



By Marcia Ryder, Ph.D., MS, RN

## Health-care-acquired infections: Unfortunate complication or medical error?

John Hill is permanently disabled despite multiple surgeries and extensive antibiotic therapy because of an infection acquired during a routine arthroscopic procedure. Alice Henderson is being treated for severe depression after bilateral mastectomy caused by a staphylococcus infection after breast implantation. Harry Dillard died after developing endocarditis from an infected central venous catheter placed for parenteral nutrition.

Are these just the unfortunate and inevitable risks of receiving health care or are they preventable adverse events due to medical errors?

The exorbitant increase in health-care costs and the declining quality of health care in the United States has been a subject of considerable concern for quite some time. In each of two large studies evaluating quality of care in hospitals, one conducted in Colorado and Utah and one in New York, it was discovered that over half of the large number of adverse events in the delivery of medical care was a result of medical errors that could have been prevented<sup>1</sup>. With these findings, the Institute of Medicine (IOM) established the Committee on the Quality of Health Care in America in June of 1998 to develop a strategy for substantial improvement in the quality of health care in the United States over a ten-year period.

At the same time, hospital infections were the focus of public attention. An article in the San Francisco Chronicle dated March 12, 1998 entitled "Rising number of patients get sicker at hospital," reported that:

Every year, 2 million Americans who go to hospitals to get well get sicker after they check in – victims of a growing wave of hospital-acquired infections that the CDC say now claims 90,000 lives annually. CDC official said hospital-acquired infections are up 36 percent in the last 20 years. Aside from

the human toll, the CDC says, the cost of these infections is now \$4.5 billion a year.

A year and a half later, the IOM published the report "To Err is Human: Building a Safer Health System<sup>1</sup>." In this shocking report, medical errors and adverse events in the delivery of health care were ranked as the eighth leading cause of death in the U.S. at a cost of \$29 billion. To put this in perspective, the estimated 98,000 deaths are more than deaths due to automobile accidents (43,458), breast cancer (42,297) or AIDS (16,516)<sup>2</sup>. The report pointed to poorly designed and fragmented systems of care as the root cause of the adverse events and thus positioned the national agenda to improve patient safety by a systems approach. The expectation was to reduce the number of medical errors in hospitals by 50 percent within five years.

Within weeks of the IOM report, in January 2000, the Senate Committee on Appropriations held hearings on patient safety issues. The Agency for Healthcare Research and Quality (AHRQ) was assigned as the lead agency for the federal government to direct a national patient safety effort to control medical errors and reduce adverse events. The next month, the Quality Interagency Coordination Task Force, assigned by President Clinton, published a federal action plan that was consistent with the IOM's findings and recommendations<sup>3</sup>. The Center for Disease Control and Prevention (CDC) was to take an active role in the prevention of healthcare-acquired infections.

On August 23, 2001, the CDC posted the "CDC's 7 Healthcare Safety Challenges" to reduce healthcare-associated infections by 50 percent in five years<sup>4</sup>. Four of the challenges were directed toward the reduction of catheter-associated adverse events, hospitalization and mortality from respiratory infections among long-term care patients, the

reduction of targeted surgical adverse events, and the reduction of targeted antimicrobial-resistant infections.

The inclusion of the CDC in the patient safety initiative raises several questions. Are health-care-acquired infections (HAI) a significant patient safety issue? Are health-care-acquired infections preventable? What measures can be used to evaluate deviations in the standard of care for the prevention of HAIs?

### Are health-care-associated infections a significant patient safety issue?

The NNIS system defines a nosocomial infection as an infection that occurs after 48 hours of admission to a hospital and associated with medical care<sup>5</sup>. Community-acquired infections are infections with original onset outside of the hospital and not associated with medical care. These definitions exclude those infections occurring in patients cared for in alternate settings such as long-term facilities, clinics, dialysis units and home care. The new term "health-care-associated infections" includes all infections associated with medical treatment, regardless of the location of provision of care<sup>6</sup>.

