardization and commitment to safety as a precondition of caring for patients.

3. The costs of these preventable infections in both human and economic terms are staggering and largely unappreciated by both payers and hospitals.

4. Preventing these infections could free up limited resources now wasted in their care.

Mr. Chairman and Members of the Committee:

It is an honor to be asked to testify before this distinguished body on a matter of vital national interest. You are undoubtedly aware of the litany of statistics from the Institute of Medicine and Centers for Disease Control defining the national epidemic of hospital acquired infections and you have heard specifically about the magnitude of the problem in the Commonwealth of Pennsylvania. I will not reiterate these findings. The fact remains that these numbers are so staggering as to be almost imponderable, suggesting that the problem is complex and insolvable.

Rather, it is my goal today to convince you that error and harm in healthcare is not inevitable, but a product of unreliable processes and misaligned incentives that reward activity not outcome. I will demonstrate using our own work that public reporting is not only accurate and informative, but establishes the basis for action. I will then show you that at an individual hospital level, hospital acquired infections in general and central line infections and ventilator associated pneumonias in particular cost our hospital and others like it millions of dollars and hundreds of human lives, illustrating the conspiracy of error and waste prevalent in healthcare.

The work that I will present was performed at Allegheny General Hospital, a large academic medical center located in Pittsburgh's inner city. We are a major teaching affiliate of the Drexel University College of Medicine, a mentor hospital of the Institute for Healthcare Improvement and a founding member of the Pittsburgh Regional Healthcare Initiative, a regional collaborative established by former Treasury Secretary Paul O'Neill and Karen Feinstein PhD.

The Theory of Inevitability

A major challenge to the integrity of public reporting is the notion that hospital-acquired infections are an inevitable consequence of complex care and therefore an acceptable form of collateral damage in a daily battle against human disease. The notion of inevitability has its genesis in the fact that when infections occur, the root cause is not determined immediately. Three or more months after the fact when the infection is finally reported, the cause of the infection is not apparent, leading to the conclusion that it must be inevitable. Yet, there is no biological basis or genetic mutation that predisposes to hospital-acquired infections, although there are recognized conditions that pose a greater risk.

A major barrier in addressing the issue of hospital-acquired infections is the fact that we shroud the problem in epidemiological metrics that obscure the human face, thereby mitigating the harm. As an example, in work from our Medical Intensive Care Unit and Coronary Care Unit, we were reporting average infections rates of 5.1 infections per 1,000 line-days. But how many human beings did that represent? Five? Ten? Fifty? When the data were presented in such an obscure fashion, we, and I venture to say most healthcare professionals, were unaware of the tragic human consequences or our own involvement in the events. As a result, it is then easy to dismiss these common occurrences as "unavoidable or inevitable". Until recently, the best we could do was benchmark against available "norms" such as the National Nosocomial Infection Surveillance data, generating a list of what has become known in safety circles as "the cream of the crap". We now believe that with respect to harmful conditions in healthcare, the only acceptable benchmark is the pursuit of the theoretical limit. Simply stated: zero infections. The unambiguous goal of zero…that no one should contract an infection in the hospital that they did not have when they arrived …obviates the need for any complex metrics. The Pennsylvania Healthcare Cost Containment Council should be commended for reporting the actual number of infections in just such an unambiguous fashion.

The argument that normalization of data is necessary to compare hospitals of different size and types simply focuses attention on the wrong set of comparisons. The correct approach is for each hospital to demonstrate consistent progress toward the theoretical limit. To those that argue that their patients are sicker, I say then all the more reason to perfect your processes as no critically ill patient gets better with a superimposed hospital acquired infection.

I would like to challenge the notion that hospital-acquired infections are inevitable by demonstrating that it does not have to be this way. Over the course of the last 32 months, we have dedicated ourselves to the proposition that we can eliminate hospital acquired infections through work redesign borrowing from the lessons of Toyota and Alcoa, industry leaders in producing reliable products. The principals of Perfecting Patient Care™ are an adaptation of the industrial methods employed by the Toyota Production System and the Alcoa Business System, but designed for healthcare and taught in a 5-day course developed and sponsored by Pittsburgh Regional Healthcare Initiative. I will not focus on those processes here to but rather refer you to the PRHI website (www.prhi.org) where the process is outlined in greater detail.

Figure 1 illustrates the progress toward the eradication of central line infections. We have reduced the number of central line infections progressively from 49 to 3, deaths associated with these infections from 19 to 1 and improved the safety and reliability of the process from 1 infection in every 23 lines placed to 1 in every 535 lines placed as of the end of February, 2006. We have not had a central line infection in these two critical care areas since August 14,2005. The progress to zero has occurred despite a near doubling in the use of catheters and a steady increase in the severity of illness of patients in our ICUs. Stated differently, using more catheters and caring for sicker patients are not justifications for higher numbers of infections.

Do Hospitals Make Money on Central Line Infections?

Needless to say, when you define hospital-acquired infections as inevitable, you also create the rationale for paying for them. But little is known as to whether hospitals make or lose money when care is complicated by hospital-acquired infections. Therefore, understanding the economy of hospital-acquired infections is essential to changing the culture.

To explore this issue we examined the payments and expenses associated with 54 central line infections in our two ICUs over three years. In our work, each economic analysis begins with an understanding of exactly how the error occurred and specifically how it affected the patient (**Figure 2**).

A thirty-nine year old video programmer, father of four was admitted with acute inflammation of the pancreas due to elevated plasma triglycerides. On the third hospital day, he developed hypotension and metabolic acidosis related to pancreatic inflammation and required pressor support and mechanical ventilation. On day 6, he developed fever and recurrent hypotension. Blood cultures were positive for methacillin resistant staphylococcus aureus and the same organism grew from his femoral venous catheter that was placed four days previously. He developed multiple complications from the catheter related bacterial sepsis including intra-abdominal abscesses requiring multiple laproscopic drainage procedures and renal failure requiring dialysis. The prolonged course required that he undergo tracheotomy to facilitate ongoing requirements for mechanical ventilation. Finally, after 86 days in the hospital, he was transferred to an acute long-term care facility for further rehabilitation.

Now, I do not share this with you because I am proud of it, but rather, to illustrate the human face and the actual harm that can accompany these infections. Health care workers are not motivated by epidemiological metrics such 5 infections /1000 day days, but they renounce the current condition when the magnitude of the error is expressed in its human dimensions and when they come to believe that there is something that they can do about it. The consequences to the patient are considerable and a sufficient cause for action, but what are the economic implications?

In **Figure 3**, we see that Allegheny General Hospital received $200,765 in payments for the care rendered; yet the hospital costs were $241,844, such that the loss from operations was -$41, 813 on this single case. Notably, the additional care provided as a result of the preventable central line infection and its associated complications amounted to $170,565 or nearly 71% of the total cost of care with an 86-day hospitalization. Now, I want to emphasize that these are actual hospital costs, not charges that were actually billed as $828,847!

In addition, I want to share three comparisons with our case as illustrated in **Figure 3**. In the first example, you see the economics from the hospital's perspective for providing good basic care to three other patients that presented with the same diagnosis. When we do it right, the payment is much less ($5,907), the costs are much less, but so too is the hospital margin (+ $119).

Arguably, our patient had a more severe case of pancreatitis due to the initial hypotension and presence of partial pancreatic obstruction. In the second illustration, you see the common finding that our hospital is well paid ($99,214) for providing an advanced level of care, particularly surgical care, in such a complex case, with an operating margin of + $40,309.

A third comparison is made with two other patients who developed severe pancreatitis, required prolonged mechanical ventilation, and eventually underwent tracheotomy, similar to our patient. Again, our hospital was well paid ($125,576) when complex care results in a less than optimal outcome, although the margin is less (+$27,482) than that seen with complex surgical care alone.

Yet, in the case of our 39 year-old patient, when complex care is further complicated by a central line infection, the economics turn sharply negative for our hospital with an operating margin of -$41,813.

Now this is all from the hospital's perspective. These costs do not include payments to physicians and for long term care or for the patient's need for ongoing dialysis or the loss of a productive laborer in the workforce. But, let me highlight for you what society pays for these various levels of care. The payment increases progressively as care becomes both complex and complicated from $5,907 to $200,031, yet the patient's outcome is inversely proportional to the payment.

In summary, I have illustrated in **Figure 4** the economic impact on hospital operating margins of 54 central lines infections that we examined from our two ICU's. The average payments was $64,894, yet the average costs were $91,733 such that the hospital had a negative gross margin of $26,839 per infection and a total negative gross margin of $1,449,306. The average payment for a central line infection in my two ICUs is a number that is remarkably close to what has been reported by PHC4 in the Commonwealth of Pennsylvania.

In **Figure 5**, I provide a similar summary of the economic and clinical impact of 99 ventilator associated pneumonia (VAP) cases in the same two ICUs over 3 years. The average payment was $62,883, but the costs were $87,318, such that the average loss from operations was -$24,435 per case, totally a three-year loss of $2,419,065. The payments in cases of ventilator-associated pneumonias were twice those in comparable cases ($33,569) uncomplicated by this preventable hospital acquired infection. With a similar approach using the principals of Perfecting Patient Care™, we reduced the number of ventilator-associated pneumonias from 45 to 8.

Finally, I would like to highlight the economic benefits to our hospital as a result of nearly eliminating two classes of HAI over the last two years, illustrated in **Figure 6**. The work has resulted in operational improvements of +$2,238,927 and an additional $2,100,000 in incentive payments totaling $4,338,927 in improvements. We invested a total of $34,927 over two years to achieve the result. In the process, we have increased the number of admissions to the ICUs by 126 and saved 47 lives. Thus, our hospital has incurred substantial losses when care was complicated by a hospital-acquired infection. On the other hand, both our patients and we have benefited by efforts to eradicate these insidious infections.

Mr. Chairman and distinguished Members of the Committee,

The greatest and certainly most expensive healthcare system in the world is teetering on the brink of a financial crisis and is an unbearable drag on the nation's economy. The unreliable systems of care delivery and the unsafe conditions that are created as a result undermine the promise of new technology and threaten our ability to afford it. The value added from the elimination of hospital-acquired infections is more than sufficient to provide insurance for the growing number of uninsured and working Americans as well as to give us a down payment on the promising new technologies that offer real hope for eradicating disease. Before us lies the first and most important challenge to realize these goals. Are we as informed citizens and as an honorable profession willing to commit together to eliminate the harm and the waste associated with preventable hospital acquired infections?

Thank you

Figure 1

	Traditional Approach FY 03	PPC Approach FY 04 Year 1	PPC Approach FY 05 Year 2	PPC Approach FY 06 (8 months) Year 3
ICU Admissions (n)	1753	1798	1829	1394
Atlas Severity Grade	1.9	2.0	2.1	2.2
Age (years)	62 (24-80)	62 (50-74)	65 (39-71)	64 (56-76)
Gender (M/F)	22/15	3/3	4/7	1 / 2
Central lines employed (n)	1110	1321*	1487*	1605*
Line-days	4687	5052*	6705*	6667*
Infections	49	6*	11*	3*
Patients Infected	37	6*	11*	3*
Rates (infections/ 1000 line-days)	10.5	1.2*	1.6*	0.45*
Deaths	19	1 *	2 *	1 *
Reliability (# of lines placed to get 1 infection)	22	185*	135*	535*

Case 1

- **37 year old video game programmer, father of 4, admitted with acute pancreatitis secondary to hypertriglyceridemia.**
- **Day 3: developed hypotension, and respiratory failure**
- **Day 6 : fever and blood cultures positive for MRSA secondary to a femoral vein catheter in place for 4 days.**
- **Multiple infectious complications requiring exploratory laparotomy and eventually tracheotomy**
- **Day 86: Discharged to nursing home**

Figure 2

The Impact of CLABs on Gross Margin

	DRG 204/2721 (n=3)	DRG 191 (n=3)	DRG 483 (n=2)	Case 1
	Acute pancreatitis	Pancreatitis w cc	Pancreatitis w trach	
Revenue ($)	5,907	99,214	125,576	200,031
Expense	5,788	58,905	98,094	241,844
Gross Margin	119	40,309	27,482	-41,813
Costs attributable to CLAB				170,565
LOS	4	38	41	86

Figure 3

The Losses Attributable to CLABs are Staggering

- **Average reimbursement: $64,894**
- **Average Expense: $91,733**
- **Average Loss from Operations: -$26,839**
- **Total Loss from Operations:-$1,449,306**
- **In only 4 cases did the hospital make money!**
- **The cost of the additional care averaged 43% of the total costs of care**
- **Average LOS: 28 days (5-86)**
- **Only three patients were discharged to home.**

Figure 4

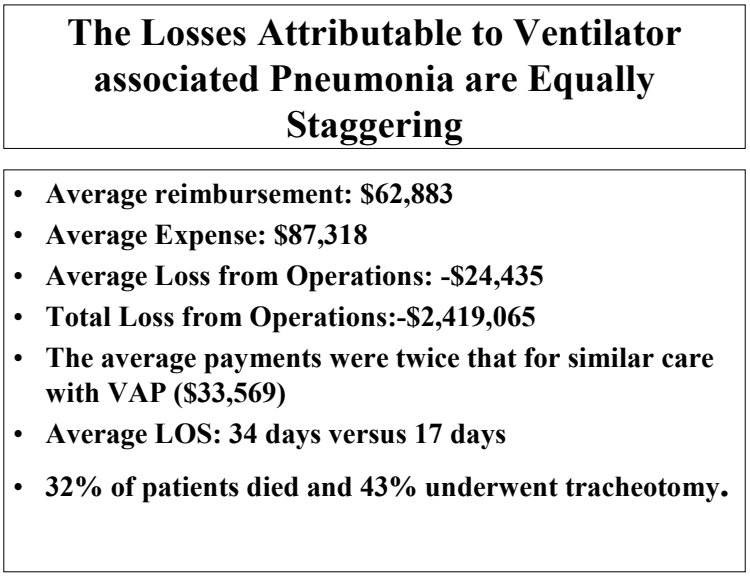

Figure 5

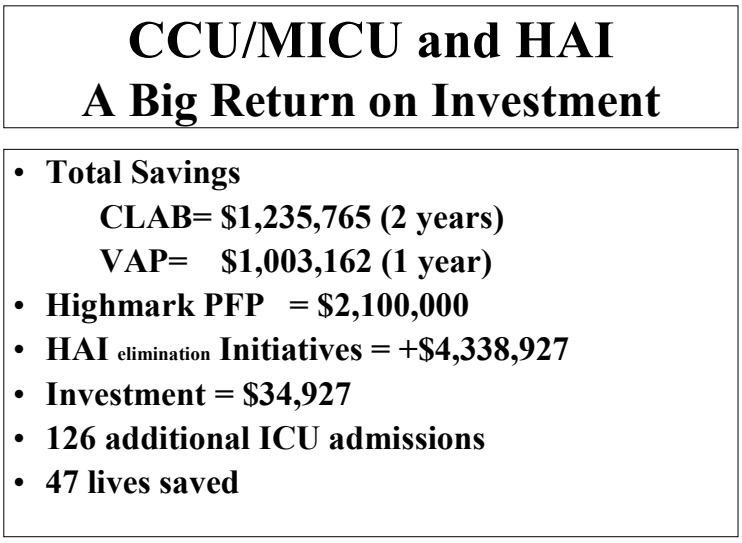

Figure 6

MR. WHITFIELD. Thank you, Dr. Shannon.
Dr. Hammer, you are recognized for five minutes.

