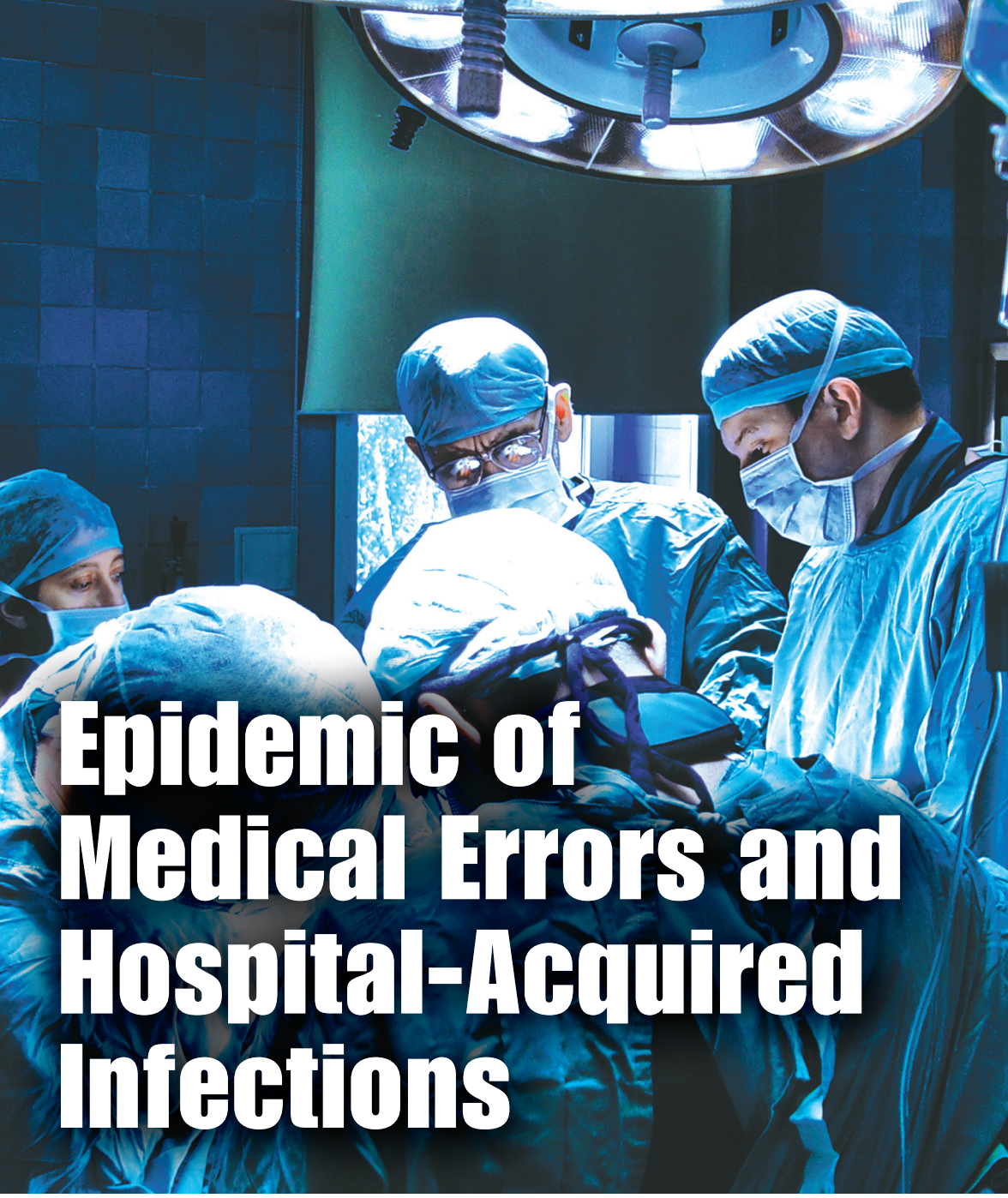

Epidemic of Medical Errors and Hospital-Acquired Infections

Systemic and Social Causes

Edited by William Charney

CRC Press
Taylor & Francis Group

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Dedication

This book is dedicated to the millions of patients who suffered medical problems after seeking health care. This book is dedicated to changing the deeper causes of the pain and suffering incurred when medical intervention goes awry. In other words, changing of the status quo ante.

Contents

Acknowledgments

Thanks, first, to Michael Hurley of the Ontario Council of Hospital Unions (CUPE) for his tireless efforts in bringing attention to correctable causes of medical errors and hospital-acquired infections; to Anita Badri, my very trusted and unbelievably competent administrative assistant, without whom this book would not have seen the light of day; to all of the chapter authors who worked under extremely difficult deadlines and never complained or whined, especially John Lange, who immediately got the scope of this book and produced an unbelievable amount of research; to Jocelyn Villeneuve of L'Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTSAS) for his wonderful connections in Quebec; to Guillaume Ducharme for his assistance in getting the participation of Quebec; and to Ann Hunstiger, who put up with my tensions and stress during the making of this book and guided me through many doorways.

Editor

William Charney has thirty years of experience as a health and safety officer in health care and as an activist for community health and safety issues. For five years, he was a safety officer at the Jewish General Hospital in Montreal, Quebec. For ten years, he was the director of environmental health at the Department of Public Health in San Francisco based at San Francisco General Hospital. Then for five years, Mr. Charney was a safety coordinator for the Washington Hospital Association. For the last ten years, he has been a consultant in the field of occupational health.

