Written Testimony of Michael Bennett
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Introduction

Methicillin-resistant staphylococcus aureus (MRSA) and Vancomycin-resistant enterococcus (VRE) are types of bacteria which are resistant to antibiotics that are used to treat infections caused by normal types of the same bacteria. MRSA has been a growing problem in most health care institutions in the United States for about four decades. The rise of VRE infections in health care facilities has paralleled that of MRSA for about the last twenty years. Both MRSA and VRE are associated with high rates of morbidity (illness) and mortality (death). MRSA and VRE are virtually always acquired through contact with another colonized or infected person or through contaminated equipment.

The most recent data indicate that approximately 86% of all MRSA infections in the United States are associated with health care. Current data suggests that virtually all VRE infections in the United States are associated with health care. Nationally, the annual cost of treating infections caused by MRSA and VRE are in the tens-of-billions of dollars.

Background

"After long steady increases in MRSA and VRE infections in NNIS System[1] hospitals, the Society for Healthcare Epidemiology of America (SHEA) Board of Directors made reducing these infections a strategic goal in January 2000. After 2 more years without improvement, a SHEA task force was appointed to draft this evidence-based guideline on preventing MRSA and VRE because they were the 2 most out-of-control antibiotic-resistant pathogens in healthcare."[2]

The spread of lethal infections from patient to patient via contaminated healthcare workers has been recognized for more than 150 years.[3] The 2003 SHEA guideline focuses on the importance of controlling the spread of MRSA and VRE from patient to patient in healthcare settings.

[1] The National Nosocomial Infection Surveillance System (NNIS) are a group of hospitals which voluntarily and confidentially report their infection data to the CDC. It is now called the National Healthcare Safety Network (NHSN)
[2] 2003 SHEA guideline
[3] 2003 SHEA guideline

In October of 2007, the Association for Professionals in Infection Control and Epidemiology (APIC) published the results of the largest survey ever conducted of MRSA. The data from that study suggests as many as 1.2 million patients infected with MRSA every year, with 86% of these infections occurring in healthcare and an associated mortality rate of as high as 10%.

The APIC survey indicates that Maryland is in the 72nd percentile of the states with the highest rates of MRSA infections. Using data from the Maryland Hospital Association and calculating the average number of patient admissions for the years 2004-2007, and based on the results of the APIC survey, Maryland has more than 36,000 MRSA infections per year and perhaps causing as many as 3,600 deaths.

In October 2007, Resources for the Future (RFF), a large well-respected Washington-based think-tank, published the results of a study on MRSA. The data from the RFF study show a two-fold increase in MRSA infections over the 5-year period 1999-2004. The authors of that study stated that control of MRSA must be "a national priority".

In October of 2007, the CDC published a study in the Journal of the American Medical Association (JAMA) which shows that deaths from invasive MRSA sterile site infections (a minority of all hospital-acquired MRSA infections) now surpass those from AIDS. In this study, Baltimore had the highest rates of any of the 9 sites that participated. In fact, the Baltimore rates were so high as compared to the other 8 sites involved in the study, the study's authors re-checked their methods and the data to make certain that they were accurate. Some local healthcare leaders claimed that the high rates in Baltimore were due to its urban setting or high rate of IV drug use. However, San Francisco, Atlanta and Denver (3 other sites included in the study) are also urban settings with high rates of IV drug use. Additionally, in January of this year, the Baltimore City Health Department released the results of a recent study conducted by the Rand Corporation which focused on hospitalizations in Baltimore resulting from MRSA cellulitis (a type of soft tissue infection). That study showed a 74% increase in MRSA rates from 2000-2006 despite a 40% decrease in such infections among IV drug users.

Three years ago, this committee was presented with the results of a CDC study of MRSA infections occurring in dialysis patients which showed Maryland as having the highest rates among those participating in that study.

MRSA and VRE are endemic in virtually all of Maryland's hospitals, nursing homes and dialysis clinics. In the early 1990s, VRE emerged in a single hospital in Baltimore. Because it was not controlled at that time, VRE spread throughout Maryland and then across the country[4].

The proliferation of these deadly pathogens has been officially called an epidemic by the CDC, IHI, The Joint Commission, APIC, SHEA and others. The data show that Maryland is clearly among those states at the epicenter of what the former acting director of the

[4] Written Testimony of Dr. William Jarvis based on CDC data.

CDC's Hospital Infections Division[5] stated in written testimony before this committee four years ago "a public health disaster".

OTHER STUDIES

In 2007 an NIH funded randomized controlled trial (RCT) using ADI (active detection and isolation) which was conducted in a number of US institutions. The results of that study showed no effective gains from routine use of ADI. The STAR ICU study has been widely criticized for its faulty design and to date has not been published in any peer reviewed journal.