DR. HAMMER. Thank you. Mr. Chairman and distinguished members of the committee, good afternoon. Thank you for convening this hearing on policy issues surrounding the benefits of reporting healthcare associated or hospital-acquired infections. My name is Dr. Scott Hammer and I am the Chief of the Adult Division of Infectious Diseases and a Professor of Medicine and Epidemiology at the New York Presbyterian Hospital/Columbia University Medical Center, the largest single hospital in epidemic medical center in the New York metropolitan area. On behalf of the NYPH, I appreciate the opportunity to testify this afternoon and share my insights on the benefits and challenges presented by measures requiring hospitals to collect, monitor, and report HAI data.

At the outset, I would like to acknowledge the importance of the committee's inquiries into HAIs, an issue that poses significant challenges to the public health system in the United States. In a February 2005 report, HICPAC estimated that each year, HAIs account for two million infections and $4.5 billion in excess healthcare costs. As significant as these statistics may seem, they do not adequately convey the impact that HAIs can have on the lives of patients and their families. Accordingly, NYPH supports efforts to require the public reporting of HAI data, provided that it is collected and calculated properly and conveyed to the public in a responsible, comprehensive, and meaningful manner. Thus, any approach mandating the disclosure of HAI rates should address two fundamental issues.

First, any effort should establish national standards regarding methodologies for the collection of HAI data, the collection of HAI rates, and the presentation of HAI rates.

Second, the reporting framework should establish an effective risk adjustment procedure to direct for variances amongst patient populations with respect to underlying risk factors for infection. Currently, multiple Federal and State regulatory frameworks provide guidance for the collection and dissemination of HAI data. These approaches differ in certain respects, however, often directing facilities in different States to adopt varying definitions and methodologies.

This present lack of methodological consensus means that hospitals adopting different approaches will not be subject to valid comparisons, which is one of the primary goals of public reporting. Thus, in order to be of value to the healthcare community and the public, any public reporting system should establish uniform methodologies for collecting data and calculating rates. It is important to assure that hospitals be required to provide data in a consistent manner.

Even when opting to gather similar types of data, hospitals can choose to monitor different processes and outcomes. Each of these

approaches may be equally valid, yet quite distinct. As a result, comparisons among hospitals using disparate measures would be uninformative. Attempts to produce a comparison among these statistics could prove misleading and potentially harmful to our Nation's healthcare consumers.

Another concern inherent to HAI reporting is that healthcare facilities treat an array of patient populations reflecting various levels of acuity. For instance, as an academic medical facility, NYPH often performs very specialized and high-risk procedures. NYPH also serves as the burn center for the New York City Fire Department and cares for numerous patients who have received an organ transplant. Due to the use of immunosuppressant medications, each of these patient groups inherently is vulnerable to the threat of elevated HAI rates, which would require risk adjustment prior to being reported so as to allow meaningful comparison to other patient groups and facilities.

Furthermore, without effective risk adjustment to correct for these disparate patient populations and acuity levels, it could be quite challenging to generate a meaningful comparison between HAI rates at academic medical centers and other tertiary hospitals with the rates observed at a typical community hospital. Moreover, it has become increasingly difficult to identify whether some infections were acquired while at the hospital or within the community. Risk adjustment, therefore, is critical because it enforces the validity of inter-hospital comparisons and addresses whether an infection likely was acquired during or prior to a patient's hospital stay.

Unfortunately, the risk adjustment methods currently available are limited in their ability to account for these differences. The result may be that unadjusted or poorly adjusted HAI rates may lead to unintended and undesirable public health consequences. For example, a patient misinterpreting HAI data may avoid seeking treatment at a particular facility, despite its being more experienced and better equipped to treat the patient's condition. In order for the public reporting of HAI rates to achieve the committee's objectives, to improve hospital performance and to provide patients and their families with educated decision-making tools, such rates should be reviewed and adjusted for among other considerations, acuity level, and patient mix.

In addition, Federal and State reporting agencies should remind consumers that HAI rates are not to be viewed in isolation. Consumer interest groups and professional associations also should play a role in this process to educate patients and their families about the benefits and limitations of HAI data. In the end, the public should understand that HAI rates represent only one of a myriad of factors to be used in deciding where to receive quality healthcare.

Thank you, Mr. Chairman, and I would be pleased to answer any of your questions after the opening statements.

[The prepared statement of Dr. Scott M. Hammer follows:]

PREPARED STATEMENT OF DR. SCOTT M. HAMMER, MD, CHIEF, DIVISION OF INFECTIOUS DISEASES, NEW YORK PRESBYTERIAN HOSPITAL/COLUMBIA UNIVERSITY MEDICAL CENTER

Mr. Chairman, distinguished members of the Committee and staff – good afternoon. Thank you for convening this hearing on policy issues surrounding the data collection and reporting of hospital-acquired infections ("HAIs").

My name is Dr. Scott Hammer, and I am the Chief of the Adult Division of Infectious Diseases and a Professor of Medicine and Epidemiology at the NewYork-Presbyterian Hospital/Columbia University Medical Center ("NYPH"). NYPH is the largest single hospital and academic medical center in the New York metropolitan area, and is affiliated with two medical schools: the Columbia University College of Physicians & Surgeons; and Cornell University's Weill Medical College. Collectively, our five separate campuses serve a vast geographic region and a diversity of communities. On behalf of NYPH, I appreciate the opportunity to testify this afternoon and share my insights on the benefits and challenges presented by legislative measures requiring hospitals to collect, monitor and report HAI data.

I. Overview

At the outset, I would like to acknowledge the importance of the Committee's inquiry into HAIs – an issue that poses significant challenges to the public health system in the United States. In a February 2005 report, the Healthcare Infection Control Practices Advisory Committee ("HICPAC") estimated that each year, HAIs account for two million infections, and $4.5 billion in excess healthcare costs. As significant as these statistics may seem, they do not adequately convey the impact that HAIs can have on the lives of patients and their families.

Accordingly, NYP supports efforts to require the public reporting of HAI data, provided that it is collected and calculated properly, and conveyed to the public in a responsible, comprehensive, and meaningful manner. Thus, any approach mandating the disclosure of HAI rates should address two fundamental issues. First, any effort should establish national standards regarding methodologies for: (i) the collection of HAI data; (ii) the calculation of HAI rates; and (iii) the presentation of HAI rates. Second, the reporting framework should establish an effective risk-adjustment procedure to correct for variances among patient populations with respect to underlying risk factors for infection.

In order to formulate an effective national reporting system, this process will require consultation among the various public and private stakeholders, including: (i) the Centers for Disease Control and Prevention ("CDC"); (ii) state health departments; (iii) hospitals and other health care facilities, including academic medical centers; (iv) national associations representing infection control practitioners, such as the Association for Professionals in Infection Control and Epidemiology ("APIC"), and the Society for Healthcare Epidemiology of America ("SHEA"); and (v) non-profit patient advocacy groups.

II. Lack of Consensus Among Federal and State regulatory frameworks on Methodologies for Collecting and Calculating HAI Data

Currently, multiple federal and state regulatory frameworks provide guidance for the collection and dissemination of HAI data. These approaches differ in certain respects, however, often directing facilities in different states to adopt varying definitions and

methodologies. This present lack of methodological consensus means that hospitals adopting different approaches will not be subject to valid comparisons, which is one of the primary goals of public reporting. Given the technology, effort and expense required to gather accurate HAI data, it is important to insure that hospitals be required to work within a single regulatory regime with respect to HAI reporting.

On the federal level, no law currently in effect requires public reporting of HAI data. On a voluntary basis, however, some hospitals presently report HAI data to the National Nosocomial Infections Surveillance Network ("NNIS"), sponsored by the CDC. NNIS requires participating hospitals to collect HAI data using standardized protocols called "surveillance components," which target the adult and pediatric intensive care, high-risk nursery, and surgical patient units. For a minimum period of one month, participating hospitals must track all incidences of HAIs within the surveillance components. They then categorize incidences of HAIs into major and specific infection sites, using definitions developed by the CDC.

The CDC/NNIS methodologies for collecting HAI data and calculating HAI rates have been influential and form the closest existing approximation to a national standard. But the CDC/NNIS standard has not achieved universal acceptance. Notably, the only federal legislation that would require hospitals to report HAI data appears in a provision of the Deficit Reduction Act ("DRA"). Enacted on February 8, 2006, but not yet in effect, the DRA adopts neither the CDC definitions for HAIs, nor the CDC/NNIS rate-calculation methodologies. Rather, the DRA directs the Secretary of Health and Human Services (the "Secretary") to develop the agency's own definitions and methodologies for collecting HAI data and calculating HAI rates, in consultation with the CDC and other appropriate national consensus building entities. The Secretary also must select two HAIs for acute care hospitals to track through admission and discharge codes, and include pneumonia and surgical site infection data in its group of quality indicators. The DRA expands the number of quality indicators that acute care hospitals must monitor and report in exchange for receiving the maximum price inflation adjustment under the Medicare program. And, under the DRA, by October 1, 2008, Medicare would not provide a facility with full reimbursement of treatment expenses if patients develop either of these two selected HAIs.

On the state level, six legislatures have enacted laws mandating public reporting of HAIs.[1] Many of these have yet to become effective, with others merely in the early stages of implementation. Like the DRA, however, a number of these states have opted to direct the development of their own methodologies on collection of HAI data and calculation of HAI rates, rather than adopt the CDC or NNIS models. New York, for example, requires its Department of Health to create methodologies for infection identification, coding, tracking and reporting. The Pennsylvania law establishes similar requirements. On the other hand, Florida requires its hospitals to collect HAI data using the distinct methodologies developed by the Centers for Medicare and Medicaid Services ("CMS").

Given that federal and state regulatory frameworks employ disparate methodologies for collection of HAI data and for calculation of HAI rates, attempted comparisons among hospitals falling within different regulatory frameworks may yield results that are suspect and difficult to interpret. Thus, in order to be of value to the healthcare community and the public, any HAI reporting system should establish uniform methodologies for collecting data and calculating rates

One proposed approach towards achieving this uniformity would be to require hospital participation in NNIS. NNIS then could make its HAI database available to state

[1] Two additional states – Nevada and Nebraska – also have enacted legislation to require the collection and calculation of HAI rates, however, the resulting data are reported only to the state agencies responsible for public health, and presently are not disclosed to the public.

agencies, which could use the data to compare hospitals and identify potentially problematic trends. Where appropriate, such state agencies could take further action against specified hospitals.

Such mandatory hospital participation in NNIS would pose challenges for two reasons. First, the CDC is in the process of redesigning the NNIS system into a user-friendly web-based resource, called the National Healthcare Safety Network ("NHSN"). Although there has been no formal announcement of a precise launch date, the CDC projects that the NHSN will be operational at some point in 2006. Until that occurs, and understandably for some period of time afterwards, the system may undergo additional changes toward becoming an effective resource for the health care community.

Second, the NNIS (as well as the successor NHSN), is designed to report only outcome measures, which establish the rate of infection for certain diseases within targeted patient populations (*e.g.*, the number of patients who contract pneumonia from ventilators). Moreover, the NHSN changes the current list of NNIS outcome measure requirements by collecting data for a narrower range of HAIs – namely, central-line associated bloodstream infections, ventilator associated pneumonia, catheter-associated urinary tract infections, and surgical site infections.

Highlighting the lack of consensus with respect to HAI reporting, the NNIS approach does not provide for the collection or distribution of information regarding adherence to process measures, which determine the hospital staff's adherence to procedures believed to reduce the spread of HAIs (*e.g.*, the number of influenza vaccinations administered to staff). Notably, the HICPAC report concluded that outcome measures, like the ones required by NHSN and NNIS, often are more difficult to observe accurately than process measures. In its view, process measures should form the core of a mandatory reporting system because: (i) they are easy to observe; (ii) hospitals should unambiguously aim for 100% adherence to measured processes; and (iii) they do not have to be adjusted for a patient's underlying risk of infection. Consequently, HICPAC believes that outcome measures are more costly to implement, but ultimately produce a less reliable indication for the performance of HAI control programs.

III. Lack of COnsensus Among Hospitals on Methodologies for COllecting and Calculating HAI Data

Hospitals have long employed differing methodologies for collecting HAI data and calculating HAI rates. For instance, a given facility may track process measures, outcome measures, or a combination of both as indices of their own internal HAI-related performance. Accordingly, it would not be meaningful to attempt a comparison between the HAI rates of a hospital using primarily process measures with one primarily observing outcome measures.

Even when opting to gather similar types of data (i.e., process measures vs. outcome measures), hospitals can monitor different processes and outcomes. For example, NYPH calculates HAI rates through outcome measures by conducting targeted surveillance of specific types of infections, including: (1) central venous catheter bloodstream infections in the Intensive Care Unit ("ICU"); (2) surgical site infections in select patient populations; (3) epidemiologically-significant resistant organisms, such as Methicillin-resistant Staphylococcus Aureus ("MRSA") and Vancomycin-resistant Enterococcus ("VRE"); (4) Rotavirus infections; and (5) Respiratory Syncytial Virus ("RSV") infections. NYPH also monitors certain process measures associated with HAIs, such as hand hygiene (through a direct observation program), and influenza vaccination rates (based on the number of staff members who receive an immunization).

On the other hand, our peer hospitals that also monitor process measures may reasonably have selected alternative procedures to target. Similarly, when tracking outcome measures, other facilities may collect data on different infectious agents. Each of these approaches may be equally valid, yet entirely distinct. As a result, comparisons

among hospitals using disparate measures would be uninformative. Attempts to produce a comparison among these statistics could prove misleading and potentially harmful to our nation's healthcare consumers.