The best available data on incidence rates of nosocomial infections is produced by the CDC's National Nosocomial Infection Surveillance System (NNIS)<sup>7</sup>. The NNIS system analyzes and publishes yearly data collected from nearly 300 voluntary reporting hospitals in the U.S. The data measures infection rates of the four most common nosocomial infections: catheter-associated bloodstream infection, ventilator-associated pneumonia, catheter-associated urinary tract infections, and surgical site infection. The NNIS provides benchmarking data only for those infections occurring in intensive care units (ICU). Hospital-wide surveillance was discontinued in the 1980s when the infection risk became greater in critically ill patients undergoing more proce-

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dures and medical device utilization than those patients outside of the ICU.

As the length of a hospital stay shortened over the last two decades and patient care shifted earlier from ICUs to hospital wards and outpatient settings, so did the use of medical devices. In a recent point prevalence study, the CDC found that 67 percent of central venous catheters (CVC) in hospitalized patients are outside of the ICU but are not typically included in nosocomial infection surveillance<sup>8</sup>. At this time, there is no formal surveillance system that measures the incidence of “health-care-acquired infections” inclusive of general hospital wards, outpatient settings or homecare. The limited data most assuredly represents severe underreporting.

Nosocomial infections are among the most common preventable adverse events in healthcare, affecting about one in seven hospital patients<sup>9</sup>. Currently, the CDC estimates that there are approximately 1.7 million nosocomial infections in U.S. hospitals, 99,000 of which result in death. There are approximately 4.5 infections per 100 hospital admissions, two surgical site infections per 100 operations and 9.3 infections per 1000 patient days in intensive care units<sup>10</sup>. Four types of infections account for more than 80 percent of all nosocomial infections: bloodstream infection mostly related to central venous catheters (CABSI), surgical site infection (SSI), pneumonia usually associated with mechanical ventilation (VAP), and urinary tract infections that are most often catheter associated (CAUTI).

The least serious and least expensive nosocomial infections reported to NNIS in the 1990-2004 database are urinary tract infections (34 percent), which are primarily associated with a urinary catheter (CAUTI)<sup>10</sup>. Approximately 25 percent of patients have a urinary catheter at some time during their hospital stay<sup>11</sup>. Interestingly, the CDC did not specifically target this infection in the challenges even though they occur in as many as 10 million catheters each year<sup>12</sup>. The risk of bacteriuria increases from 3 to 10 percent for each day of catheterization and extends the hospital stay by one day at an average cost of \$676 per case for treatment; \$2836 if bacteremic<sup>13</sup>. About

two to four percent of CAUTI patients develop a more serious bloodstream infection.

Surgical site infections represent 17 percent of reported nosocomial infections in the NNIS database. Of the 30 million surgical procedures performed in the U.S. each year, five percent will result in a surgical site infection and over 20,000 deaths<sup>14</sup>. For each infection, patients may spend an additional seven days in the hospital at an extra cost of \$3000 per SSI. They are 60 percent more likely to spend time in the ICU, five times more likely to be readmitted to the hospital, and have twice the incidence of mortality<sup>14</sup>.

Surgical wounds are classified into four categories: Class I – clean (uninfected operative wound not entering respiratory, gastrointestinal or urinary tract); Class II – clean-contaminated (wound entering the respiratory, gastrointestinal or urinary tract with no contamination); Class III – contaminated (open, fresh accidental wound or gross spillage from gastrointestinal tract); and Class IV – dirty or infected (old wounds, perforated bowel where infecting pathogens were present in the wound before surgery)<sup>15</sup>. The CDC defines an incisional SSI as one that occurs at the incision site within 30 days after surgery, or one year if a prosthetic implant is in place<sup>16</sup>.

The interplay of four determinants lead to either the uneventful healing of the wound or SSI: the inoculum of bacteria, the virulence of bacteria, adjuvant effects of the microenvironment in the wound, and the host innate and acquired defense mechanisms<sup>17</sup>. On this basis, NNIS categorizes SSI based on three risk factors: wound classification, duration of operation and the American Society of Anesthesiologist (ASA) perioperative risk score. From this, the CDC developed the NNIS Risk Index system for consistent reporting among hospitals<sup>16,17</sup>. Class I procedures are of lowest risk for infection at two percent; an estimated 40 to 60 percent of these are preventable. As such, Class I procedures resulting in infection are then most likely to be the result of medical error. Class II infections occur at five percent and Class III and IV at approximately 20 percent of Infections in

Class II or III may or may not be preventable<sup>18</sup>.