Mr. Charney has published nine books in the field of health-care safety, including two volumes of the *Handbook of Modern Hospital Safety,* three volumes of *Essentials of Modern Hospital Safety, Emerging Infectious Diseases*, and *The Epidemic of Healthcare Worker Injury* in the United States. He has also published more than 30 peer-reviewed articles in the field. As an activist in the field of health-care safety, he has successfully organized legislative drives for safe patient handling in various states and spearheaded legislation for safe needle devices, which became law in many states as well as federal law. He has won the State of California Health and Safety Award as well as an Advocacy Award for Safe Patient Handling.w

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1 Do No Harm

A Social Science Approach to Medical Errors and Hospital-Acquired Infections—A Systemic Approach to the Epidemic

William Charney

CONTENTS

> According to "Dead By Mistake," a report detailing the findings of an investigation by the Hearst Corporation, approximately 200,000 people die in the United States every year from hospital infections and preventable medical errors. To make matters worse, the situation has not changed in 10 years.
>
> *http://www.naturalnews.com/medical_errors.html*

INTRODUCTION

"Do no harm," a particularly leading and important phrase in the delivery of health care, is not working. In fact, depending on the epidemiological approach and which data sets one applies, medical errors, hospital-acquired infections (HAIs), and pharmaceutical errors combined are the second or third leading killer of Americans

annually: approximately 300,000 deaths (100,000 per category). Add to these numbers the hundreds of thousands who are harmed (morbidity) but not killed (mortality), changing the quality of life, and a substantial problem is defined. Although the numbers are hard to quantify from study to study and they have to be divided by millions of procedures as the denominator, the present reality is unacceptable.

Some Headlines

- Hospital uses wrong kidney for transplant (*Los Angeles Times*, February 18, 2011)
- Surgical errors continue despite protocols (*Archives of Surgery* study as quoted by *The New York Times*, Science section, October 19, 2010)
- Infection control lapses plague outpatient surgical centers (*Seattle Times*, June 9, 2010, p. A8)
- Boy accidentally given double dose of medication at Tacoma Hospital (*Seattle Times*, November 12, 2010, p. B3)
- X-ray beam strays invisibly harming instead of healing (*The New York Times*, December 29, 2010, p. A1)
- West Virginia Hospital overradiated brain scan patients' CT procedures (*The New York Times*, March 6, 2011, p. 18)

Some Preliminary Data

Please note that the data fluctuate according to year and study, from a high of 788,588 iatrogenic deaths per year (found in 'Top Screwups Doctors Make and How to Avoid Them' Graedon, J, Graedon, T; 2011) as these authors counted and referenced such categories as fatal drug reactions in hospitals (106,000), fatal drug reactions per year in out patient settings (198,000), fatal drug reactions in nursing homes (41,652), deaths from misdiagnosis (counted as a mean 132,000), hospital acquired infections (100,000) deaths from C-difficile in nursing homes (16,500) excessive radiation (29,500), deaths from unnecessary surgeries (12,000), venus thromboembolisms (119,000, and surgical and post-operative complications (32,591).[1] To get a true picture of the scope of the error problem, medical and medication errors and HAIs must be added together. One must also add to the data picture the number of nonfatal injuries in each category.

The Epidemic

- 44,000–98,000 preventable medical errors per year.[2]
- 195,000 preventable errors deaths per year.[3]
- 99,000 deaths per year because of hospital nosocomial infections; most common, methicillin-resistant *Staphylococcus aureus* (MRSA).[4]
- 99,000 nosocomial deaths per year.[5]
- Depending on the data set used, medical errors, HAIs, and pharmaceutical errors (if added together) are the second, fifth, or eighth leading cause of death.

- Medical errors affect 1 out of 25 (or 4%) hospital-admitted patients per year.[6]
- 1.14 million medical errors out of 37 million hospitalizations (3.1%) in the Medicare population from 2000 to 2002.[7]
- According to Food and Drug Administration (FDA) data, 1.3 million patients are injured per year from medication errors.
- One in five Americans (22%) report that they or their family member experienced a medical error.[8]
- In Canada, reports show between 9,000 and 24,000 deaths per year because of medical errors.[9]
- It is also reported in Canada that 1 in 13 patients admitted to an acute hospital suffered an adverse effect.
- In a report to Parliament in 2008, Britain reported 11,000 deaths per year because of medical errors.
- Germany, with one-fourteenth of the U.S. population, reported 17,000 deaths per year because of medical errors.
- Fifteen thousand Medicare patients die each month in part because of hospital care including such events as bedsores, excessive bleeding from blood thinners, infections, and mismedications.[10]
- Of the 1 million Medicare patients discharged each year, 134,000 were harmed by medical care.
- A North Carolina study in 2008 shows 25.1 per 100 patients are injured because of medical errors.[11]
- A University of Toronto study shows 2 million adverse drug effects with 100,000 deaths per year.[12]
- A study shows 2,000 deaths per year due to unnecessary surgery, 7,000 deaths due to medical errors, 20,000 deaths due to other medical errors, 80,000 deaths due to infections, and 106,000 deaths due to adverse effects from medications; or 225,000 deaths per year because of hospitals; or the number 3 killer in the United States. (Note: This study is 10 years old, and now the data shows higher exposures.)[13]
- A study by the Society of Actuaries in 2008 showed the cost of medical errors to be almost $20 billion per year, $17 billion of which went to pay for treatment of those harmed. This study estimated 7% of patients admitted will be exposed to a medical error.
- One-third of all patient admissions result in some form of medical error.[14]
- Forty wrong-site surgeries occur every week in the United States.[15]
- In 1999–2001, the sixth leading cause of hospital deaths in the United States was by MRSA, costing $50 billion.[16]