IV. The Importance of Standardizing Risk-Adjustment Procedures

From one facility to the next, healthcare facilities treat an array of patient populations, reflecting various levels of acuity. By virtue of our geographical location and affiliation with Columbia University Medical Center and Weill Cornell Medical Center, NYPH serves a wide range of communities, including some of the nation's most vulnerable, living within economically-disadvantaged neighborhoods such as Harlem and Washington Heights. Moreover, as an academic medical facility, NYPH often performs extremely specialized and high-risk procedures for patients with diseases that community hospitals lack the expertise or resources to treat. For instance, NYPH serves as the burn center for the New York City Fire Department, and cares for numerous patients who have received an organ transplant. Each of these patient groups is inherently vulnerable to the threat of elevated HAI rates due to the use of immunosuppressant medications, which would require risk adjustment prior to being reported, so as to allow meaningful comparison to other patient groups and facilities.

Furthermore, without effective risk adjustment to correct for these disparate patient populations and acuity levels, it would be quite challenging to generate a meaningful comparison between HAI rates at academic medical centers (and other tertiary hospitals), with the rates observed at a typical community medical center. Moreover, in some situations it has become increasingly difficult to identify whether an infection was acquired while at the hospital, or within the community (*e.g.*, the current epidemic of community-associated MRSA infections). Risk-adjustment of outcome measures therefore is critical, because it enforces the validity of inter-hospital comparisons and addresses the issue of whether an infection likely was acquired during or prior to a patient's hospital stay.

Unfortunately, the risk adjustment methods currently available are limited in their ability to account for differences in patient population and acuity levels among facilities. As noted in the HICPAC report, "current risk adjustment techniques improve but do not guarantee the validity of inter-hospital comparisons, especially comparisons involving facilities with diverse patient populations *(i.e.*, community versus tertiary-care hospitals)." Current risk adjustment procedures thus incorporate only a portion of all potential confounding variables, and as such they are limited in their ability to correct for variability among data collectors in the accuracy of locating and reporting events.

Unadjusted or poorly-adjusted HAI rates may lead to unintended and undesirable public health consequences. For example, a patient misinterpreting HAI data may avoid seeking treatment at a particular facility, despite its being more experienced and better-equipped to treat the patient's condition. And as noted above, with reimbursement rates increasingly becoming tied to outcomes, the public reporting of HAI rates may lead to decreasing reimbursements from third-party payors and a loss of patient revenues at facilities with higher infection rates.

Given this lack of uniformity in the current HAI methodologies for collecting data, calculating rates, and adjusting for risk, facilities that publicly report also may face undue negative publicity and misplaced legal liability, each of which would undermine efforts to serve patients and their communities. In the absence of a consensus for definition, measurement, data capture and denominator consistency, the release of current data may misrepresent the HAI environment to the public.

In order for the public reporting of HAI rates to achieve the Committee's objectives – to improve hospital performance, and to provide patients and their families with educated decision making tools – such rates should be reviewed and adjusted for, among other considerations, acuity level and patient mix. Moreover, the federal and state

reporting agencies should remind consumers that HAI rates are not to be viewed in isolation. Consumer interest groups and professional associations also play a role in the process to educate patients and their families about the benefits and limitations of HAI data. In the end, the public should understand that HAI rates represent only one of a myriad of factors to be used in deciding where to receive quality healthcare.

Thank you, Mr. Chairman, and I would be pleased to answer any of your questions.

MR. WHITFIELD. Thank you, Dr. Hammer, and Dr. Hanrahan, you are recognized for 5 minutes.

DR. HANRAHAN. Mr. Chairman, members of the committee, thank you for allowing me to speak today about a subject that is very important.

Those of us who work in infection control know how critical what we do is, and we wish that everyone would pay more attention to infection prevention. Public disclosure may be one of the methods to get people to pay more attention to infection prevention. The question is how to do it properly.

Ideally, all infections would be reported in order to get the most comprehensive picture of what goes on, but the problem is that you really do need standard definitions and adjustments for patient factors that contribute to the risk of infections. Right now, we don't have precise and valid definitions and appropriate rate adjustments for all infections. We have this for some.

In order for public reporting to provide useful information, clear definitions have to exist that can be followed by the people that are doing the surveillance, and this is really critical. I can tell you of several instances where our infection control personnel have called the CDC to get guidance on some of the NNIS definitions, the National Nosocomial Infection Surveillance system, and we found out that the definitions that we were using were not exactly what they had intended. And so it really is important to be unambiguous.

HICPAC, the Hospital Infection Control Practices Advisory Committee, has made recommendations for process measures to be used in addition to outcome measures. They have recommended things like influenza vaccination rates, adherence to hand hygiene, and so on, and they have also recommended reporting of central catheter bloodstream infections and select surgical site infections, because these have the least ambiguous definitions. They have also recommended standardized methods for case findings as well as validation methods to ensure accuracy and completeness of hospital reporting. This is really critical so that hospitals that are doing the most complete case finding are not looking worse than hospitals that are actually doing less complete a job.

Influenza vaccination has been mentioned as one of the process measures for hospitals. In theory, this is a really great idea, but in

practice, this may not really work too well. Let us keep in mind that influenza vaccine availability has been a perennial problem, and is going to continue to be so in the near future. Sanofi Pasteur, one of the major suppliers for influenza vaccine in the United States, released a statement on February 1, 2006, regarding unprecedented demand for influenza vaccine for the coming flu season, 2006-2007, and acknowledged that it will be unable to supply influenza vaccines to all those who are requesting it. There were people that were not even able to get through to place their order because their phone lines were so busy. Our hospital was one of those. Until sufficient influenza vaccine is available to all those individuals for whom it is recommended, this process may not be a useful measure. In order to reduce infection risks in hospitals, the influenza vaccine supply problem has to be resolved for both patients and healthcare workers.

NNIS is currently the method by which hospitals benchmark their hospital-acquired infection data. This system was established in order to track the incidence of hospital-acquired infections and the risk factors for these infections. NNIS does adjust for risk factors to an extent, but the risk stratification may not be sufficient. For example, NNIS publishes benchmark data for infection rates in surgical intensive care units. Surgical intensive care units vary a great deal as to whether they are taking predominantly patients who have had elective surgery or people who have had trauma. Trauma patients can differ a great deal, depending on what the mechanism of injury is, whether you are dealing with blunt trauma related to motor vehicle accidents, industrial accidents, gunshot wounds, stab wounds, et cetera. Trauma patients with severe injuries are at higher risk for infections because of the nature of the trauma itself, and their hospital stays are often long and they usually include numerous procedures. The risk of infection in these patients is different than the risk of infections in a patient undergoing elective or emergency surgery, and should not be grouped together. However, the current NNIS definition for trauma intensive care unit includes those surgical intensive care units where 80 percent of the bed days consist of trauma patients. The hospital that I work in is the major trauma center in northeast Ohio. When a really bad accident happens on the news, I know that if that patient survives that accident, I am going to be seeing them at some point.

Our surgical intensive care unit typically has about 70 percent bed occupancy from trauma patients. That means that our rates are compared to community hospitals that have surgical intensive care units who are not caring for trauma patients. This is clearly inappropriate and really does not yield a valid comparison. Methods to control for this need to be instituted prior to public reporting.

The last item that I want to mention is C.diff colitis, clostridium difficile colitis, which is an infection that has been in the news a great deal. Currently, there is a hypervirulent strain of this organism in hospitals throughout the United States, Canada, and Europe, and this disease is causing a great deal of morbidity and mortality. C.diff can be transmitted in hospitals on the hands of healthcare workers and from contaminated surfaces. There has been demand for public reporting of this infection, and currently is a reportable infection in the State of Ohio.

Public awareness has been somewhat good in that it has led to increased awareness among healthcare workers, and I have seen increased attention to infection control precautions and hand washing. The problem with this infection is that currently there is no standard definition that is used by all hospitals to collect data, so you can't compare the rates that we are reporting in Ohio to other places that are reporting. For example, Quebec is one of the places that initially noticed this outbreak. You cannot make the comparison because we are not using the same definitions.

It is often not possible to determine where C.diff originated. One of the problems is that patients may be hospitalized in several different hospitals and long-term care facilities over a period of months. While C.diff is often a healthcare-acquired infection, the location where an individual became exposed is often difficult to determine. In our institution, many of the C.diff cases that we see were acquired elsewhere. Currently, there is no standard definition that allows for complete reporting of all of the cases in Ohio.

There are potential adverse effects from public reporting. The process of public reporting should be carefully thought out in order to avoid these consequences. The HICPAC guidelines list potential diversion of resources from infection control education and prevention, disincentives for hospitals and healthcare workers to treat patients at higher risk for infection, as well as a potential for dissemination of misleading information if public reporting is not well planned.

I will stop there. Thank you.

[The prepared statement of Dr. Jennifer Hanrahan follows:]

PREPARED STATEMENT OF DR. JENNIFER HANRAHAN, D.O., CHAIRPERSON, INFECTION CONTROL COMMITTEE, METROHEALTH MEDICAL CENTER

Summary

Hospital-acquired infections are a major problem in the United States, and are one of the most common complications of hospitalization. Infections develop as a consequence of hospital factors and patient factors. Factors related to healthcare worker behavior and hospital systems can be changed, while patient factors often cannot be changed. Public reporting of hospital-acquired infections has the potential to impact infection rates by increasing awareness among healthcare workers and patients, and by increasing

adherence to infection control measures. In addition, public reporting has the potential to allow comparison of infection rates between institutions if it is done properly. One of the problems with hospital-acquired infections is that the definitions currently being used by infection control are not all precise and uniformly applied. This means that comparison between institutions using current definitions may not be valid. There are infections for which definitions are more precise, and these include select surgical site infections and central catheter-related bloodstream infections. In addition to using precise definitions for infections, risk adjustment is necessary to account for different patient populations. Hospitals that serve patients with a greater severity of illness are expected to have higher infection rates due to patient factors. Risk stratification as performed by the National Nosocomial Infection Surveillance System may not be sufficient to account for the differences in patient populations.

Hospital-acquired infections are a major problem in the United States, and elsewhere throughout the world where healthcare is available. These infections constitute one of the most common complications of being hospitalized, and lead to a great deal of morbidity and mortality.[1,2] Some of these infections are preventable, and there are steps that can be taken by both healthcare workers and patients to decrease infection rates. In recent years there has been increasing discussion about mandatory public reporting of healthcare-acquired infections. A number of states currently mandate reporting or have pending legislation regarding this issue. Should public reporting be mandated? The answer to this is an unequivocal yes. Public reporting has the potential to increase awareness and accountability, and may lead to increased attention to infection control measures by healthcare workers. It may lead to increased funding for hospital infection control personnel, and anyone working in infection control would welcome this change.

Public reporting has the potential to give patients and families important information about risks of hospitalization and surgical procedures. In an ideal world, people would be able to make informed decisions about where to get healthcare, and would be able to understand the differences between healthcare institutions. Public reporting should allow comparison between different types of hospitals, and should allow for direct comparisons of specific types of infection rates. The challenge before you is to decide how public reporting should take place so that it gives people this kind of useful information.

One of the difficulties in deciding how to proceed is determining which types of infections should be reported. Ideally, all infections would be reported in order to give the most complete picture. However, this would require standard definitions and clearly-defined methods to adjust for patient factors that contribute to the risk of infection. In 2002, Dr. Gerberding described the following characteristics as desirable for characterizing hospital-acquired infections, "Precise and valid definitions of infection-related adverse events, standardized methods for detecting and reporting events, confidentiality protections, appropriate rate adjustments for institutional and case-mix differences, and evidence-based intervention programs..."[3] All of these characteristics are desirable and would facilitate reporting of hospital-acquired infections. The problem is that precise and valid definitions and appropriate rate adjustment do not exist for all infections. Current legislation for public reporting includes language about adjusting for risk factors for infection. The Society for Healthcare Epidemiology of America states the following in their position paper on public disclosure, "Although the language in these laws may be appropriate, unfortunately, there is currently no widely agreed upon, scientifically validated method for risk adjusting healthcare-acquired infection indicators."[4]

In order for public reporting to provide useful information, clear definitions must exist that can be followed by infection control personnel throughout the United States. The Hospital Infection Control Practices Advisory Committee (HICPAC) outlined the essential elements of a public reporting system.[5] The first step involves identifying

appropriate measures of health care performance. HICPAC recommends inclusion of process measure because these can be followed in a variety of healthcare settings, and do not depend on adjustment for patient risk factors. Examples of process measures include influenza vaccination rates, adherence to hand hygiene, adherence to surgical antibiotic prophylaxis, etc. HICPAC also recommends inclusion of outcome measures, meaning specific types of infections. These outcome measures must have unambiguous definitions, and because of this, not all hospital-acquired infections should be included in public reporting. HICPAC recommends reporting of central catheter-related bloodstream infections and select surgical site infections. These infections have the most unambiguous definitions, and require less interpretation by infection control personnel. Standardized methods for case-finding are recommended, as well as validation methods to ensure accuracy and completeness of hospital reporting. Validation is critical to ensure that infections are comparable from hospital to hospital, and to ensure that some hospitals do not report less than others because their case-finding is less complete.

Influenza vaccination has been recommended as a process measure for hospitals. In theory this is a great idea. This should be easy to measure, and should be easy to replicate between hospitals. However, influenza vaccine availability has been a perennial problem in recent years, and promises to continue being a problem. Sanofi Pasteur, one of the major suppliers for influenza vaccine in the United States, released a statement on 2/1/06 regarding an unprecedented demand for influenza vaccine for 2006-2007, and acknowledged that it will be unable to supply influenza vaccine to all of those who are requesting it. Until sufficient influenza vaccine is available to all of those individuals for whom it is recommended, this process measure may not be useful. One of the problems in the last few years has been that influenza vaccine has arrived too late in the season to be useful. It is difficult to convince healthcare workers to get vaccinated once the annual epidemic has occurred. Influenza vaccine supply problems should be resolved prior to implementing this as a process measure.

In choosing outcome measures, infections for which clear definitions exist should be included. Hospital-acquired pneumonia is an example of an infection for which substantial problems with definitions exists. One of the problems with using healthcare-acquired pneumonia as an outcome measure, is that definitive diagnosis is difficult. According to 2005 guidelines of the American Thoracic Society and the Infectious Disease Society of America, "the diagnosis of hospital-acquired pneumonia is difficult, and most studies have involved clinical diagnosis, with sputum culture, but bronchoscopy has been used less often, making the reliability of the bacteriologic information uncertain and the specificity of the diagnosis undefined." [6] A number of different clinical criteria and diagnostic criteria have been proposed for the diagnosis of hospital-acquired pneumonia, and still no clear definition exists. Infection control personnel currently use a definition that includes a number of clinical criteria, and leaves too much room for interpretation. These definitions are useful to individual institutions in that they can be used to follow trends over time for an individual hospital. However, valid comparisons to other hospitals would be difficult, as individuals performing surveillance may interpret the definitions differently.