In 2008 a study was conducted at a large Swiss hospital. This study (Harbarth et al) involved universal screening (screening all patients) in certain units within the institution. Results of that study showed no appreciable reduction in MRSA rates from that intervention, and were therefore deemed to be not cost effective. While opponents of the 2003 SHEA guideline approach cite this study as being critical of the approach, it is important to understand that the Swiss study took place in a hospital which has been successfully using the 2003 SHEA guideline approach for decades to keep their MRSA rates below 1%. In addition, the 2003 SHEA guideline does not recommend universal screening. Other limitations and numerous problems with the Swiss study have also been highlighted in peer reviewed scientific journals.

OTHER GUIDELINES

Most infection control guidelines in the past, such as those offered by the CDC, were based on expert opinions and did not cite evidence from scientific studies showing that they would work. For example, the CDC isolation guidelines in 1983 and 1996 did not cite the evidence from scientific studies that they would control MRSA. As demonstrated by the enormous growth of MRSA in US health care institutions, both CDC guidelines obviously failed. Neither of those guidelines recommended active detection and isolation (ADI).

In 2006, the CDC published on its web site a guideline for controlling multi-drug resistant organisms (MDROs) in health care. This guideline offers 87 different options in two tiers. It opposes the 2003 SHEA guideline's emphasis on ADI, but then it seems to reverse course by making option V.B.6.i in the second tier its only Category 1A (the highest priority) control measure: "Implement Contact Precautions routinely for all patients colonized or infected with a target MDRO." This is basically what the 2003 SHEA guideline says and it needs to be understood that isolating all colonized patients, as it recommends, requires active detection because otherwise the vast majority remain unrecognized.

The first tier of the 2006 CDC guideline include multiple options which are long recognized not to work without ADI (such as isolating only those patients found positive

[5] Now called the Division of Healthcare Quality Promotion (DHQP)

by clinical cultures). Because of the multitude of options offered by the 2006 CDC guideline as well as the guideline's structure, an institution would likely endure many years of failure to control MRSA and VRE before even reaching the non priority 2nd tier recommendations.

The 2008 SHEA Compendium seems to be influenced by the 2006 CDC guideline. Like the 2006 CDC guideline, the 2008 SHEA Compendium consists of two tiers. The first tier is strikingly similar to the 2006 CDC guideline in its recommending control measures which are known not to work without ADI---such as isolating only those with positive clinical cultures. Like the 2006 CDC guideline, the 2008 SHEA Compendium fails to even mention the approximately 160 studies reporting that ADI controlled MRSA and VRE.

All of these guidelines have in common their association with failure to control MRSA and VRE, whereas the 2003 SHEA guideline is strongly associated with success.

Hand Hygiene

Hand hygiene has been called the single most important intervention in preventing infection. However, there are plethora of studies—such as Susan Huang's 9 year study at Harvard's Brigham and Womens Hospital—which show that even as much as 80% compliance rate with hand hygiene guidelines have no effect on MRSA rates unless routine active detection and isolation are also implemented. Studies show that the average compliance rate with hand hygiene among health care workers is less than 50%.

Mandating the 2003 SHEA Guideline

The approach advocated by the 2003 SHEA Guideline is the only one that has been shown to effectively achieve sustained control of MRSA and VRE in a wide variety of healthcare settings. Therefore, it represents the minimum standard for effective and sustained control of these organisms.

As mentioned previously, the 2003 SHEA guideline approach is supported by over 160 studies. It has been shown to be cost-effective by 14 studies.

Over the last four years, opponents to this legislation have stated that the 2003 SHEA guideline approach is too rigid, controversial or too burdensome. Opponents have also claimed that implementing this approach may compromise patient safety (a claim based on a single study in which the authors stated that their findings were not conclusive and "…requires further study."), deplete valuable infection control resources, derail current progress and that it is a "one-size-fits-all" approach which is inappropriate. It is intriguing to note that these are the same arguments put forth by the automobile industry in

opposing mandates for seatbelts and airbags (too expensive, not scientifically proven, may actually harm passengers, not appropriate for all circumstances, etc.). Despite these arguments, opponents to this approach yearly cite more and more examples of institutions that are actually implementing it.

Since the introduction of this legislation four years ago, the 2003 SHEA guideline approach for control of healthcare-associated MRSA has been standardized in all Veterans Administration (VA) hospitals and nursing homes and preliminary reports show major decline (40-60%) in MRSA rates and significant decline in the rate of other pathogens, such as Clostridium difficile, as well. The same approach is now deployed in all facilities owned by Hospital Corporation of America (HCA). It has been recommended by the Institute of Healthcare Improvement (IHI) for the approximately 3000 hospitals that voluntarily participate in IHI initiatives. And it is being implemented in various measures in hundreds of other hospitals across the country. The University of Maryland has deployed the approach throughout the hospital and Johns Hopkins which has been using it in its ICUs for years has expanded its program, as are other hospitals in Maryland. The Joint Commission has called the approach one that is easily applicable to any healthcare facility. Additionally, the 2003 SHEA guideline has recently been named the "Most cited document in the medical literature."