After billions of dollars being spent, national campaigns being waged, and clinical applications being implemented, no real dent has been seen in the data. The equivalent of six jumbo jets full of people dying each day who enter a hospital has created a set of problems that the health-care delivery system seems unable to solve. A recent study in North Carolina hospitals showed that harm to patients was common and not decreasing over time.[17]

SOCIAL SCIENCE APPROACH

The social sciences deal with the interrelationships within a societal framework. The social science pioneers, Max Weber, Emile Durkheim, and Karl Marx, integrated symbolic interpretations with societal critiques. A social science approach combines humanism, relativism, demography, communication, behavior (interaction between organisms), and other approaches in a broad-based theoretical analysis instead of just constructing empirically falsifiable theories. This book's idea is that each health-care delivery system and its partner hospital is a society within itself where departments interact much in the same way as different groups within a society interact.

One of the premises of this book is to take a look at the problem of medical errors and HAIs not necessarily from a clinical perspective but from a social science and political framework. This allows for a reasonable discourse on systemic causes, the concept in which health-care delivery is designed and the manner in which those design characteristics themselves play a pivotal role in causing error and infection. Unless this type of analysis takes place, it is believed that the health-care community will miss the underlying reasons why error and infections are prevalent and only allow for the "low-hanging fruit" causalities to be selected for remediation. What follows in the "Hypothesis" section are the multiple systemic causes that we have identified for this book, which need to be part of any ongoing national prevention dialogue to systematically address this "epidemic" of medical error, HAI, and pharmaceutical error.

Interestingly, they can be seen as parts of a whole or a totality. It is believed for the purposes of this book that there exists interconnectivity, a linkage between the parts of the list that follows. By addressing each one separately, but in a collective framework, a deeper impact on medical errors and infections and a more reasonable approach to real solutions that will stand the test of time will be achieved.

HYPOTHESIS

Our hypothesis is that health-care delivery itself has evolved improperly and has built within itself constructs that lead to medical error and hospital infection. If we remain open to the possibilities this creates, our abilities to reframe the discussion on medical errors and HAIs could emerge, and could open new doors of thinking and enlighten such issues as patient safety. In reframing the discussion, we will look at such macro issues as "for-profit care," hierarchies in human relationship systems (bullying), over-reliance on technologies, stress, health-care working conditions, staffing, legal issues that conflict with safety issues, and cost–benefit issues that put safety on the negative side (spending side), rejecting the savings side of the equation, all of which are directly related to medical errors and/or HAIs. Rarely do these systemic issues arise during a "root cause" as they appear too large in scale to tackle. But unless we dive head first into these direct and systemic causes, we will not solve the epidemic of harm. The following is a preliminary list of causal factors in medical errors and HAIs:

- Profit motive, which drives so much of our system (see Chapter 2), contributes to both medical errors and HAIs. The *Journal of General Internal Medicine* published a study in March of 2000, "Hospital ownership and preventable adverse effects," showing that patients in for-profit hospitals are

two to four times more likely than patients in not-for-profit hospitals to suffer adverse events such as postsurgical complications, delays in diagnosis, and treatment of an ailment. The editor of the journal also cited that for-profit hospitals lowered costs by cutting nursing services.

Documented features of for-profit hospitals include lower staffing and expenditures on nursing and more preoccupation with survival in the market than survival of their patients. Even for-profit systems for blood collection have shown that for-profit systems have a cost of 5–15 times more to collect, 1000% more blood wasted, and higher transfusion-related infections such as hepatitis.

- Staffing ratios or, expressed alternatively, the number of staff to patient census, are not at acceptable levels (see Chapter 7). Only two states have regulations. Lack of staff increases the potential for medical error, and without adequate staffing, the health-care delivery system is just "pushing the can down the road" to the budget of someone else that will eventually pay for the error.
- Shift work contributes in so many ways to the safety of patients. Longer shifts translate into higher numbers of medical errors (see Chapter 9).
- Injury to health-care workers (10% apply for workers' compensation every year with tens of thousands of lost days) contributes in a systemic way to medical errors and compromises patient safety with a proven loop wherein hurting a health-care worker hurts a patient (see Chapter 16).
- Hospital working conditions contribute directly to medical errors (see Chapter 8). It has been argued for quite some time that adverse working conditions have a negative effect on staff and that creates an increase in medical errors. With 62% of nurses leaving the profession because of the physical demands of the job, working conditions are contributing to both negative patient outcomes and national and state nursing shortages.
- Bullying has direct and indirect effects on medical errors and negative patient outcomes. It especially impairs nurses in their cognitive effectiveness. Therefore, two chapters have been devoted to this phenomenon (see Chapters 10 and 11). If a new nurse in your hospital saw a senior physician placing a catheter but not complying with the (hospital's) checklist, would the nurse speak up and would the physician comply? The answer is almost always, 'there is no way the nurse would speak up.' What other industry would accept a routine safety violation that is associated with the deaths of tens of thousands of patients and not be held accountable?
- A study of 1700 nurses, physicians, clinical care staff, and administrators found that fewer than 10% address behavior by colleagues that routinely includes trouble following directions, poor clinical judgment, or taking dangerous shortcuts. Specifically, 84% of medical doctors (MDs) and 62% of registered nurses (RNs) and other clinical care providers had seen coworkers taking shortcuts that could be dangerous to patients—fewer than 10% said they directly confronted their colleagues about their concerns, and one in five MDs said they have seen harm come as a result.[18]
- Root-cause analysis: It is believed that the system of analysis of medical errors and HAIs lacks a rigorous science to unveil causality. Despite