The National Nosocomial Infections Surveillance System (NNIS) is currently the method by which hospitals benchmark their hospital-acquired infection data. This system was established in order to track the incidence of hospital-acquired infections and the risk factors for these infections. NNIS does adjust for risk factors to an extent, but the risk stratification may not be sufficient. For example, NNIS publishes benchmark data for infection rates in surgical intensive care units. Surgical intensive care units may vary substantially in patient populations. These intensive care units may care for critically ill surgical patients and for trauma patients. Trauma patients may have had a variety of injuries such as blunt trauma related to motor-vehicle accidents, industrial accidents, gunshot wounds, etc. Trauma patients with severe injuries are at higher risk for

infections because the nature of the trauma itself may lead to infection, and their hospital stays are often long and include numerous procedures. The risk of infection in these patients is different than the risk of infection in a patient undergoing elective or emergent surgery, and should not be grouped together. However, the current NNIS definition for a trauma intensive care unit includes those surgical intensive care units where 80% of the bed days consist of trauma patients. The hospital that I work in is the major trauma center in Northeast Ohio. We care for critically ill trauma patients with multiple injuries, and serve as a referral center for critically ill medical and surgical patients. Our surgical intensive care unit typically has about 70% bed occupancy from trauma patients. That means that our surgical intensive care unit is compared to other surgical intensive care units that do not care for predominantly trauma patients for NNIS benchmarking purposes. Because of the severity of the injuries that our trauma patients have, comparison to other non-trauma intensive care units does not yield a valid comparison. Methods to control for this need to be instituted prior to public reporting. Case-finding methodology for NNIS is also costly and definitions are complex and may be difficult to apply.[1]

Clostridium difficile colitis (C.diff) is another infection that has received a great deal of attention recently. This infection is caused by bacteria that may be part of the normal bacterial flora in the intestines, and can manifest as an infection after exposure to antibiotics. Currently there is a hypervirulent strain of this organism in hospitals throughout the United States, Canada and Europe, and this disease has caused a great deal of morbidity and mortality. There have also been isolated cases of this disease occurring in individuals not previously exposed to antibiotics, which is unusual for this infection. C.diff can be transmitted in hospitals on the hands of healthcare workers and from contaminated surfaces. There has been demand for public reporting of this infection, and currently this is a reportable infection in the state of Ohio. The public awareness has led to increased awareness among healthcare workers, and I have seen increased attention to infection control precautions and handwashing. The problem with this infection is that currently there is no standard definition that is used by all hospitals to collect data regarding rates of infection. For public reporting to be most useful, there should be a standard definition followed be hospitals throughout the United States that would allow valid comparisons. The current definition being used in Ohio does not account for all cases of C. diff, and is different than the surveillance definitions that were previously being used by hospitals. It is often not possible to determine where C.diff originated. One of the problems is that patients may be hospitalized in several different hospitals and long-term care facilities over a period of months. While C.diff is often a healthcare-acquired infection, the location where an individual became exposed is often difficult to determine. In our institution, many of the C.diff cases that we see were acquired elsewhere. Currently there is no standard definition that allows for complete reporting of all of the cases.

There are potential adverse effects from public reporting. The process of public reporting should be carefully thought out in order to avoid these consequences. HICPAC states the following:

> Conversely, as with voluntary private reporting, mandatory public reporting that doesn't incorporate sound surveillance principles and reasonable goals may divert resources to reporting infections and collecting data for risk adjustment and away from patient care and prevention; such reporting also could result in unintended disincentives to treat patients at higher risk for HAI. In addition, current standard methods for HAI surveillance were developed for voluntary use and may need to be modified for mandatory reporting. Lastly, publicly reported HAI rates can mislead stakeholders if inaccurate information is disseminated. Therefore, in a

mandatory public report of HAI information, the limitations of current methods should be clearly communicated within the publicly released report.[5]

These potential adverse consequences must be carefully considered in the implementation of public reporting. A system that diverts infection control personnel from surveillance and education of healthcare workers could have the unintended consequence of increasing hospital-acquired infections.

In conclusion, public disclosure of hospital-acquired infections has the potential to make useful information available to the public, and may lead to improvement in quality of healthcare in the United States. In order for the public to get useful information that allows valid comparisons between hospitals, the process and outcome measures must be carefully considered, and it is imperative that definitions exist that can be applied at hospitals throughout the country. Further, there need to be methods to validate reported information, and adequate personnel so that reporting does not detract from current infection control responsibilities.

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MR. WHITFIELD. Dr. Hanrahan, thank you.

Dr. Daley, you are recognized for 5 minutes.

DR. DALEY. Thank you for inviting me here today, Chairman Whitfield and Congressman Stupak and other members of the committee. I both appreciate the opportunity to address you and also compliment you for your interest in this issue, which is a passion for all of us here on the panel.

I am the Senior Vice President for Clinical Quality and the Chief Medical Officer for Tenet Healthcare Corporation based in Dallas, Texas. I have had that position since July of 2003.

Since joining Tenet, I have collaborated with my boss, who is the CEO of Tenet Healthcare, Trevor Fetter, to develop a new quality

program for all of our hospitals, which is called the Commitment to Quality. Its sole purpose is to bring evidence-based practices to improve safety and quality for all our hospitals. One of the critical components of that is reducing hospital-acquired infections.

We have endorsed two goals. Our primary one is to reduce the incidence of these infections to zero, and the second is to share accurate data with our patients and our consumers.

One critical component of our infection control program is the creation of a web-based system that allows us to identify every hospital-acquired infection in every hospital concurrent with the patient's hospitalization. If you went to almost any hospital in the United States and asked to meet the hospital infection control person, you would find them in the basement, somewhere distant from healthcare, collecting data on patients from six months ago. This allows our infection control practitioners to, every morning when they come to work, identify all the hospital-acquired infections for that day and get out on the floors within a matter of an hour to start preventing the next infection.

We have taken the philosophical approach that every hospital-acquired infection should be taken as an opportunity to review the root causes and to change our approaches to proactive prevention so that we can prevent any subsequent infection. This system also produces comparative reports across our hospitals, and secondarily, while we have done that for comparative reasons, it has also given us the ability to develop incentives toward achievement of our goal of zero infections.

So my boss, Mr. Fetter, and I have collaboratively developed something known as the balance scorecard, which puts significant weight on improvement in quality and safety, and in 2006, all executive compensation calculations for bonus in Tenet include a component for reducing the rate of hospital-acquired infections with our own form of paper performance.

We also want to provide reliable and credible information to the public and our patients. We believe in being transparent with our patients and their families, as well as our physician and payer partners, about the quality and safety in our hospitals and who benefits from them, and that is a reinforcement of our commitment to quality.

As everyone has noted on the panel, State legislatures are stepping up to this plate in an aggressive way, and we support that. I personally have a concern that the State experiments will result, in my case, where we provide healthcare in 13 different States, that I will have 13 different reporting requirements to incorporate into my systems. That presents somewhat of a burden to us as a national healthcare company. I would prefer to see standard definitions, strategies for surveillance and identification, and reporting of hospital-acquired rates. If you decide that

that single approach is in the best interest of the country, I would encourage you to examine what the NQF is doing. I am a little more optimistic than some of my panel members that we will have both process and outcome measures come out of that.

I think we can do this. In a life prior to my life at Tenet, I was the co-chair of the National Surgical Quality Improvement Program in the VA. We were able to reduce in major surgery in the VA the complication rates which primarily consisted of surgical site infections, ventilator-associated pneumonia, and central line infections by 50 percent, and those have continued to drop subsequently. We saw a 25 percent decrease in the number of deaths related to surgery in the VA, and as you know, it is now recognized as one of the best high-quality healthcare systems in the United States.

On the issue of risk adjustment, in a former life with my colleagues at Harvard, we wrote three books about risk adjustment. I think we have to explore this very carefully because there are some populations of patients, you mentioned trauma patients, you mentioned burn patients and immuno-compromised patients, like Congressman Ferguson's mother, where we do need to understand whether they are at higher risk and how we can mitigate those risks.

We take this issue extremely seriously. We are absolutely committed to quality healthcare that is both effective and safe. Let me reiterate that we at Tenet are willing to cooperate in any way that we can and to implement the best standards for reducing the incidence of hospital-acquired infections. We do know how to reduce the incidence of these infections, and indeed eliminate them. The evidence exists. Those of us in this profession know what bundles are. For reducing ventilator-associated pneumonia, there are five things that you can do that work. There is a bundle for every single one of the things that we are talking about. We can do this.

Thank you again for the opportunity to speak to you, and for your commitment in making care safer for all our patients.

[The prepared statement of Dr. Jennifer Daley follows:]

PREPARED STATEMENT OF DR. JENNIFER DALEY, MD, SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, TENET HEALTHCARE CORP.

Chairman Whitfield, Congressman Stupak, Subcommittee members:

I thank you for inviting me to appear today before the Subcommittee.

I am the Senior Vice President of Clinical Quality and Chief Medical Officer for Tenet Healthcare Corporation, headquartered in Dallas, Texas. I have served in this capacity since July 2003. Prior to joining Tenet, I was the Director of the Center for Health Systems Design and Evaluation at Massachusetts General Hospital and an Associate Professor of Medicine at Harvard Medical School. Tenet Healthcare owns and operates 69 acute care hospitals in 13 states, including four leading academic medical centers and one children's hospital.

Since 1990, I have been researching and applying quality improvement activities in hospitals and am proud today to oversee Tenet's commitment to improving the areas of quality of care and patient safety in our hospitals. Since joining the company, I have worked with CEO Trevor Fetter to develop and implement a new quality program for our hospitals known as the "Commitment to Quality," which is designed to enhance the overall quality and productivity of our care delivery process. The Commitment to Quality consists of a comprehensive set of initiatives all aimed at one purpose: to utilize evidence-based medicine and demonstrable best practices across a large hospital system to improve clinical outcomes and patient safety. The initiatives focus on quality of care and patient safety, nursing practice, medical staff governance and other important areas related to patient care.

I am pleased to be able to speak with you today about an important component of our Commitment to Quality and a critical challenge facing the nation's healthcare system – reducing the incidence of hospital-acquired infections ("HAIs"). I would like to begin by emphasizing the fact that Tenet endorses two goals, the most important of which is reducing the incidence of HAIs, and the second of which is sharing accurate and useful information about infection control efforts with patients and the public.

Tenet's commitment to reducing the incidence of HAIs and resultant infections in our own hospitals is evidenced by several aggressive programs implemented by Tenet. Our infection prevention and control efforts focus on four main categories of HAIs: surgical site infections, ventilator-associated pneumonia, central venous catheter-associated bloodstream infections, and urinary catheter-induced urinary tract infections. We are also targeting infections resulting from antibiotic resistant strains of bacteria, such as methicillin-resistant *Staphylococcus aureus* ("staph" bacteria/infection), vancomycin-resistant *Enterococci* (VRE), and *Clostridium difficile* (colitis).

In mid-2005, Tenet issued a Model Infection Control Program Plan as a framework to assist our hospitals in the development of hospital-specific infection control and prevention programs. The model plan, a copy of which has been provided to the Subcommittee, is designed to meet the 2005 regulatory requirements from the Centers for Medicare and Medicaid (CMS) Conditions of Participation and the 2005 Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards for Practice. The plan also takes into account the position statements for the infrastructure and essential activities of infection control and epidemiology in hospitals from the Society for Healthcare Epidemiology of America (SHEA) and the Association for Professionals in Infection Control and Epidemiology (APIC). In distributing the model plan, Tenet advised our hospitals that notwithstanding the fact that they might have existing policies, those policies at the very least were to be modified to include all components of the model plan.

The basic purpose of Tenet's extensive Infection Control Program Plan is to actively identify infections and reduce the risk of disease transmission through the introduction of proactive preventive measures. We at Tenet recognize that effective infection control programs no longer consist of generating incident infection reports from a cubicle in the hospital basement. Superior infection control programs require a systematic approach, including the adoption of specific infection control procedures and efforts to ensure compliance with those procedures. Tenet's infection control program exemplifies this high standard and includes the creation of an Infection Control Committee, provisions for risk assessment, and numerous specific strategies for preventing infection. Moreover, Tenet's own infection control program, coupled with our participation in the "100,000 Lives Campaign," provide effective and uniform standards across all 69 of Tenet's hospitals. Local variations in infection control programs, within Tenet's hospitals, are being eliminated as Tenet strives to create a unified set of the highest infection control standards.

As previously stated, in addition to implementing our own, very rigorous and uniform Infection Control and Prevention Plan as part of an effort to reduce the occurrence of HAIs, Tenet and all of its hospitals were founding members of IHI's "100,000 Lives Campaign." The overall goal of the Campaign, consistent with Tenet's infection control program goal, is to make healthcare safer and more effective to ensure that hospitals achieve the best possible outcomes for all patients. Like Tenet's infection control program, the campaign implements specific targets which aim to reduce or prevent infection in hospitals.

A critical component of Tenet's approach to infection control is the company's creation of an internal system of reporting the incident-rate of HAIs in our hospitals. This system, which is currently being implemented, produces comparative reports of HAIs within Tenet and will be an effective tool in improving the quality of care and patient safety in all of Tenet's hospitals.

Finally, I know that the Subcommittee, others in Congress, and officials at CMS are exploring mechanisms by which "pay for performance" can be used to provide incentives for improving quality among healthcare providers. Since assuming leadership of Tenet in 2003, Trevor Fetter has spearheaded the development of an innovative compensation program for corporate and hospital executives, know as the Balanced Scorecard, which places significant weight on achieving quality improvement goals. This year, and for the first time, success in reducing the rate of HAIs in Tenet hospitals will be a significant factor in all executive compensation calculations. This change will affect all levels of executive management, including Trevor himself.

In addition to Tenet's and my primary goal of reducing HAIs, it is also our goal to ensure that reliable information is properly disseminated to patients and the public. Getting information to consumers not only allows them to make informed decisions about their healthcare, but more importantly, it enables hospitals to analyze their own infection control methods and see what is working effectively to reduce the incidence of HAIs and what areas of infection control need improvement.