Pneumonia accounts for 13 percent of reported HAIs. In 2002, the median rate for ventilator-associated pneumonia was as high as 14.7 per 1000 ventilator days in participating hospitals<sup>19</sup>. On average, VAP extends the hospital length of stay by seven to 10 days at a cost of \$10,000 to \$40,000 per case<sup>20</sup>. The mortality attributed to an episode of nosocomial pneumonia may be as high as 30 percent.

While catheter-related bloodstream infections account for only 14 percent of reported nosocomial infections, they are the most serious, most deadly, and most costly of the healthcare-acquired infections. The incidence of CRBSI in short-term CVCs used primarily in the ICUs is approximately 5.9 per 1000 catheter days and as much as 8.7 per 1000 catheter days in longer-term temporary hemodialysis catheters<sup>7,21</sup>. CRBSIs increase the length of hospital stay by 22 days and are a frequent cause of re-hospitalization in home care patients with CVCs. The attributable mortality of CRBSI is 12 to 25 percent. The cost per case has been documented to be from \$10,000 to as much as \$56,000<sup>21</sup>. Data on the incidence and impact of these infections in alternate care settings is sparse.

While these statistics are alarming, an even more serious consequence of health-care-acquired infections is the increasing rate of antimicrobial resistance in health-care-associated pathogens. Inadequate or delayed therapy and severe underlying disease are primarily responsible for the adverse outcomes caused by antimicrobial resistant organisms<sup>23</sup>. More than 70 percent of organisms that cause HAIs are resistant to at least one of the drugs most commonly used to treat them<sup>24</sup>. The lack of new antibiotics and the increasing rates of antimicrobial resistance are now considered a global threat. Costs for patients with infections due to antimicrobial resistant organisms are higher (\$6,000 to \$30,000) than those infections in patients caused by antimicrobial-susceptible organisms<sup>23</sup>.

The growing awareness and fear of HAI by the public has driven the pressure for mandatory reporting of hospital infections by organizations such as the Consumer's Union. Seven states (Florida, Illinois, Missouri, Nevada, New York, Pennsylvania and Virginia) have enacted legislation mandating hospitals and other healthcare organizations to report HAI rates. Twenty-two additional states have 2006 legislative activity underway and six more have bills requiring further study on the issue<sup>10</sup>. California's mandatory reporting bill (S.B. 739) was passed by the Senate but failed to get the necessary votes on the Assembly floor on the final day of the 2005 legislative session. Jackie Speier [D-8th] will continue to address the bill in the current session.

Pennsylvania was the first state to enact mandatory reporting. Pennsylvania's Health Care Cost Containment Council (PHC4) recently released the state's first report of hospital-acquired infections including CRBSI, CAUTI, VAP and SSI. Marc Volavka, Executive Director of the Council, testified to the outcomes in a hearing before the U.S. House of Representatives Committee on Energy and Commerce on March 29, 2006<sup>25</sup>. For the year 2004, the hospitals reported 11,668 HAIs associated with an additional 1,510 deaths, 205,000 extra days of hospitalization and \$2 billion in additional hospital charges. However, he indicated that while these numbers are disturbing, it is even more chilling that the figures were severely under-reported. During the first nine months of 2005, 13,711 HAIs identical to the four categories reported in 2004 have been confirmed and reported. These were associated with 1,456 deaths, 227,000 extra hospital days and \$2.3 billion in additional charges. Extrapolated nationally, this translates to almost 40,000 additional deaths annually or about 110 people dying each day. He further reported that 13 percent of patients with HAI died compared to 2.4 percent who died and did not have infection; a five-time greater chance of death with infection. The cost of these HAIs in the first nine months of 2005 was \$2.3 billion, which extrapolated nationally amounts to \$46 billion.

Are healthcare-associated infections a significant patient safety issue? HAIs involve considerable morbidity; they are deadly and the financial impact is staggering.

### **Are health-care-associated infections preventable?**

The 1999 IOM report defined safety as freedom from accidental injury. An accidental injury resulting from a medical intervention is an "adverse event." A "medical error" is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. The medical error definition implies that an adverse event can be considered a medical error if it was "preventable." Historically, the medical community has nullified nosocomial infection as an inevitable risk of illness, an unavoidable phenomenon. The Study on the Efficacy of Nosocomial Infection Control Study (SENIC Study) was a 10-year CDC effort completed in 1984<sup>26</sup>. This study documented that infection prevention programs can reduce the incidence of nosocomial infections by 32 percent per year. The implication was that a majority of HAIs were not preventable and were an accepted consequence of medical care.