millions being spent on hiring airline experts, there still remains a fundamental disconnect in getting to exact causes. For example, if legal experts of any given institution demand silence on issues to protect against higher litigation claims, then the effect is that "truth leaves the room" and the great "white wall" remains in its place. There has been some progress on this as some hospitals are now coming forward and offering apologies for medical errors and are finding they are sued less often (see Chapter 14).

- Legal accountability (see Chapter 14): The legal system may be contributing to the overall problems of medical error. By not admitting error and maintaining silence because of fear of liability and litigation, professional root-cause analysis is compromised, therefore compromising care.
- Technology: There seems to be a consensus that technology is the panacea. It is and is not (see Chapter 15).
- The Canadian situation is very similar to that of the United States, as HAIs represent the fourth leading cause of death to Canadians (see Chapter 5).
- Cost–benefit analysis: Attaching cost per facility to medical errors and HAIs is a challenge, especially when health-care facilities do not understand the true science of cost–benefit of medical errors and many reject the premise of "indirect cost." This can lead to miscalculations and decisions that are erroneous, and instead of seeing prevention as being on the profitable side, the system sees expenditures to prevent as a cost. The Society of Actuaries has stated that medical errors cost $20 billion a year; bedsores directly linked to error cost $3.9 billion annually.
- The number of medical errors (see Chapter 3) is not a concise science, but the numbers are still staggering.
- The number of HAIs (see Chapter 4) is again not a concise science, but the numbers too are still staggering.
- Epidemiology: The number of medical errors and infections is high. A new study published by *Health Affairs* in April 2011 cited that one in three patients that enters a hospital setting experiences some form of medical error. The number of HAIs is also alarmingly high (see Chapter 6).
- Industrial hygiene: It is the belief of this book that there is an association between patient safety and health-care worker safety (see Chapter 16). Lack of injury prevention programs, which leads to health-care worker injury, creates the atmosphere of less workers on the job, which in turn leads to less quality patient time and lower staff/patient ratios. Chapter 17 on industrial hygiene presents an overview of the exposures that health-care workers confront.
- The nurse's story is a key to understanding at least one nurse's struggle to navigate the obstacles of safe patient care (see Chapter 18).

To open the discussion of the social science approach, there are two major themes, as follows:

1. The health-care delivery system as it is designed in the United States has built within it the causes of medical errors and HAIs, as many of its

functions contribute to the problems and the solution to these design flaws is considered too expensive.

2. The solutions may lie in the redesign of many of the delivery systems. Labor relationships would need to change, staffing levels would need to change, the "for-profit" mentality would need to change, protecting against health-care worker injury and investing in safety programs would need to radically change, health-care working conditions would need to change, accountability practices and the design of the "consequences" would need to be fundamentally reexamined, training programs would need to be raised to the "level of risk" for health-care workers, and the manner in which budgets are allocated would need to be reexamined in order that access to money does not become a struggle between departments. Legal approaches would need to be examined and changed to eliminate loopholes that contribute and sometimes license error. These are all social science cause and effects and causal interactions that are not at present considered when looking at prevention models of medical errors or HAIs.

Although we use some clinical analyses in this book, we focus on analyzing the problem from a more social/political viewpoint in which the answers and solutions rest more within the frameworks around which hospitals are organized. Therefore, checklists, technology, computerization, and so on, in and of themselves will impact some of the issues but not solve the underlying reasons why our health-care delivery systems cause harm at the rates they do. More dots need to be connected, and many of the negative loops created by the system need to be recognized.

One such loop is the injury rate of health-care workers and its impact on the causation of medical error. Thousands of health-care workers (HCWs) are injured every year, miss work, and impact staffing ratios, which impacts errors, and this is not even discussed at any level, especially concerning medical error. This is but one example. The health-care community tends to think micro when it needs to look at the macro, where whole systems need to be modified. Redesigning working conditions and tackling the patient/staff ratio paradigm, two precursors to medical error, are not given real scrutiny due to cost and a misunderstanding of cost–benefit and prevention. For example, there are only two states that have patient/staff ratio bills (Washington and California), and there is no federal standard. Cleaning hospitals to reduce HAIs is a by-product of time in an area versus the number of cleaners hired to do the job. Fewer cleaners means management saves money in labor costs. Therefore, cleaners are not allowed enough time in each area to adequately disinfect and many areas are not even touched because of time; in our present system, time equals money.