Recently, state legislatures have taken aggressive steps to ensure that public reporting of HAIs becomes a priority. As it currently stands, more than thirty states have passed or are considering legislation regulating the reporting of HAIs. Three of the states in which Tenet owns or manages hospitals currently mandate the public reporting of HAI rates: Pennsylvania, Missouri and Florida. Over the next year, four additional states in which Tenet operates hospitals will consider implementing public reporting requirements of HAI rates: California, Alabama, Georgia and Mississippi. Finally, three states in which Tenet operates hospitals currently have study bills: Texas, Tennessee and Louisiana.

While it is our goal to see that data related to hospital infection rates are collected and accurately publicly reported, it is critical to point out that not all reporting methods will necessarily be helpful or effective. The legislation varies among states, creating the very real possibility that Tenet and other national healthcare providers will be subject to multiple and varied reporting requirements and methodologies. Some state legislation requires reporting according to specific procedures, and different states may require reporting for different procedures. Individual state legislation also varies according to the particular type of HAI for which reporting is required. State legislation can also vary according to the type of healthcare facility in which infection occurs, such as critical care units, hospitals, ambulatory surgical centers, and nursing homes. With such varied approaches to reporting requirements among several states, following each state's law accurately will create a significant burden for national healthcare providers such as Tenet.

Because of the difficulty and burden inherent in having different reporting requirements, there would be some benefit to establishing a single national standard for the identification, definition and reporting of HAI rates, provided that the single standard is established after thoughtful and collaborative evaluation. If it is decided that a single

standard is the best approach, I would encourage Congress to examine current industry efforts to establish reporting requirements. One good example of such an effort is the National Quality Forum ("NQF") expert panel, currently being formed by the NQF. Members of the National Societies of Hospital Epidemiologists (SHEA and APIC), as well as representatives from the CDC, will be represented on this panel. I believe this group is capable of arriving at scientifically sound and feasible methods and definitions that will serve as reasonable national references and standards.

In addition to establishing a reasonable national standard, the NQF panel is in the best position to make recommendations on how to adjust for a higher baseline risk of infection in acute care units. Currently, Tenet has several hospitals with high patient acute care units, such as trauma units and burn units, in which the baseline risk of HAIs is higher than in many intensive care units and general medical/surgical units. Appropriately adjusting for this higher baseline of risk of infection in critically ill patients would ensure that the information provided to public consumers is more useful and accurate.

Hospitals across the country are taking the issue of HAIs and resultant infections very seriously and increasing their efforts to combat this problem. I am particularly proud of Tenet's work on implementation of infection control and prevention plans in all of our 69 hospitals and our participation in the IHI's "100,000 Lives Campaign," which provide strong examples of industry efforts to reduce the incidence of HAIs and resultant infections. With industry cooperation and increased awareness of the issues created by hearings such as this, the healthcare industry can further our dual goals of reducing the incidence of HAIs and disseminating accurate and useful information to patients and the public.

Tenet is absolutely committed to quality healthcare that is both effective and safe for patients. As part of this commitment, let me reiterate that Tenet is willing to cooperate to help establish the best standards for reducing the incidence of HAIs and for public reporting of HAI rates. Thank you again for the opportunity to speak with you today.

MR. WHITFIELD. Dr. Daley, thank you, and thanks to the entire panel. We appreciate it very much.

Dr. Daley mentioned these risk adjustment factors, Dr. Hanrahan certainly referred to them, and Dr. Hammer referred to them. In my brief involvement in this issue, it appears that risk adjustment factors continue to be an area that creates quite a bit of concern by a lot of people.

Dr. Haley, you heard Dr. Hammer and Dr. Hanrahan and their discussion about risk adjustment factors, Dr. Shannon, you also. Would you comment on the concerns that they had, and then I would like for you all to comment on what they say as well.

DR. HALEY. I think it has to do with where you use the data, and I think Dr. Shannon's comments were appropriate. In the hospital when you are trying to incent doctors and nurses to be more careful and so forth, looking at numbers of infections is good. In fact, at Parkland, we have a chart where we look at the risk adjusted rates and the numbers and all of that on the same graph, and we share that information.

On the other hand, when you are trying to put up a website where you have data that consumers are going to look at, and presumably it is there so they can make a decision which hospital to go to. If you don't

risk adjust the data, chances are the hospital with the lowest infection rate is going to be the one that takes care of the least acute patients, the wellest patients, and the ones with the highest rates are going to be the ones that take care of the sickest patients. To some extent, that is unavoidable. You can't reduce the surgical wound infection rates to zero. No one has ever shown that you could ever do that. And so if you don't risk adjust, that confounding is going to automatically send the patients to the ones with the lower rates, which are the ones that take care of the least acute patients, and you are looking at apples versus oranges. Whereas if you risk adjust, you might find that a big hospital that takes care of the most complicated patients actually does the better job when you risk adjust, and the patient would then go to the one with the higher rate because that is actually where they do a better job and prevent infection better.

So if you don't risk adjust, you are in the paradox of sending the patients to the place where they had the highest risk of infection.

MR. WHITFIELD. All right. Dr. Shannon, what comment do you have?

DR. SHANNON. Briefly, I certainly would be willing to pull all of the burn unit patients out of public reports and compare them separately. I would be willing to pull all the cancer center patients out of the public reports and compare them separately. I would be willing to pull all the trauma unit patients out of the public reports and compare them separately.

In our experience in the 54 central line infections that I showed you, only one patient was immuno-compromised. The most common diagnosis was heart failure, not a disease that I would say anyone would identify as at high risk for a line infection. It is not diabetes; we have looked at this.

So I think we could pull out the high risk patients, and in the experience in Pennsylvania Mr. Volavka could comment, but of the 11,668 reported infections, only 300 were in any of the high risk groups you have heard mentioned today, so what about the 11,300 other people that aren't in high risk groups?

So I would be willing, in deference to the risk adjustment, to take out of public reports, or compare separately, if that is what you want to do. But I think to hold up the process by virtue of waiting for an acceptable risk adjustment methodology to account for that is going to be a delay.

MR. WHITFIELD. What about you, Mr. Volavka?

MR. VOLAVKA. I can give you the numbers. Dr. Shannon just gave them to you. I would agree with all the panelists. I would take issue with the framing of the concept of risk adjustment. I don't believe it is appropriate to risk adjust. I do believe it is inappropriate to exclude. I

would absolutely concede--and we had this argument--to trauma patients, burn victims, transplants. I don't want to compare a community hospital that doesn't do burns, doesn't do trauma, doesn't do transplants with a hospital that does. But we went in and actually looked at the data that was reported in Pennsylvania, and as Dr. Shannon indicated, of the 11,668 patients that got an infection in Pennsylvania hospitals, that the hospitals put their hands up and said yes, we gave this patient an infection. Less than 300 of them fell into any of those categories. I will exclude them. I don't want to risk adjust for them, I will exclude them.

Further, I think it would be very helpful to look at those patient populations in and of themselves, but that is an exclusion. That is not a risk adjustment. There were still 11,368 patients that fall into the category that don't fall into those major areas where I would agree it is not fair to compare a hospital that takes a lot of those patients with a hospital that doesn't. So it is terminology.

MR. WHITFIELD. Dr. Hammer, any comment?

DR. HAMMER. I think what you are hearing is that there is more agreement here than disagreement. That in fact, we are all in the business of improving patient care and improving quality at the same time, and it is a win/win situation, which was mentioned earlier, to reduce lengths of stay and to reduce hospital-acquired infections.

I personally think I would like a system that it more inclusive and risk adjusted than where we start carving out exclusions, because I think the country has many centers and many academic medical centers that take on these more complicated patients. In fact, these more complicated patients--and I will be brief--are not as uncommon as we think. Organ transplantation, for example, is a widespread issue across the Nation, and I think we have to keep those patients in the mix. We just have to risk adjust and stratify properly for them.

I will defer to my colleagues on my left.

MR. WHITFIELD. Any comment, Dr. Hanrahan?

DR. HANRAHAN. Yeah, I agree. It sounds like we actually all mostly agree on this. I certainly am in favor of public disclosure. I would like more people to pay attention to infection prevention, so I am very much in favor of it and I am not suggesting holding it up for purposes of risk adjustment, but I want to make sure we really are comparing apples to apples.

And so one of the things in our hospital, I can tell you in our medical intensive care unit and our cardiac intensive care unit, we have had zero catheter-related bloodstream infections since July of 2004. That is not where we are seeing it. We are seeing it in our trauma and burn patients. And so in our hospital, we have tried to implement some of the same

things that we did to get our rates down in those other areas, and it has not been successful on the trauma patients.

And so I think that there are certain infections that you can't prevent.

MR. WHITFIELD. Dr. Haley, I may have misunderstood you, but I had the impression in your testimony that you were saying we really didn't need a national system that the States could do this. Yet, on the other hand, it does look like you get a patchwork of different systems, and if there was one area where Federal government should be involved, it would be in this area.

DR. HALEY. Yeah, I think eventually that would be a good idea. I just think at this point you see the disagreement over the nuts and bolts of how this should be done. And I think we have seen like four Medicaid and other Federal areas, when you have States experimenting for a period of time, you get all kinds of different models. Then over time, you learn about them, you have national meetings and scientific meetings where people debate it, and then two or three or four years from now, we might be in a position where you would want to have a national standard, or one might just evolve, if we all sort of agree on what needs to be done.

So I think to freeze it right now, before there is the experimentation, I think might reduce innovation.

MR. WHITFIELD. Right. What about you, do you agree with that, Ms. Goeschel?

MS. GOESCHEL. I think that in Michigan we agree that transparency is important, but we think that overall, we dedicate far too many resources to debating how to report data versus how to eliminate infections.

And so when I started my testimony by saying we aren't about public reporting, we will report anything anyone wants, because we don't have the infections. The reality is, we want to go about continuing to support getting rid of the infections, not laborious debate over how to report them.

MR. WHITFIELD. In our exhibit book here, the HICPAC report warns that mandatory public reporting may have unintended consequences, such as diverting resources away from patient care and creating disincentives to treat high risk patients. Do you all share those concerns?

DR. HALEY. I don't. I think what we are seeing in Missouri, for example, I was talking to them just the other day. When they passed their law, suddenly hospitals started hiring a bunch of new infection control practitioners. There was a big hiring frenzy going on. So I think hospitals are responding responsibly when they see they are going to have to measure.

MR. VOLAVKA. That is a great question. It really is. Before the Pennsylvania requirement went into business, the rumor was around the country that ICPs were already leaving Pennsylvania in droves. The reality is that we have seen exactly what you are seeing, and quite frankly, because we have started to do some public disclosure of potentially under-reporting hospitals. I can tell you, even as late as yesterday, I got a letter from a CEO who had been identified as a potential under-reporter, and quite frankly, that hospital is now undergoing an independent audit. I won't tell you the nature of the conversation I had with him three weeks ago, but I will tell you what the letter said. The letter said we are hiring additional ICP personnel to ensure that we meet the goals of public reporting. It is happening all over.

I would like the opportunity to congratulate Michigan, number one. I think that is the ultimate goal. I may be one of the few that actually has known about what has been occurring in Michigan. I think Michigan is a shining example of where a hospital association is way out in front of the curve. There are others in this country, and Texas is another one. I know some Texas people in the hospital association very well.

MR. WHITFIELD. Ms. Goeschel?

MS. GOESCHEL. And I was just going to say, I think a key point, and hopefully it came through in my testimony, is that although there wasn't public reporting, we were all about measurement. This is hard work and people pushed back in terms of how to define. But the minute we created that these are the definitions, this is what we are doing, this is how we are going to collect, this became a learning community like no other.

And that is where the tough balance is, between is it reporting or is it eliminating the infections, and that is part of the debate.

MR. WHITFIELD. And Dr. Daley, do you have any comment on this HICPAC report?

DR. DALEY. I think it will create positive incentives for hospitals.

MR. WHITFIELD. Okay.

DR. DALEY. I am not worried about that at all. The goal is to reduce infections.

MR. WHITFIELD. My time is expired. Mr. Stupak?

MR. STUPAK. Thank you.

Ms. Goeschel, did Michigan have to hire all kinds of infection control officers?

MS. GOESCHEL. To my knowledge, we did not hire. I didn't hear anything about hiring infection control practitioners in droves. What I will tell you is that the infection control community is highly involved in our project, extremely supportive, because the reality is every clinician in

Michigan in ICUs is now an infection control practitioner. The awareness of what we need to do to eliminate infections doesn't belong to infection control practitioners, it belongs to everyone.

MR. STUPAK. Let me ask this question. It came up earlier. In your experience, and since you are all infection people you are probably tuned into it, but does the doctor, as a general rule, know the infection rate of the hospital he is licensed at? Most of you are shaking your head no.

DR. HANRAHAN. I can tell you that is definitely not the case at our hospital.

MR. VOLAVKA. I can tell you further that when we have started to show them their infection rates, they get astounded and they engage.

DR. HALEY. Now, remember, the majority of hospitals are not measuring, so if they don't measure, nobody can know the rate.

MR. STUPAK. And even CDC only did less than 10 percent of the hospitals in the United States.

DR. HANRAHAN. Can I just make a clarification?

We do get feedback to physicians about their infection rates, but somebody else, another physician is not going to know the hospital infection rates.

MR. STUPAK. In surgery, one of the issues that came up today is infection in surgeries. When you go to surgery, before you actually go to surgery, don't you get an antibiotic to try to prevent infection? Isn't that sort of like standard operating procedure?

DR. HANRAHAN. It depends what the procedure is. It is not recommended for all surgical procedures. For clean surgical procedures, there is no need, you know. It really depends what you are talking about. If you are having--

MR. STUPAK. Let us say Mr. Wagner's son here who had the broken humerus. Would it have been--given him an antibiotic before--

DR. HANRAHAN. You know, I don't want to comment specifically--I don't know the details of that case.

MR. STUPAK. Right, but without knowing the details, isn't it sort of standard operating procedure? Isn't there a protocol you have to follow? No?

DR. HANRAHAN. Not unless there is going to be an implant.

DR. HAMMER. I would just say that for an orthopedic procedure of a fracture as described, and I don't know the details, with metal implanted there would be a prophylactic antibiotic given.

DR. HALEY. You know, there is a push-pull here, and there is huge scientific literature on this. There are certain procedures where it is proven that prophylactic antibiotics reduce the infection rate. There are others where it has been proven that they don't.

MR. STUPAK. Sure.

DR. HALEY. And if you give antibiotics on those, what you are doing is exposing the patient to the untold side effects of antibiotics, which can be very serious sometimes, with no prospect of gain. And so surgeons are much better these days than they were 20 years ago in giving it in those cases where it is indicated and not giving it when it is not indicated.