This premise is no longer accepted in light of outcomes from recent initiatives to prevent hospital infections. In fact, the Association for Practitioners in Infection Control and Hospital Epidemiology (APIC) has adopted a "No Excuses/No Tolerance" (NET) campaign regarding HAIs<sup>27</sup>. The organization has made dramatic effort to change the culture of disregarding infection prevention among physicians and hospital administration. The benchmark is zero infections.

The ability to achieve the zero or near zero mark of CRBSI has been accomplished<sup>28</sup>. For example, Dr. Richard Shannon described Pittsburgh's Allegheny General Hospital's results before the March congressional hearing about implementing the principles of "Perfecting Patient Care," an adaptation of the most successful business improvement models in the world employed first by the Toyota Production System<sup>29</sup>. As of

February 2006, the number of CVC infections decreased progressively from 49 to three, associated deaths from 19 to one, and from one infection in every 23 to one in every 535 catheters. They have experienced no CVC infections in two critical care units for six months.

Are HAIs preventable? The testimony of two of the presenters before the U.S. House of Representatives speaks well to the question.

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.

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 the daily battle against human disease.

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.

– Richard P. Shannon, MD,  
Allegheny Hospital, Pittsburgh, PA

Hospital-acquired infections are not inevitable, nor should they be expected. These infections can be prevented. For years, there had been this so-called myth of inevitability; that is, hospital-acquired infections are the inevitable byproducts of providing hospital-based care.

– Marc P. Volakis, Executive Director,  
PHC4

### **What measures can be used to evaluate deviations in the standard of care for the prevention of HAIs?**

In 1999, the National Quality Forum (NQF) with support from the AHRQ and through the work of the UCSF/Stanford Evidence-Based Practice Center (EPC) endorsed 30 evidence-based Safe Practices to be universally employed to reduce the risk of error and harm to patients<sup>30</sup>. They went on to transform these practices into measurable and reli-

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able quality indicators (QIs) that health-care providers, policy makers, and researchers could use with inpatient data to identify variations in the quality of inpatient and outpatient care. The new QIs are organized into three modules: Prevention Quality Indicators (2001), Inpatient Quality Indicators (2002), and Patient Safety Indicators (PSIs) (2003).

The PSIs focus on potentially preventable complications and iatrogenic events for patients treated in hospitals including “selected infections due to medical care.” The indicators are used in a public reporting system for quality tracking, reporting and linking payment to quality or pay-for-performance for U.S. hospitals. The PSIs were included in the AHRQ’ Healthcare and Utilization Project (HCUP) that was established to provide a uniform format for reporting multistate, administrative, population-based data on both insured and uninsured patients. In December 2005, HCUP published the first National Healthcare Quality Report. Only modest improvement occurred in CRBSI, VAP, SSI, and CAUTI in the 20 percent of U.S. hospitals contributing data<sup>31</sup>.

The National Quality Forum in conjunction with Leap Frog, a privately held group formed by executives of some of the nation’s largest companies also utilized the 30 Safe Practices developed by the UCSF/Stanford EPC to survey and rank targeted urban hospitals and non-urban hospitals on a voluntary basis. The Leap Frog website at [www.leapfrog-group.com](http://www.leapfrog-group.com) provides consumers with the survey results and rankings to make informed decisions about where to receive hospital care. The program also allows for rewards to doctors and hospitals for improving the quality, safety and affordability of healthcare.

HealthGrades, Inc., a private health-care quality ratings and services company founded in 1999, set out to identify patient safety incidence rates for nearly every hospital in the country by applying the AHRQ’s Patient Safety Indicator methodology to Medicare data. The most recent report was published in April 2006, and is the first study to evaluate patient safety performance for each state

in the U.S. using the AHRQ PSIs<sup>32</sup>. This report disappointingly indicated a decrease in improvement of HAIs. The HealthGrades website [www.healthgrades.com](http://www.healthgrades.com) also provides consumer reports on hospitals and physicians.