Resistance in thinking organizationally, or to changing the design, or to altering whole procedural practices is caused by the "expense." The same question always arises: "Where will the money come from?" Or, "We are just barely surviving." Yet the short answer to this riddle is that we create so much unnecessary expense with medical errors and HAIs (the Society of Actuaries estimates $20 billion per year), that needed money is hemorrhaging out the back door.

It is axiomatic in risk-management science that prevention is much cheaper than paying the cost of injury. In today's dollars, litigating an injury (including legal fees,

judgments, loss of administrator time, paying insurance and indemnity fees, etc.) runs in the billions, if not hundreds of billions, of dollars annually. Yet prevention has somehow been categorized as being on the cost side of the balance sheet and not included in profit dollars.

For example, a patient with a major bedsore can cost $85,000. It can be assumed that the bedsore developed as a result of not turning the patient, which can perhaps be attributed to a lack of staff. The cost of treating a bedsore can pay for at least two to three additional staff per year, and then the numbers begin to make more sense; investing dollars in personnel pays for itself in prevention dollars.

Medical error and HAI have become a riddle. To solve the riddle, a "third eye" is necessary. The premise of this book is that the "third eye" is organizational and social. Safety science sees any error as a series of preexisting conditions, which eventually leads to a downstream event. If, for example, our hospitals have become factories, scheduling loads of patient visits per day, operations per day, or patients per hour, then overloading mistakes will occur because of these pursuits. If working conditions for health-care workers are stressful, mistakes will occur because of fatigue and overexertion. If there is not enough staff per patient, then errors will be made because quality time per patient is suspended. If conditions are legal but questionably ethical, situations will arise that will create mistakes. If the costs of improving the systemic conditions that contribute to medical errors and infections are always deemed too expensive, then the choices to repair will remain weakened and will not be put on the table for discussion.

If health care has designed into its delivery system the causes of medical errors and HAIs, as assumed in this book, then the solution is reasonable: design them out. If hiring more staff to clean properly will reduce HAIs, then the system should just do it. If repairing the working conditions in hospitals will ameliorate medical error rates, it should just be done. If hiring more staff to increase patient staff ratios will decrease medical errors, it again should just be done. If bullying is caused by hierarchical relationships, then we must turn our attention to a remedy—and on and on. All we really need to do is follow the science and the literature for most of our answers and solutions. Much peer review science is cited in this book by our authors. It is the hope of this book that a more efficient dialogue will be produced with a new, more systemic targeting of the causes of medical errors and HAIs. If one out of three patients that walks through the door of a hospital experiences an adverse event,[19] then we must put our "shoulders to the wheel."

WHAT ARE THE PROBLEMS?

1. Admitting there is a problem: If we concede that the numbers are staggeringly high, an epidemic as defined by most dictionaries, then action on a national scale is warranted. The American Hospital Association, a group that is employer owned, made a laudable case and embarked on the "100,000 Campaign." This campaign shone a light on a situation that was not on the national radar. Much was done, and in some cases, decreases in categories were achieved. However, the weakness of this effort is seen in the voluntary

buy in, and each individual health-care system designing its own version of what is considered "intervention." There was never any national effort at legislating for safety and obligating the health-care delivery system to develop standards that can be quantified. At present, we have a voluntary data system for medical error and HAI, which some health-care systems post on their websites. But these numbers are arbitrary as each event is self-defined, so the numbers are much lower than what is realistically occurring.[20]

2. Money: Money is always the devil. If, as we presume, the real causes are systemic, then changing the system will be expensive. But expensive is a relative term. If we believe the Society of Actuaries that $20 billion is spent on medical errors alone and we divide that number by the one million hospital beds in the country (assuming an equal error rate per facility), we are spending $20,000 per bed on medical errors. Here the axiom "an ounce of prevention" would apply. Changing systemically is not inexpensive, but the numbers will actually speak for themselves if they are disseminated impartially. If, for example, increasing staff would prevent *X* number of medical errors and/or infections, the dollar costs at expanding labor costs would be offset by the decreasing costs of errors and infections. That would apply to many cases. Yet even if cost–benefit did not prove beneficial, the ethical case takes precedence.

ETHICAL CASE

The ethical case has been made since the beginning. The Hippocratic Oath, the nightingale effect, "do no harm" is the vision statement in all hospitals as posted. Yet we are still doing harm. Zero tolerance for medical errors or HAIs would be unrealistic. However, each case that develops should be considered a disaster by each facility, bringing all its expertise to bear. That would begin to bring some accountability to the issue. Causes for medical errors and infections abound; we look the other way at sloppy and unsafe practices, the great white wall, the bottom line, overwork and fatigue, working conditions, rationalization of unsafe practices, contradictions between safety and budgets, lack of protection for whistle-blowers, and increases in workload without the concomitant increase in staff. Each one of the above has an ethical component. A 3% error rate might seem low to administrator for medical errors, but then add a 3% HAI rate and a 3% drug error rate, and you have a 9% error rate—almost 1 out of 10 patients that passes through the door—and, to each of the affected patients, each rate is 100%.