Since the introduction of this legislation, seven states (PA, IL, CA, NJ, MN, TN, TX) have passed bills targeting MRSA, including routine screening for MRSA in ICUs and other high risk units. Currently, the most far reaching of these is the California law, which is an unfunded mandate. Five other states (CT, IN, MS, NY, and WA) are now considering bills targeting control of MRSA and more states are expected to follow. There are currently four federal bills being considered which target controlling MRSA using ADI.

With the possible exception of Pennsylvania, state and federal bills thus far have significant scientific shortcomings.

While much noteworthy progress has been made over the last four years, most hospitals in Maryland still do not routinely implement the 2003 SHEA guideline approach. No public data is available on compliance rates or on the rates of MRSA and VRE infections. For these reasons and more it is of paramount importance that legislation is enacted or regulation is imposed which is both evidence-based and best-practices. The approach advocated by the 2003 SHEA guideline is the only one which fulfills these essential criteria. Based on the science, we know that it works.

The 2003 SHEA guideline requires that each facility's infection control expert select the appropriate criteria for surveillance testing (risk-assessment) to find and isolate all colonized patients. Because MRSA and VRE are spreading throughout the entire healthcare system, all facilities need a screening program. Effective and sustained control of MRSA and VRE will not be achieved without a regional approach, the goal of which is to identify and isolate the entire reservoir for spread of MRSA and VRE.

Some have suggested that screening programs be limited to intensive care units (ICUs). The 2007 APIC study showed that the majority of MRSA infections occur in places other than ICUs. Additionally, most facilities have small ICUs or none at all. Most or all patients in these facilities would be left unprotected by such an ICU-only program and MRSA and VRE would continue to proliferate as has been shown in numerous studies.

In recent years, strains of MRSA that are genetically different than the traditional hospital strains have appeared and increased outside of healthcare settings. Because most hospitals were not implementing comprehensive active detection and isolation programs, these strains have now become endemic in healthcare as well. These community-acquired strains of MRSA (CA MRSA) produce a virulent toxin which rapidly destroys tissue and it is these strains that are mostly responsible for the deaths of students and other young healthy individuals which have been highlighted in recent media reports.

Northern Europe and Western Australia have controlled healthcare-associated MRSA to very low levels for decades despite long time proliferation of community-associated strains of MRSA by essentially using the approach advocated by the 2003 SHEA guideline. In other words; the proliferation of community-associated MRSA has not caused an increase in healthcare-associated MRSA where routine active detection and isolation are used to contain the entire reservoir for spread of MRSA.

Conclusion

Clearly the most egregiously out-of-control hospital bugs are MRSA and VRE and they have grown into this category not because of a lack of resources or a lack of knowledge as to how they can be controlled. Healthcare leadership has known for decades that identifying and isolating the entire reservoir for spread of these pathogens are essential components to achieve sustained control but healthcare leaders have chosen not to recommend such an approach.

There are many strains of bacteria that cause disease in hospitalized patients and it is important to control all of them, but none of them have reached the level of epidemic that MRSA and VRE have. No other health care spread pathogens can be said to cause more deaths each year than AIDS as does MRSA. And studies show that an aggressive approach to controlling MRSA actually results in decrease of infections caused by other pathogens. Hospitals routinely screen for HIV but they do not do so for MRSA and VRE.

The laudable progress on this issue that has taken place over the last several years deserves to be recognized. It is also important to recognize that this progress has been largely driven by initiatives from consumer advocates, such as this legislation.

Unfortunately, consumer activism has also resulted in some protectionist moves such as the 2007 SHEA/APIC joint position paper on legislative mandates, the 2008 SHEA Compendium and the most recent HHS Action Plan. The 2008 SHEA Compendium and the SHEA/APIC joint position paper have no relationship to the 2003 SHEA guideline or its authors and do not in any way revoke the 2003 SHEA guideline.

It would be better if hospitals were implementing the 2003 SHEA guideline on their own and consumer activism was not necessary for progress on this serious public health issue. Mandating infection control guidelines is not the ideal course. However, in the absence of all health care institutions in the region doing it on their own, a mandate to implement such an approach becomes an obligation in order to prevent the injury and death of patients.

Without mandating an effective infection control program based on the approach advocated by the 2003 SHEA guideline, these deadly bugs will continue to be passed to more and more patients, who will be sickened and killed, and the ominous threat of even more lethal organisms, such as Vancomycin-resistant staphylococcus (VRSA), which for decades has been the “nightmare scenario”, will likely increase.

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