MR. STUPAK. Okay. Dr. Daley, back in your testimony you said in your previous life, you worked at the VA and reduced infections by 50 percent?

DR. DALEY. We reduced post-operative complications, which were primarily post-operative infections, surgical site infections. This was all from major surgery, ventilator-associated pneumonia, central line infections, by 50 percent.

MR. STUPAK. Okay. You probably didn't have definitions back then, so--

DR. DALEY. Yes, sir, we did. We used the CDC definitions.

MR. STUPAK. Okay. Why can't you do that at your hospital now, at Tenet?

DR. DALEY. I am. That is my goal in life.

MR. STUPAK. Okay. This is sort of a recent goal, right, because you just put financial rewards for compensation to reduce the--

DR. DALEY. We have had the program since I arrived in July of 2003.

MR. STUPAK. Okay.

DR. DALEY. We have got all the standard definitions in place, and now we have the standard web-based reporting system. We put our hospital executives on notice that this was going to happen six months ago, and we pulled the trigger on January 1.

MR. STUPAK. Of this year?

DR. DALEY. My phone has been ringing off the hook.

MR. STUPAK. Okay, that is good. That is good.

DR. DALEY. Yes, sir, it is.

MR. STUPAK. Dr. Hanrahan, I got the impression you have a lot of reluctance about this public reporting, definitions of infections in trauma units, and risk situations that you seemed to be concerned about. But what concerns your hospital--and I guess what I didn't hear is what is your hospital doing to reduce its own incidence of hospital-acquired infections? For example, ventilator-associated pneumonia is one of the most deadly hospital infections, and in some simple steps such as I mentioned in my opening statement, elevating the head of the patient will reduce the incident. But instead, in your testimony you sort of talked about lack of a flu vaccine.

So I guess my question is what is MetroHealth Medical Center doing to reduce this infection, or any other infection, regardless of how it is counted?

DR. HANRAHAN. Thank you for giving me an opportunity to clarify that, because we certainly are doing a great deal, and I guess in my testimony today I really wanted to emphasize the things that I think are potential problems with public disclosure, not to just tell you what we have done to decrease our infection rates. I will go into that in a moment.

But I want to clarify, I am not opposed to public disclosure, I am very much in favor of it. I just think that it really needs to be done properly and it is incumbent upon all of you to make sure that this happens properly, otherwise it is not going to yield useful information. What is going on in Ohio right now with the C.diff reporting, I have serious concerns about and I think this is an example of where some of the information can potentially mislead people. People are not getting all of the information about C.diff that they think they are getting.

So what our hospital is doing, what you mentioned about raising the head of the bed to prevent ventilator-associated pneumonia, we are doing those things. The things that the IHI has recommended, and their 100,000 Lives campaign, we are doing all of those things. We have had excellent adherence to hand hygiene once HICPAC and CDC made the recommendation to change to alcohol-based hand hygiene products. Our hand hygiene compliance rates have been upwards of 90 percent, which is unheard of when you compare it to lots of other studies that are being done.

MR. STUPAK. Okay. Have your infection rates been going down?

DR. HANRAHAN. Yes. For central line associated infections in certain intensive care units, as I said before, the infection rates have gone down.

MR. STUPAK. Wouldn't you want that to be known then?

DR. HANRAHAN. Sure.

MR. STUPAK. I mean, I don't think the issue is what definitions we are using. Isn't the real issue here reducing the infections?

DR. HANRAHAN. No, I absolutely want that to be known. My comment was regarding specifically the trauma patients, and I can tell you we have not been able to have that same impact in that patient population. I think it is important to highlight that we really are talking about some different patient populations.

MR. STUPAK. Well, let me ask Dr. Shannon this, because this patient population, I am not sold on that. When we prepared for this hearing, our staffs spent a lot of time with several hospitals and the argument was made or talked about that because they were like inner city hospitals or

teaching hospitals or trauma centers, that their patients were sicker than those in other hospitals, and as thus, more susceptible to infection than other patients in other hospitals. So I guess I would ask Dr. Shannon, is it your view then that the patient should not get infections in the other hospitals or at a greater rate of risk than other patients? I mean, I just think that is--

DR. SHANNON. Yes, I believe that there isn't a differential rate of risk, except in biological circumstances in which we recognize the person has a predilection to those infections, immunosuppresion, burn patients, perhaps trauma patients.

I think this is not about biology and organisms. This is about processes of care in which one places a catheter in an arm in a standard way and then guarantees it is going to be maintained in a sterile fashion for the period that it is in dwelling. This has to do with educating operators that variations in the way to put in the line are not helpful to a process. Can't we, as intelligent people, agree that there is one way to place a subclavian line? We don't--some of us gown, some of us don't, some of us glove, some of us don't, some wear caps, some don't. Some nurses don't remain sterile when they hook the catheter up, some do. What we have done is standardized those processes so that at any moment, a variation can identify a potential harmful circumstance that might propagate into an infection. So too, we have done the standardization around maintaining the catheter's integrity. If the catheter is in for 12 days, focusing on the day it is placed alone is insufficient to guarantee its integrity.

So I would like not to focus so much on is my arm different than yours? Is my hair different than yours? And ask the question, can't we in institutions that do open heart surgery and cardiac transplantation put a catheter in safely for a period of time?

MR. STUPAK. Well, let me ask you this, then. I have only got a little bit of time left. And you started to do this a little bit, but would you explain briefly the Toyota process you are using, and I believe Tenet is going to use the same system, right? And how similar is your perfecting patient care system to that what Michigan was using?

DR. SHANNON. I can't answer the latter question, but I am confident given our results are close that it is probably pretty good. I would like to hear more about it.

Perfecting patient care is the application of the principles of the Toyota production system to healthcare delivery. It involves setting four important steps. The first is decoding your data so you understand it in its most basic human element, not 5 infections per 1,000 line days, but who are the people that get them.

The second is observing the current conditions so you understand the variation in existing processes, and then you get the workers, not the infection control committee, to agree what they think is the best way to do it. You provide guidance through established evidence, but they decide on the worker's process and then everyone agrees to it.

The third and critical step is each infection must be investigated in real time. That is the context in which you can learn how it happened. And if you don't know how it happened, you can't prevent it from happening the second time. And the fourth, then, is to continually look at the countermeasures and adjust them as you develop new processes.

MR. STUPAK. Thank you.

MR. WHITFIELD. Thank you, Mr. Stupak. One other question, Dr. Shannon. In your testimony, you referred to this conspiracy of error and waste, and do you think that most hospital administrators really do not understand the financial impact of infections?

DR. SHANNON. I believe they do not understand the financial impact of these infections. One of the important exercises that I hope this discussion will engender is an opportunity for hospitals across the country to go home and look at the cases of their hospital-acquired infections and show to their chief financial officers that in fact they are losing money on these cases, thereby aligning the incentives all across the board for getting serious about fixing them.

MR. WHITFIELD. Well, thank you all very much. We genuinely appreciate your testimony. It is quite helpful for us, and we loved your enthusiasm. I hope all the participants out there who did not serve on a panel enjoyed their day with us as much as we did with them.

And so with that, the hearing is adjourned. The record will be kept open for the appropriate number of days for additional filing.

[Whereupon, at 5:45 p.m., the subcommittee was adjourned.]

RESPONSE FOR THE RECORD BY MARC VOLAVKA, EXECUTIVE DIRECTOR, PENNSYLVANIA HEALTH CARE COST CONTAINMENT COUNCIL

Pennsylvania Health Care Cost Containment Council

May 25, 2006

The Honorable Ed Whitfield
Chairman
Subcommittee on Oversight and Investigations
The Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Representative Whitfield:

On behalf of the Pennsylvania Health Care Cost Containment Council, I want to thank you for giving me the opportunity to appear before the Subcommittee on Oversight and Investigations at the hearing entitled "Public Reporting of Hospital-Acquired Infections: Empowering Patients, Saving Lives."

Pursuant to your request, I have attached answers to the questions submitted by Representatives Blackburn and Dingell. If the Committee or its staff members need any additional information for the hearing record, please do not hesitate to contact me.

Thank you again for the honor of delivering testimony before the Subcommittee.

Best regards,

Marc P. Volavka
Executive Director

Attachment

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Question from the Honorable Marsha Blackburn

1. In your testimony, you mention that states are the great laboratories of our nation. Some on the panel have argued that we should not develop a national standard at this point and wait to see what some of the other states come up with before creating a national standard.
   - In your opinion, could the Pennsylvania tracking and reporting system quickly be rolled out nationally?
   - Do you think it more important that we wait to see what some of the other states come up with or do you believe Congress should immediately create some standard for public reporting?

As I mentioned in my testimony, Pennsylvania's reporting system involved redefining a two-character data field (Field 21d) on the *Pennsylvania Uniform Claims and Billing Form*, which is submitted along with administrative and billing data for each inpatient hospital admission. Hospital personnel enter one of a defined set of codes into this field when the relevant hospital-acquired infection (HAI) is present. Therefore, almost every state in the nation is already positioned to adopt, either directly, or with their own modifications, the Pennsylvania model. PHC4 adopted, with minor clarifications, the Centers for Disease Control and Prevention (CDC) definition of a hospital-acquired infection and asked hospitals to follow this definition.

The highly replicable nature of the Pennsylvania model would not be hard to adopt and implement quickly in a technical sense. However, despite state legislative action, many states are still struggling with implementing operational systems, wrangling over definitions and data collection methods and debating different philosophies regarding public reporting. I believe these are important and necessary discussions.

To provide a point of comparison, here are some key dates in the Pennsylvania timeline:

- The Pennsylvania Health Care Cost Containment Council (PHC4) first began its efforts to create a standardized HAI reporting system in November 2003.
- Beginning January 1, 2004, Pennsylvania hospitals were required to submit data to PHC4 on four HAI types: surgical site, urinary tract, pneumonia, and bloodstream infections. Over the next two years, the reporting requirements were gradually expanded to include additional categories of HAIs. As of January 1, 2006, hospitals are required to submit data on *all* HAIs to PHC4.
- PHC4 released its first public report on HAIs in July 2005.

As I also stated in my testimony, states need the flexibility to experiment with solutions that work best in their unique socio-economic and political environments. Therefore, I do not believe that Congress should immediately create some single standard for public reporting. Rather than setting a single standard on the "what's and "how's" of data collection, what Congress can best do is establish performance targets and goals, and then provide incentives that states can use, with flexibility, and, given their own limited resources, begin to act on reducing and eliminating HAIs.

PHC4 has already, through the National Association of Health Data Organizations (NAHDO), made our model available to other states by offering the *PHC4 Hospital-Acquired Infection Collection Guide* and Infection Screening Diagnosis Codes Methodology. PHC4 made these two tools available via a signed sharing agreement so states can use them in their own data collection and reporting efforts – and share any modifications they make to the tools so Pennsylvania and other states can improve their ongoing initiatives. The *Hospital-Acquired Infection Collection Guide* is the current manual that Pennsylvania hospitals use to identify and report HAIs to PHC4. The definitions used in the guide are based on CDC criteria, and the process described within is how hospitals identify and confirm the HAI data that is the basis of PHC4's public reports. Information derived from the Infection Screening Diagnosis Codes Methodology is simply used to assess the accuracy and completeness of the HAI data reported by hospitals. This methodology is the list of ICD.9.CM diagnosis codes reported in universal billing data that PHC4 developed to identify *possible* HAIs.

Questions from the Honorable John D. Dingell

1. In 2004, Pennsylvania reported 11,668 hospital-acquired infections (HAIs), resulting in 1,510 deaths, 205,000 extra days in the hospital, and $2 billion in additional hospital charges. Despite the emphasis on reducing these infections, however, even more such infections were reported in the first nine months of 2005. Please explain why there was such an increase, and what is being done statewide to reduce it.

The increase can be attributed to the fact that Pennsylvania hospitals are getting better and more accurate in reporting the required data, and to an expansion in surgical site infection data collection requirements. It is NOT due to an actual increase in the number of infections contracted by patients.

Beginning January 1, 2004, hospitals were required to submit data on four types of HAIs to PHC4: surgical site infections for three body system categories; and indwelling catheter-associated urinary tract infections, ventilator-associated pneumonia and central line-associated bloodstream infections. As of July 1, 2005, seven additional body system categories for surgical site infections were added to the reporting requirements. This has now expanded to hospital-wide reporting of all HAIs beginning on January 1, 2006.

Since public reporting has been demonstrated to change provider behavior and measures the scope of the problem, it is the first step in reducing the number of HAIs. One cannot improve what one does not first measure. While this is the necessary first step, the ultimate goal is to provide those who work in infection control with the tools they need to identify areas of improvement. For this reason, PHC4 has begun working on two major collaborative initiatives that emphasize infection reduction.

In 2005, PHC4 and the Jewish Healthcare Foundation issued grants to five Pennsylvania hospitals for demonstration projects to quantify the costs, and to reduce the number, of HAIs. These hospitals were selected to duplicate the groundbreaking work pioneered by Dr. Rick Shannon and the staff at Allegheny General Hospital in an effort to reduce to near zero the number of central line-associated bloodstream infections in their critical care units. More

recently, PHC4 partnered with the Highmark Foundation on an initiative which will give hospitals the needed technologies to track and proactively prevent HAIs. Eleven hospitals will receive grants that will help them implement MedMined's Data Mining Surveillance system. The MedMined system frees hospital's infection control staff from manual data collection practices and allows them to more actively focus on identifying processes and system issues that have been demonstrated to reduce HAIs.

In addition to these PHC4 initiatives, many Pennsylvania hospitals have implemented their own infection reduction programs. Previously mentioned, the work done by Dr. Rick Shannon at Allegheny General Hospital is perhaps the most well-known hospital-specific initiative. However, many other hospitals have hand hygiene programs and central-line bloodstream infection initiatives that demonstrate how simple measures and standardized processes of care can drastically reduce and/or eliminate HAIs.

2. Pennsylvania's latest report on HAIs stated that commercial insurance carriers paid for only about 10 percent of the 2004 HAIs. How many did Medicaid and Medicare pay for? What percentage of the $2 billion in additional hospital costs is billed to the patients?

Pennsylvania has just recently been granted permission from the Centers for Medicare and Medicaid Services (CMS) to purchase Medicare payment data. It was disappointing, however, to learn that the cost to purchase this data was quoted at approximately $85,000. For independent state agencies like ours, or for state health departments that have seen their budgets cut, these added costs present additional barriers to accessing data that can lead to more detailed analysis of actual payments by our Medicare program.