Committees exist in each hospital that wrestle with the problematics, but they are functioning often times within an already existing framework of systemic dysfunction. They are then asked to break free of the many constraints and pressures that are resistive to change. Most meetings last an hour.

BUILDING THE CASE

Building the case for systemic change is warranted by the statistical data. Reconfirming that millions of procedures are done without error is as an important measuring figure as the number of mistakes. However, adding the numbers for

each category of error (medical error, HAI, and drug error) does produce alarming numbers of harm. The social science perspective also encourages the formation of a social movement on issues of important societal impact, such as public health and national patient safety. The social movement would require health-care workers of all types working with public health officials, legislatures, trade unionists, government agencies, and funding agencies to write a plan of action to challenge the status quo of medical errors and infections on the basis of the systemic causes listed in this book. Fixing staff ratios, shift work, bullying, overbooking and overcrowding, hiring more labor to clean facilities, and so on are all possible outcomes, with definitions for each and possible intervention models for our hospitals. It is, after all, the systemic problems mentioned in this book that need attention at this point. We will have to confront as nations what outcomes we require, perhaps a 0.001% rate of error and infections, and proceed toward that goal.

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2 For-Profit Care
Its Effect on Medical Errors

Joseph Schirmer

CONTENTS

Not So Funny: Wrong Artery Bypassed

Two months after a double bypass heart operation that was supposed to save his life, comedian and former *Saturday Night Live* cast member Dana Carvey got some disheartening news: the cardiac surgeon had bypassed the wrong artery. It took another emergency operation to clear the blockage that was threatening to kill the 45-year-old funnyman and father of two young kids. Responding to a $7.5 million lawsuit Carvey

brought against him, the surgeon said he'd made an honest mistake because Carvey's artery was unusually situated in his heart. But Carvey didn't see it that way: "It's like removing the wrong kidney. It's that big a mistake," the entertainer told *People* magazine.

OVERVIEW

The U.S. health-care system suffers from problems with quality of care. These are due in large part to our system of economic organization, which limits access to care and distorts the quality of care delivered. Quality issues include diverging from standards of care and preventable errors. Our systematic economic issues include systems of payment, limited access to care, rising costs, and inequalities. The growing influence of for-profit companies, hospitals, health maintenance organizations, nursing homes, insurance companies, and pharmaceutical manufacturers threatens the integrity of patient care. This chapter will focus primarily on quality of care issues and what can be done to reduce errors and improve patient outcomes. Next, the focus will shift briefly to examine how economic systems influence patient outcomes. The conclusion observes that societies with more economic equality experience better health outcomes, health-care quality, and quality of life.

QUALITY OF HEALTH CARE

Studies evaluating quality of health care find that the U.S. population receives 50%–55% of recommended health care. In 1998, Schuster et al. reviewed 48 articles covering 500,000 people and found that 50% received recommended care, 70% received recommended acute care, and 30% received contraindicated acute care. For those receiving treatment for chronic conditions, 60% received recommended care and 20% received contraindicated care.[1] McGlynn et al. found that 55% received the recommended care by examining a random sample of 6712 people in 12 communities.[2] The quality of care varied widely by underlying diagnosis. Quality ranked high (>60% received recommended care) for those with cataracts, breast cancer, hypertension, pregnancy, coronary artery disease, low back pain, and congestive heart failure. Those with diabetes, headache, urinary tract infections, pneumonia, sexually transmitted diseases, ulcers, or hip fractures received less than 50% of recommended care. Those with alcohol dependence received only 10% of recommended care. The health-care system also performed poorly for aspects of care dependent on patient interaction (listening and discussing), such as counseling, education, and taking histories, and better for those features more dependent on physician initiatives for diagnosis and treatment.

Asch et al., using the same sample as McGlynn, examined differences among population groups receiving recommended care and found mostly small differences. Women under 31 and with higher incomes received slightly higher quality care. Unexpectedly, Asch et al. found that blacks and Hispanics received slightly higher quality care than whites. Other studies report lower quality health care for blacks and other minorities.[3] In discussing this finding, Asch et al. note that selecting

a less expensive mix of measures to evaluate quality of care may have influenced this finding. Those covered by Medicare and Medicaid received higher quality care than those with no insurance. The largest variation from the norm was that veterans received 67% of recommended care.[4] Since all veterans have access to the U.S. Department of Veteran Affairs (VA), this suggests that universal access may improve quality of care.

Higashi et al. examined a sample of three different adult populations and found that the quality of care increased approximately 2% for each additional chronic condition per patient, up to a maximum of six conditions, after which quality of care diminished or leveled off. Baseline quality of care for those with no chronic conditions varied among the three groups from a low of approximately 50% to a high of 62% (a sample of veterans). Patients' quality of care also improved with the number of health-care providers.[5] The findings of Higashi et al. suggest that sicker patients receive better care. It is possible that payment systems influence this finding by providing incentives for more diagnoses and treatments.