In November of 2001, the Centers for Medicare & Medicaid Services (CMS) under the U.S. Department of Health and Human Services (HHS) announced their Quality Initiative program to assure quality healthcare for all Americans through accountability and public disclosure. CMS works in conjunction with the Hospital Quality Alliance (HQA), a public-private collaboration including the American Hospital Association, American Medical Association, AHRQ, and JCAHO. CMS and the CDC launched a national quality improvement project, the Surgical Infection Prevention Project (SIP), in 2002 aimed at reducing the occurrence of postoperative SSI.

By August 2005, CMS’s Quality Improvement Organizations had joined in collaboration with ten national organizations to advance SIP to the Surgical Care Improvement Project (SCIP). The national network of QIOs helps hospitals in each state to achieve the project goal of reducing surgical complications by 25 percent by the year 2010. Seven quality indicators for prevention of SSI are included in the reporting measures. More than 4,000 hospitals have voluntarily reported data from July 2004 through June 2005. CMS’s Hospital Compare, a new website tool developed to publicly report individual hospital’s compliance to recommended quality measure, debuted in April 2005 at [www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov) and [www.medicare.gov](http://www.medicare.gov).

Many states have instituted reporting programs as well. Beginning in August 2005, more than 200 California hospitals now participate in CHART, the California Hospital Assessment and Reporting Taskforce<sup>33</sup>. The investigative phase was led by researchers at the UCSF’s Institute for Health Policy Studies. The team adopted more than 50 hospital performance indicators, including infection control. The measures are aligned with JCAHO and NQF initiatives. Seventy-five percent of all California hospitals with an

average daily census of 75 patients or more, and 100 percent of hospitals with an average daily census greater than 300 patients have agreed to participate. The first report card is expected by June 2006.

In January of 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a sentinel event alert acknowledging the severe under-reporting of deaths due to HAIs and reminded institutions that these deaths meet the requirement for sentinel event review. In 2003, the goal to reduce the risk of health-care-associated infections was added to their National Patient Safety Goals. The same year, JCAHO released revised standards for infection control in healthcare facilities. The 2005 Infection Control Standards address specific areas including ambulatory care, behavioral healthcare, home care, hospital laboratory and long-term care organizations. JCAHO also now requires that patients be informed about adverse events.

Probably the most impressive health-care improvement effort addressing HAIs is the “Saving 100,000 Lives Campaign.”<sup>34</sup> The campaign was initiated by the Institute for Quality Improvement in partnership with the American Medical Association and endorsed by American Nurses Association, JCAHO, CMS, AHRQ and other national organizations. The ambitious plan has enlisted more than 3,000 of the 6,000 hospitals in the U.S. to reduce the number of unintended deaths by 100,000 over the course of 18 months ending at 9 a.m., June 14, 2006, and each year thereafter. The underlying idea of the campaign is to save lives by implementing six best practices proven to reduce patient harm and death. Among the six are prevention of central catheter-associated bloodstream infections, ventilator-associated pneumonia and surgical site infections. A set of evidence-based practices are presented as “bundles” to be implemented and measured. Despite the intense effort, Donald Berwick, IHI’s president, and chief executive officer announced in March that the campaign is likely to fall short of its goal by about 39,000.

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Evidence-based patient safety indicators established by government and private associations for measuring patient safety, adverse outcomes and medical errors become standards of care by virtue of their applicability and measure of quality. Guidelines developed by the CDC for the prevention of healthcare-associated infections and standards of care developed by numerous professional organizations also represent measures of accountability.

Healthcare professionals are responsible for compliance to standards of care and are liable when there is deviation in practice that results in adverse outcomes. Gosfield and Reinertsen provide a brilliant overview of how the IHI's bundles position hospitals and practitioners for corporate and legal liability<sup>35</sup>. They concluded that there are likely four types of legal liabilities arising from the 100,000 lives campaign alone but could be applicable to any evidence-based guidelines or standards. These include (1) failure to keep up with the science; (2) failure to follow adopted processes, including their own internal policies and procedures; (3) failure to inquire into their fulfillment of the standards; and (4) failure to confront and take action against those who disregard the rules. The widespread and overwhelming attention to patient safety initiatives, standards and guidelines certainly sets the stage for measuring legal liability.

The prevention of prolonged suffering, needless death, and waste of financial resources by implementation and monitoring of readily available, evidenced-based guidelines and standards in U.S. hospitals, is a moral obligation and reasonable expectation by consumers of health care. The pursuit of legal action for the failure of institutions to effectively do so is predictable and justifiable.

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