In 2004, Medicare and Medicaid were billed for 76 percent of the total reported HAIs. Medicare and Medicaid were billed for 7,870 and 1,028 HAIs, respectively. The hospital admissions in which these infections were contracted amounted to an additional $1 billion in hospital charges for Medicare patients and an additional $372 million in hospital charges for Medicaid patients. Because co-payments and deductibles vary, PHC4 does not know what percentage of the $2 billion in additional hospitals costs was billed directly to the patients. (More information about the business case for reducing HAIs can be found in PHC4's November 2005 research brief at www.phc4.org.)

It is important to point out that uninsured patients were billed for 47 of the reported HAIs in 2004. Paying for hospitalizations involving HAIs is especially burdensome to the uninsured. The average charges for a stay in which an uninsured patient contracted an infection reached almost $230,000, compared to $21,000 for an uninsured patient without an infection. Furthermore, recent studies have shown that uninsured individuals are charged more than other groups for hospitals stays. Whereas government and commercial payors can negotiate large discounts for hospital charges, people without insurance have no such purchasing power and bear full responsibility for charges that can be two to three times higher than those accepted by most insurers.

3. In your testimony, you suggested that HAIs would disappear if Congress set performance goals requiring hospitals to eliminate HAIs after five years or Medicaid and Medicare

would not pay for hospitalizations in which in an infection occurred. Have you found support from this idea from anyone else?

While conversations are just beginning about not paying for hospitalizations in which an HAI was contracted, there is broad support for other types of pay-for-performance initiatives among health care purchasers and payors. The Centers for Medicare and Medicaid Services (CMS) is developing various pay-for-performance programs to support quality improvement in the care of Medicare beneficiaries. Two weeks ago, Dr. McClellan announced that CMS is studying the possibility of changing Medicare payment rules and not paying for "never events." In addition, state Medicaid agencies are starting to incorporate pay-for-performance incentives in their contracts with managed care plans. Furthermore, business-backed programs like *Leapfrog* or the *Bridges to Excellence* program, as well as the nation's largest insurance companies, are embracing the idea of paying for quality performance and not paying for non-performance.

I believe there is a simple reality in my suggestion that Congress establish goals. Providers, no different than all of us, respond more directly and more immediately when their bottom line is at risk. Establishing both a goal and a consequence (in financial terms) is imperative, and there are ample examples of Congressional use of "carrot and stick" approaches, including but not limited to, Federal Transportation Funding, enforcement of environmental laws and regulations, and in Federal funding for state Medicaid programs.

RESPONSE FOR THE RECORD BY DR. DENISE CARDO, CHIEF, DIVISION OF HEALTHCARE QUALITY PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
Congressional Responses for the Record
Questions from Rep. Blackburn and Rep. Dingell
June 1, 2006

Rep. Blackburn

1. In your testimony, you mentioned that CDC developed and disseminated evidence-based guidelines to prevent surgical site infections and follow-up studies indicated that surgeons were in large part not adhering to those recommendations.

- **In this example, where is the breakdown? Have you determined the reasons why surgeons were not following the recommendations?**
- **Did they receive the information?**
- **Would mandatory reporting help this situation?**

CDC developed and disseminated evidence-based guidelines to prevent surgical site infections in April of 1999. Examples of the recommendations in this guideline include antimicrobial prophylaxis (first dose, antimicrobial agent and duration), preoperative glucose control, and skin care.

These recommendations were made available on CDC's website. They were also published in the American Journal of Infection Control, the Journal of Infection Control in Hospital Epidemiology as well as the Journal of Surgical Outcomes.

CDC has partnered with the Centers for Medicare and Medicaid Services (CMS) in the Surgical Infection Prevention Project (SIPP)- a study to assess and promote the adoption of these practices among US surgeons. Results of SIPP revealed that, among 34,133 surgical procedures (cardiac, vascular, hip/knee, colon, hysterectomy) performed in Medicare patients, adherence to recommendations for the antimicrobial agents was high (92%), whereas adherence to recommendations for timing (48%) and duration (41%) of prophylaxis were suboptimal.

In addition, CDC conducted an assessment of the adoption of this guideline at three hospitals of varying types to identify barriers to following recommendations and to discover strategies to improve adherence. The evaluation focused on clinicians' adherence to recommended practices for surgical prophylaxis and perioperative glucose control among patients undergoing major surgical procedures (i.e., coronary artery bypass grafting, prosthetic joints, vascular surgery, and general surgery). Adherence to guideline recommendations varied by procedure and facility but overall was similar to the SIPP results. Factors identified from qualitative investigation that can foster improved adherence to guidelines included orientation and refresher training for staff, multifaceted dissemination of recommendations, feedback of infection control data to providers, integration of prevention practices into job functions, nurse/physician champions, surgical team stability, and outreach to surgeons practicing at multiple locations.

Public reporting of healthcare-associated infections can be a tool for increased adherence to recommendations. CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) has recommended surgical site infection rates and antimicrobial prophylaxis prescribing practices as measures to be included in mandatory reporting systems for healthcare-associated infections.

2. In your testimony you stated that we need standard definitions and data collections tools to improve our practices with hospital acquired infections.

- **It seems that one of the main issues is trying to agree what the definitions should be and how they should be reported. In your opinion can the CDC, working with hospitals and patients, develop these definitions without new legislation?**
- **How can this get done?**

Definitional work with a broad spectrum of partners is a major component of CDC's national leadership in prevention and control of healthcare-associated infections (HAIs). Past efforts coordinated by CDC have yielded widely used, standard definitions for specific types of infections. This work has been accomplished through CDC's programmatic initiative and its strong working relationships with multiple stakeholders. It has not required specific legislative authority. Further work is needed to update and add to the CDC definitions. To that end, CDC is actively participating in the recently launched National Quality Forum (NQF) project on consensus standards for the reporting of HAIs. Preliminary discussions in the NQF project suggest that in many instances CDC's definitions will be adopted without modification for use by NQF. The NQF project also provides an excellent opportunity to update and add to CDC's definitions as needed through a broad based, consensus process.

3. In your testimony you mentioned that recently CDC staff were sent to North Carolina to study an increase in a certain type of bacteria. As I understand, North Carolina is not one of the states that require mandatory reporting. In this example;

- **How did you determine this bacteria, *Clostridium difficile*, was increasing? What reporting mechanism was used?**
- **In this case, would mandatory public reporting for this bacteria have helped either the patients or you? Expound on this.**

The investigation of *Clostridium difficile* infections in North Carolina is a good example of the importance of outbreak investigations to better understand the characteristics of the illness, the source of infection, and prevention strategies. Although *Clostridium difficile* is the most common identified cause of diarrhea among patients in healthcare facilities, the investigation in North Carolina is focused on a change in the way this organism is infecting people outside of healthcare facilities. These persons were presenting to North Carolina hospitals after they become infected and it was a physician at a major teaching institution there who first noticed the increased number of patients with this infection. The healthcare facility contacted the State Health Department and they called CDC for assistance. Because these infections were likely acquired outside the hospital, it is unlikely that public reporting of healthcare facility-associated infection rates alone would have detected this change.

This episode highlights the important role that outbreak investigations conducted by CDC and local partners can play in the discovery and characterization of emerging infectious diseases and other health threats. These cases of *Clostridium difficile* were reported to CDC and were investigated as an outbreak of an unusual infection (community associated *Clostridium difficile*). This and other outbreak investigations of *Clostridium difficile* led to the discovery of the new strain in this country.

Rep. Dingell

1. You testified that hospitals that report the number of certain hospital-acquired infections (HAI) as part of the National Nosocomial Infections Surveillance System (NNIS) also took steps to reduce their level of infection, but they represent only 10

percent of the Nation's hospitals. As The New England Journal of Medicine (348:7, 2003) stated in an editorial, "If collecting data in isolated hospital areas represents "best practices" when 2 million Americans develop a hospital-acquired infection resulting in 90,000 deaths, and $5 billion in costs, then best is just not good enough." What is the Centers for Disease Control and Prevention doing to expand this network (National Nosocomial Infections Surveillance System) and to institute changes at non-participating hospitals to reduce infection rates and deaths?

In January 2005, CDC introduced the successor system to its National Nosocomial Infections Surveillance (NNIS) system. The new system, the National Healthcare Safety Network (NHSN), enables participation by all healthcare facilities that want to voluntarily join with CDC in national surveillance of healthcare-associated infections (HAIs). The information technology infrastructure used to build NHSN is more scalable and extensible than the infrastructure used to support the NNIS system. As a result, more healthcare facilities can participate, and CDC can more easily add data collection and analysis features that focus on facility-level process of care improvements. In addition, non-participating facilities can take advantage of the national comparative data produced by NHSN to gauge their progress in reducing infection rates and associated costs and mortality.

2. Will the National Healthcare Safety Network be easier and cheaper for participating hospitals? Are more hospitals expected to participate?

Yes, the National Healthcare Safety Network (NHSN) will be cheaper and easier for hospitals to use. CDC has streamlined manual data collection by reducing the number of data fields that had been required for the National Nosocomial Infections Surveillance (NNIS) system. No additional hardware or software purchases will be necessary for hospitals that participated in the NNIS system, and new hospitals will not incur substantial information technology costs to join the successor system. As a result, many more hospitals are expected to participate in NHSN. NHSN is being considered as a primary tool by several states with public reporting legislation and CDC is working with those States to facilitate the use of NHSN for public reporting and local prevention of healthcare associated infections.

3. CDC has its own definitions for HAIs, which many agree are quite adequate. But under the recent Deficit Reduction Act, the Secretary of Health and Human Services is mandated to develop definitions and methodologies for collecting information on HAIs, and the Nation Quality Forum is just beginning a project to establish uniform definitions. How is this (CDC, HHS, NQF) all going to work together? Are there going to be three sets of definitions?

CDC is working closely with other HHS agencies, including the Center for Medicare and Medicaid Services (CMS), and with the National Quality Forum (NQF) to assure that a single set of healthcare-associated infections (HAIs) definitions will be used in mandatory and voluntary data collection activities. This work requires close collaboration across public and private sector organizations. CDC has considerable experience and success in working with other organizations to establish and maintain definitional standards.

4. **What role is CDC playing in the "Save 100,000 Lives" initiative? Is CDC or any other branch of the Federal Government putting any money into this effort, or is it completely privately funded?**

Three of the six initiatives of the "Save 100,000 Lives" campaign are based on CDC's evidence-based guidelines to prevent bloodstream infections, surgical-site infections, and pneumonia. CDC joined the Save 100,000 Lives campaign in April 2005. CDC serves as a scientific partner to the Institute for Healthcare Improvement (IHI) and provides its expertise in preventing healthcare-associated infections to the local and regional hospital teams taking part in this campaign to save 100,000 lives. CDC has also partnered with IHI in the development of recommendations and tools to promote hand hygiene. The initiative also has been endorsed by two other agencies of the Department of Health and Human Services – the Centers for Medicare & Medicaid Services and the Agency for Healthcare Research and Quality.

5. Please describe CDC's efforts to collect infection rates from other healthcare institutions, such as long-term care facilities, and from outpatient procedures performed in both hospitals and specialty medical centers.

CDC's National Healthcare Safety Network (NHSN) is designed for use by any healthcare facility that chooses to participate. The initial version of NHSN focuses on healthcare-associated infections reported from acute care facilities, including those that perform outpatient operations. CDC is actively enrolling outpatient hemodialysis centers in NHSN at this time.

Although the technical infrastructure of the NHSN application can be used by any type of healthcare facility, surveillance protocols and healthcare-associated infection definitions for settings other than acute care and hemodialysis are currently lacking. CDC is working with partners to develop these definitions and protocols. They will need to be developed and tested in other types of healthcare settings, such as long-term care facilities, before the full potential of NHSN can be realized.

Currently, facilities such as long-term care facilities can use the system to collect other important pieces of information such as antibiotic usage or needlestick injury rates while these other components are being developed and tested.

6. You testified that both the Keystone and Pittsburgh projects are using CDC's recommended practices to reduce HAIs. But both of those projects have copyrighted their processes. Are they just copyrighting CDC's guidelines? How does CDC distribute its guidelines? Please include the guidelines in your response to this question.

The copyrighted materials to which you refer (for example, PRHI's Perfecting Patient Care™ system), are designed to facilitate the successful and complete implementation of evidenced-based preventive practices, such as CDC recommendations. Neither PRHI nor Keystone, for example, created the evidence based practices they used for preventing catheter-associated bloodstream infections or ventilator-associated pneumonia; those practices come directly from CDC guidelines (which are in the public domain). Rather, such organizations are helping to create innovative approaches to changing the culture and organization of healthcare delivery in order to help hospitals overcome local barriers to successful implementation of evidence-based practice, such as the guidance CDC provides. There exists a valuable and synergistic relationship between CDC, who provides specific evidence-based practice recommendations for preventing healthcare-associated infections, and organizations such as PRHI, Keystone, IHI, and others who provide innovative ways to ensure that CDC-recommendations are followed.

CDC distributes its guidance via the Mortality Morbidity Weekly Report, through publication in peer reviewed journals, and through the CDC website. The guidance documents can be viewed on line at http://www.cdc.gov/ncidod/dhqp/index.html. Hard copies are also attached for your perusal.

7. At the hearing, you agreed to provide information on the efforts on the CMS to reduce HAIs at hospitals serving Medicare patients. Please provide that information for the record.

The following response was provided by CMS. CMS states:

> "As is indicated in the email received from CDC, it was asserted during the E&C oversight hearing that CMS has the authority to withhold Medicare and Medicaid payment from hospitals with high rates of healthcare-associated infection. Section 1864(c) in the Social Security Act was referenced as giving us this authority. Section 1864(c) grants authority to use state agencies to determine compliance by providers with Medicare's conditions of participation.

In response to the questions raised below, Medicare establishes conditions of participation (CoPs) that hospitals must meet to participate in the program. To determine compliance with these Medicare CoPs, CMS contracts with state agencies that survey providers to identify situations in which the hospital is out of compliance with the standards established by Medicare (in so doing, the survey agency identifies "deficiencies"). In the case of hospitals, the Social Security Act permits such surveys to be conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), if the hospital so chooses. In the case of complaints about particular CoPs, the state survey agencies and CMS can also conduct surveys to determine whether the hospital is in compliance with CoPs related to the complaint.