Studies of U.S. children also find quality of care deficits. Most studies involving children have found somewhat lower rates of quality health care than for adults, perhaps because children, being generally healthy, require more preventive services and are less profitable as health-care customers. Mangione-Smith et al. studied ambulatory (outpatient) care using a sample of 1536 children from 12 areas of the United States and found that children receive 46.5% of recommended care, 67.6% receive recommended acute care, 53.4% receive recommended chronic care, and 40.7% receive recommended preventive care.[6]

Many studies focus on the quality of pediatric preventive care. Zuckerman et al. reviewed preventive care provided to a sample population of 2041 children and found relatively positive results, with two-thirds receiving good or excellent preventive care and one-third receiving fair or poor preventive care. Zuckerman et al. found higher quality preventive care was associated with parental reports of more counseling regarding risk factors. Well-child doctor's visits of longer duration were associated with better care; those receiving excellent care averaged 20-minute visits for well-child exams and those receiving poor care had average well-child visits of 12 minutes.[7]

Irwin et al. reviewed over 8000 adolescent records and found that only 38% of adolescents received the appropriate recommended visits and only 10% received the recommended anticipatory guidance.[8] Similarly, Chung et al. reviewed 180 articles, focusing especially on 58 large studies, and found that 37%–81% of children received recommended preventive visits and less than half of all children received recommended preventive care. As an example, less than half of at-risk children receive the recommended testing for lead exposure. While health-care providers can do little to treat lead exposure, their role in testing and early detection is crucial for triggering public health systems to investigate and to intervene with property owners to prevent exposure to housing-based lead paint hazards. Chung et al. identified barriers to improving pediatric preventive care, such as (1) lack of insurance, (2) lack of provider continuity, (3) lack of privacy, (4) lack of provider skill, (5) racial, ethnic, gender, and language barriers between patient and provider, and (6) lack of time for appropriate care.

MEDICAL ERRORS

Medical errors have received increasing attention over the past decade. In 1999, the Institute of Medicine (IOM) published *To Err Is Human*, estimating that 98,000 Americans die every year as a result of medical errors.[9]

Public opinion reflects this growth in knowledge. According to a Kaiser Foundation poll, 47% of the public is very concerned about medical errors for themselves and their family members when they go to a hospital for care.[10] While individual members of the public are concerned about their own personal risk, the public underestimates the scale of the problem. About half (49%) of the public believes that 5000 people or less die each year as a result of medical errors.[11] This is far lower than the estimate by the IOM or other estimates in peer-reviewed journals (Brennan 1991; Leape 1991; Thomas 2000).

A major theme in literature about medical errors is that the complexity of medicine contributes to the probabilities of error.[12] Gawande, for example, in the Checklist Manifesto, notes that currently there are 13,000 diseases, syndromes, and injuries; 6,000 drugs available; and 4,000 medical surgical procedures, making the practice of medicine extremely challenging.[13] The challenge in preventing errors is to learn how to make complexity simple; hence, the need for checklists.

However, there is also good evidence that many errors do not result from complexity. If complexity caused most errors, errors could perhaps more easily be accepted as an inevitable price we pay for technological progress. Many medical errors result not from complexity but from not acting on what we already know. These errors reflect misplaced priorities, practices, and systems that devalue patient safety. Leape notes, for example, that "we (in the United States) have the highest resistant infection rates in the Western world and yet we tolerate the fact that fewer than 50% of doctors routinely disinfect their hands."[14] Many expensive and common medical errors are relatively simple in origin. Consider how easily preventable are postoperative infections, pressure ulcers, and infections in central venous catheters, for example; these are among the most common and costly medical errors.[15]

Error prevention is possible. Leape cites examples of clinical effectiveness for safe practice interventions showing improvements in adverse events (AEs) for 12 predictable problems; most reduced errors by more than 50%.[16] These examples prove that medical errors are preventable with study, effort, practice, and systems approaches to changes that put patients first. The German Coalition for Patient Safety recommends simple procedures and checklists, including patients in communication and studying errors to learn from them.[17] The IOM also calls for a systems approach to medical errors and a paradigm shift to a patient-centered system. Our challenge is to create the political will to make patient-centered safety research a higher priority. Recently, $50 million was available for patient safety research, of a National Institutes of Health budget of $28 billion.[18]

Leape cited seven barriers to safety: (1) medical complexity, (2) individualism, also known as "professional autonomy," (3) fear, (4) hierarchical authority structure, (5) lack of leadership, (6) paucity of measures to demonstrate improvement, and (7) a reimbursement system that rewards errors.[19] More recently, Emanuel et al. added yet another barrier to this list, a culture of blame and punishment for

individuals rather than looking at systems failures.[20] While progressive and concerned health-care providers and researchers are generating evidence on specific measures that improve patient outcomes to address the sixth barrier, the other barriers will be more challenging, especially the reimbursement system, since those who benefit from the current system will be resistant to change.

Starr identified another barrier in his book on the history of medicine: secrecy. He notes that our medical system grew out of the guild system designed to keep knowledge and skills secret.[21] In contrast, transparency is crucial to building a culture that values patient safety. Our challenges in the area of secrecy, hierarchy, and a culture of blame are illustrated by results of a survey asking internal medicine house officers about their most serious errors. Of those reporting, 31% had death as an outcome, 24% discussed the error with patient's families, and only 54% discussed the error with the attending physician.[22]