One such hospital CoP relates to infection control. The focus of the CoP is on monitoring, preventing, and controlling infections and communicable diseases. The hospital Infection Control CoP can be found in the Medicare regulations at 42 CFR 482.42. Hospitals have had to meet the infection control requirements since 1986. To be in compliance with this requirement the hospital must:

> (1) have an active hospital-wide program for the prevention, control, and investigation of infections and communicable diseases;
>
> (2) provide a sanitary environment to avoid sources and transmission of infections and communicable diseases;
>
> (3) designate an infection control officer(s), who must develop and implement system for preventing, identifying, controlling, investigating, and reporting infections as well as maintain a log of incidents related to infections and communicable diseases; and
>
> (4) hospital leadership must ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer(s) and they are responsible for the implementation of successful corrective action plans in affected problem areas.

The CoP does not require hospitals to post their infection rates; it also does not establish thresholds regarding high or low infection rates. However, high infection rates are a clue to surveyors that a hospital's program is not preventing infections. Surveyors evaluate both outcomes (such as high infection rates) and processes (such as required practices and systems in place to prevent infections) when evaluating compliance with the CoP. Additionally, if a surveyor finds a hospital with high infection rates, he/she would also target in on their Quality Assessment and Performance Improvement (QAPI) program (which is another CoP) to see if they have addressed the infection problem in accordance with the QAPI CoP.

If the hospital is found to be out of compliance with the CoP (i.e., the hospital is cited for having a serious deficiency related to the CoP), then the hospital is put on a track to be terminated from the Medicare program. A hospital in this situation has to

respond to the deficiencies with a plan of correction. In its plan of correction, the hospital must develop and implement a system-wide plan that corrects the problem and improves their performance by implementing measures to correct the identified problem, monitor their corrective action(s), and sustain the improvements. If the plan of correction is accepted by the state agency then the termination is stopped. Under this process, the primary enforcement mechanism is termination from the program; we do not assess civil money penalties."

8. Can HAIs be reduced by the single step of requiring hospitals to report on the steps they are taking to reduce infections, or does the infection rate itself need to be tracked?

CDC recommends that States considering mandatory public reporting of healthcare-associated infections collect both the steps for reducing infections (also called process measures) and the risk adjusted rates of infections. This combined information can provide a roadmap for reducing infections if it is used to inform local action.

9. What is CDC's budget for healthcare quality promotion in FY 2006? What has been proposed for FY 2007?

The FY 06 budget for the Division of Healthcare Quality Promotion, CDC to detect, monitor and prevent healthcare-associated infections was $14,759,590. Level funding is expected for FY 07.

RESPONSE FOR THE RECORD BY DR. ROBERT WARE HALEY, MD, DIVISION OF EPIDEMIOLOGY, SOUTHWESTERN MEDICAL SCHOOL, UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

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Holder of the U.S. Armed Forces Veterans
Distinguished Chair for Medical Research,
Honoring America's Gulf War Veterans

Department of Internal Medicine
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Reply To: Ed Whitfield
Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building,
Email to Michael Abraham (Michael.Abraham@mail.house.gov)

From: Robert W. Haley, M.D.
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Date: June 22, 2006

Subject: Your questions (in bold) and my replies (following)

1. In your testimony, you mentioned that the NNIS risk index is used all over the world. Relating this to reporting of hospital infections;

- **How do European or other developed economies track and handle these issues?**
- **How do we compare?**

Yes, the NNIS risk index is used in many countries throughout the world. Here is the evidence.

- Scientific papers reporting validation and use of the NNIS risk index have been published by scientists from the U.S., Germany, Spain, Belgium, France, Brazil, Vietnam and Pakistan. I have attached 24 references to these papers.
- An infection control expert in Spain provided the following information: "SSI surveillance is routinely carried out in most tertiary and secondary hospitals in Spain. The situation is something different in primary (small local) hospitals. The NNIS has become the predominant index and it is used to adjust for differences between services and hospitals, even for changes in patients' intrinsic risk of infection across time. The Spanish Society of Hospital Preventive Medicine has sponsored a software which allows to estimate indirect standardized rates using as reference the American NNIS strata rates. To my knowledge in Germany and Denmark there are similar systems to the

> Spanish and currently are giving indirect standardized SSI rates. In the United Kingdom surveillance is performed mainly by microbiologists and the use of the NNIS or the SENIC indices is not very common. In Italy and France the situation is something between Spain and the UK: some centers do routine SSI surveillance and others don't."

It is difficult to say how the U.S. compares with other countries in the implementation of SSI surveillance using the NNIS risk index because no recent surveys have documented these practices here. I would make the following comments on this question.

My impression is that a sizeable minority of U.S. hospitals measure rates of SSI and compare their rates to the national standard rates within NNIS risk index categories. Although I have seen no measurements of the prevalence of this practice, I suspect it is more than 20% of hospitals and probably less than 50%. From the comments above, the prevalence of this practice in U.S. hospitals is probably less than in Spain, Germany and Denmark but probably more than in the U.K. and perhaps comparable to Italy and France. Clearly, our practices in U.S. hospitals are not up to what they should be if we are serious about employing cost-effective practices proven to reduce SSI rates to a practical minimum. This approach is not expensive and yet has been shown to have a powerful effect in reducing SSI rates. The problem is that SSI outcome measurement has never been a high priority for many hospitals and in recent years has gotten lost in a sea of well intentioned but unproven quality improvement ideas. Our best opportunity right now is to get all hospitals measuring HAI rates while coupling this with implementing the "bundle" concept or process control popularized by (Institute for Healthcare Improvement) IHI. These appear to be synergistic measures.

As a note of caution, I would add that we have as yet no experience in using the NNIS risk index in public reporting of HAI rates to consumers. Undoubtedly, we will need to experiment with a variety of statistical approaches to learn the best way to use the NNIS index so that we can provide consumers with scientifically valid comparisons of hospitals which at the same time are understandable. This may require new statistical methods for using the index and constructing summary rate scores. Such research is starting to pop up in states that are grappling day to day with the new mandated reporting systems. These types of innovations are unlikely to come out of expert panels of the NQF or other national standard-setting committees.

2. In your testimony you mentioned that you are in full support of public reporting but are *not* in support of a national mold preceding the states activities. You also mention that you expect that the movement within the states and with the consumer's union will *eventually lead* to meaningful reduction in hospital infections.

- **When Americans read the articles about 90,000 hospital infection deaths, they probably won't like to hear that the deaths will *eventually* be less. In your mind, how long is *eventually?***

Yes, I am in favor of public reporting of HAI rates but I am not in favor of a single national mold for public reporting, such as that being explored by the National Quality Forum. Here is my reasoning.

- National standards are useful for issues where strategies are well worked out and broadly tested. Then national standards bring the few laggard states and communities up to the proven mark. With public reporting of HAI rates, there is little experience yet with which to judge which organizational and logistic approaches are going to be useful and which useless or destructive. It is one thing to say that outcome measurement of HAI rates for the public is a good

think and to identify the exact way of doing it on a statewide basis. Therefore, I think it is premature to establish a national standard for organization and implementation because the substance of the standard will be based on speculation rather than on broad experience.

- Establishing a national standard here at the very start of the public reporting movement will curtail valuable experimentation by the states—it will dumb down the practice to a common mediocre level. We have seen in countless programs in the past from highway safety to Medicaid models that, when allowed to try creative solutions, states come up with all kinds of good ideas that eventually catch hold and become de facto standards. The legislatures of several states have empanelled expert committees to design their own solutions, and creative ideas have already emerged. If a national standard is postponed, we could have potentially 50 competing experiments from which to choose the most successful. If we encourage or force all states to conform to a single model at this early moment, we would lose the benefit of the states' creative ideas and experiments and thus do a disservice to patients over the long haul.
- I am extremely concerned that a national forum, such as that to be convened by the NQF, will be usurped by special interests represented on their panels that will steer the national standard toward proprietary or ideological solutions that will ultimately prove ineffective. Such panels are also likely to be swayed by enthusiastic reports of anecdotal successes not representing truly proven and tested approaches. Hopefully the expert panels in various states will steadfastly pursue their own creative ideas so that in the end the effective strategies will rise to the top.
- Fundamentally public reporting of HAI rates has risen as a state issue being effectively addressed by state legislatures and expert panels within those states. I see no basis for the federal government to become involved in standard setting at this time. The federal funding programs will be better served to watch the states reporting programs emerge and weigh in when effective approaches are identified and studied.

I believe that the public reporting movement will eventually lead to large reductions in HAI rates in all U.S. hospitals. Outcome measurement with feedback of outcome rates has been demonstrated widely in industry to improve manufacturing quality (reference the quality control principles of W. Edwards Deming based fundamentally on outcome measurement). The only scientific evidence from controlled studies on reducing HAI rates demonstrated that outcome measurement with feedback to surgeons and other hospital personnel drives the reduction of HAI rates. This has been known for over 100 years, is proven, and has been successfully implemented in a sizeable minority of U.S. hospitals. Therefore, I am confident that implementing outcome measurement in all U.S. hospitals will have a large impact and reduce HAI rates far below their present level.

Very simply, I believe that the numbers of deaths, as well as the suffering, disability and costs, from HAIs will immediately start falling as more and more hospitals implement outcome measurement with risk stratification and feedback of rates to surgeons and other hospital personnel. State laws requiring outcome measurement for the different purpose of informing the public will greatly hasten its wide implementation, and if the rates reported to the public are also effectively fed back to surgeons and other hospital personnel, rates will fall. With the rapid progress in adoption by state legislatures that we are seeing at present, I suspect that outcome measurement could be happening in perhaps half the states within 2 years. As successes from these become publicized, I suspect the remaining states will be on board in 4-5 years time.

To the impatient, I would urge restraint. The biggest threat to implementation of approaches that have been proven to work is a hasty dash to require all hospitals to

conform. This is likely to lead to some national standard-setting body's decreeing the wrong organizational and logistical approaches and ending up with no reductions in the deaths, morbidity, disability and costs at all. We saw a vivid illustration of this problem in Pennsylvania in its first years of public reporting.

Right now, we see a healthy grass roots movement, fueled by the Consumer Union, taking root in state after state. If the states are left to experiment and evolve the best programs, in several years we will know what works and then we can develop national standards to bring the laggard states and hospitals up to par. But premature standard-setting at this critical moment is likely to clutch defeat from the jaws of victory.

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RESPONSE FOR THE RECORD BY RAYMOND T. WAGNER, JR., LEGAL AND LEGISLATIVE VICE PRESIDENT, ENTERPRISE RENT-A-CAR

June 1, 2006

Congressman Ed Whitfield
Chairman, Subcommittee on Oversight and Investigations
Committee of Energy and Commerce
Rayburn House Office Building, Room 2125
Washington, DC 20515

Re: Questions submitted during open period following March 29, 2006 hearing on Hospital Acquired Infections.

Dear Chairman Whitfield:

I write in response to the questions forwarded to me by the Subcommittee on Oversight and Investigations, following the hearing entitled "Public Reporting of Hospital-Acquired Infections: Empowering Patients, Saving Lives" held on March 29, 2006. Two questions were presented by Honorable Marsha Blackburn. I will repeat each question and then provide my comment below.

Question 1) This past Sunday, the *Lexington Herald Leader* ran a story on hospital acquired infections. In this article, an epidemiologist is quoted as saying, "The more honest you are, the more you put yourself in a bad light." He was referring to some hospitals being aggressive in reporting while others less so. Through your experience with your son as well as your experience as a Legislative Vice President, I know you understand the inner workings of hospital infections as well as the regulatory process.

- **What is your reaction to that comment?**
- **Is it valid?**

At first blush, this statement ("The more honest you are, the more you put yourself in a bad light.") could have some credence, however, looking at the converse of that statement ("The more dishonest you are, the more you put yourself in a favorable light."), suggests a different answer. I do not believe that hospital professionals will intentionally or negligently circumvent the rules. Any potential for differences in data collection based upon the aggressiveness of the hospital collecting staff will be smoothed out through proper hospital training, as well as proper guidance from state health departments, hospital associations, the Centers for Disease Control (CDC), and other professional organizations. Furthermore, a state's regulatory and oversight process will also provide a checks and balance on information gathering and reporting techniques.

Finally, the notion that there will be different outcomes based upon the level of implementation or aggressiveness, strikes me as a typical response of any "regulated group" when guidelines or regulations are proposed. Restaurants certainly comply with uniform health and safety codes. Businesses comply with uniform employment laws and tax codes. Many industries are subject to inspections by oversight governmental bodies. The argument of uneven application of a regulation, if followed by governmental entities as a rule, would lead to paralysis in the promulgation of health and safety standards throughout the country. Reporting laws can be uniformly implemented, and will be improved in the course of time with experience.

Question 2) In your testimony, you mentioned, "the hospitals were not leading the discussion, as they should." Through you taking the bull by the horns, you worked and earned the support of the Missouri Hospital Association.

• In your experience, are the hospitals now leading this discussion, or are at least willing to make steps forward?

• On our third panel, we have Administrators representing 7 different hospitals or hospital chains. What would you like to hear from them regarding this issue?

In response, I believe that hospitals are increasingly willing to take steps forward in response to the increased demand from the public across the country. It is my understanding that similar reporting bills have been introduced in thirty or more states throughout the country. Hospital associations are increasingly taking part in these legislative efforts. That said, there is room for substantial improvement on the part of the hospital community. To date, the states and the Federal government have not come far enough to address the problem of hospital-acquired deadly infections, largely due to hospital opposition and claims that "this can't be done."

In Missouri, I was very pleased and proud that the Missouri Hospital Association took a leadership role in supporting legislation once the bill was introduced. They provided necessary expertise during the course of the legislative and the subsequent rule-making process. This cooperative effort between hospitals, medical professionals, consumers, patient groups, and the business community has served the Missouri process well. I believe the other states could be well-served with pro-active hospital participation and aggressive CDC participation.

Regarding hospital administrators, I would like to hear that they are committed to progressively addressing the problem of hospital-acquired infections. I would like to see them pledge to establish appropriate long term goals to minimize or rid hospitals of these deadly infections, e.g., reducing hospital-acquired infection rates by 50% or 75% within five years, or 100% compliance with hand-washing guidelines within 12 months. Hospitals should recognize that patients and their families are demanding attention to this problem. Only through proper regulations and implementation of best practices can this problem effectively be addressed.

I would respectfully ask administrators to commit to raise the level of awareness of the seriousness of hospital-acquired infections with their staff and with patients. Action under this commitment would include proper training of hospital staff and education of patients and visitors when visiting hospitals.

I hope that this is responsive to Congresswoman Blackburn's questions. I would be pleased to offer any additional follow-up to Members of the Committee. Again, I thank you very much for holding this important hearing. I stand ready to continue to assist the important work with your Subcommittee in every way possible.

Very truly yours,

Raymond T. Wagner, Jr.
Legal and Legislative Vice-President
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