PATIENT-REPORTED ERRORS

A national telephone survey found that 22% of 1500 people reported mistakes in health care affecting themselves, family members, or close friends at doctor's offices.[23] Another study examined patient's personally experienced mistakes in outpatient settings. Of 1700 people surveyed in North Carolina, 15.6% reported mistakes in their own care, 13% reported wrong diagnoses, 12% reported wrong treatments, and 14% switched doctors as a result. Persons in poor health, more educated, and aged 40–60 were more likely to report mistakes.[24] Other research finds similar rates for patients reporting complications in outpatient settings. For example, a review of 2248 outpatient records found that 18% of patients reported drug complications following treatment and that side effects were a major problem. The study concluded with a recommendation for better communication about side effects, especially for patients with multiple problems.[25]

ERRORS IN OUTPATIENT SETTINGS

While most of the literature on medical errors is focused on hospital settings, ambulatory or outpatient care is also very important. Most health care is delivered in ambulatory settings (nearly 1 billion visits per year to doctors' offices in the United States).[26] More than 77% of all medical procedures are now done in ambulatory settings. Partly for economic reasons, more surgeries are done as outpatient procedures. While the volume of inpatient surgeries remained relatively steady at 17 million per year from 1980 to 1995, the number of surgical procedures conducted in outpatient settings has grown rapidly from 3 to 27 million from 1980 to 1995; as a percentage of all surgeries, outpatient surgeries have risen from 16% to 61% during this time period.[27]

Errors in ambulatory care are more often diagnostic or medication related rather than as a result of surgery, but patients experiencing errors during outpatient surgery tend to have more severe outcomes than patients who experience other kinds of error.[28] Although the trend for increasing numbers of procedures to be done in outpatient settings is undeniable, the relatively uncontrolled nature of follow-up care

after outpatient procedures makes it more difficult to measure outcomes and errors. Thus, it is harder to measure and evaluate the impact of this shift to more ambulatory care. The available evidence shows that the error rate in ambulatory care is lower than the error rate in hospitals. Some errors are hidden from view. Some negative outcomes occur at home, and responsibility for continuing treatment and compliance with medications has shifted to the patient's family.

Fischer et al. examined 5 years of administrative data and found AEs at a rate of 3.7 per 100,000 clinic visits.[29] This is far lower than the rates found in hospital settings. Part of the contrast in rates stems from the obvious fact that outpatient visits are of short duration and less is done; that is, less health care is provided during an outpatient visit than during a hospitalization, so the probability of error is naturally reduced. Hammons et al. thoroughly surveyed the field of ambulatory care safety and point out that while outpatient care is generally safer than hospital care, the increasing reliance on outpatient care does put a larger share of responsibility on patients and families. More communication is needed as a result.

While outpatient care is less technologically complex than inpatient care, it is more complex logistically. For example, Hickner et al. examined errors in diagnostic testing procedures in ambulatory care among 243 clinicians in 8 family practice offices. This study found multiple opportunities for error throughout the testing process, such as (1) ordering tests, (2) implementing the tests, (3) reporting results, (4) notifying patients, and (5) interpreting results and acting on the findings.[30] The general principle here is that the probability of error increases as the square of the steps involved. If patients must travel to multiple sites to get tested, this increases the likelihood of delay or error. If insurance companies require patients and providers to use new laboratories with which they have had no previous relationships, this increases the likelihood of errors in communication, compliance, testing processes, or reporting. In a companion follow-up paper published simultaneously with Hickner, Graham et al. reported on recommended strategies based on practice. Graham found that providers who acknowledged errors and who sought to mitigate testing errors had lower odds of patient harm and negative consequences.[31] The themes that emerge from this research are (1) errors are learning opportunities and (2) more open communication leads to more successful outcomes.

Certain populations are more vulnerable to problems (errors in intended treatment and follow-up) as a result of the growing proportion of direct care delivered in outpatient settings. These include persons with hearing or sight handicaps, mental illnesses, language barriers, the elderly, and those who cannot afford to purchase needed follow up medications of supplies. People who experience health problems following outpatient visits may not be counted as medical error statistics, but they do suffer harm. Indeed, Wood et al. projects that 75,000 hospitalizations per year are due to preventable AEs in ambulatory care, causing 4,839 serious permanent injuries and 2,587 deaths.[32]

ERRORS IN HOSPITAL SETTINGS

Two large population-based studies of hospital discharges, one in New York and the other in Colorado and Utah, found disturbing evidence of AEs, defined as an injury caused by medical management rather than the disease process. Brennan et al.

studied over 31,000 records of hospitalized patients in New York in 1984 and found that 3.7% of patients had an AE. In addition, this study found that 1% of patients had negligent care, meaning that the medical team should have known better and that the care was below the community standard of care.[33] Surgical specialists were more likely to have higher rates of AEs than other medical specialties, but not higher rates of negligent care. In the New York population sample, receiving care in the emergency room also increased the probability of an AE.[34] The authors discuss several factors that could explain the higher risk for emergency room care: (1) Many part-time doctors work in emergency rooms who are not trained in emergency care. (2) There is great time pressure for diagnosis in this setting. (3) There is uneven demand for services, making appropriate staffing a management challenge. (4) Emergency rooms are more likely to be used by severely ill patients.

Thomas et al. used similar methods to examine 15,000 hospital discharges in Colorado and in Utah and found that 2.9% of patients experienced an AE and that approximately 1% of patients experienced negligent care.[35] Thomas et al. considered 2.9% to be the lower bound of the true rate for AEs because of the conservative effects introduced by accounting for inter-observer variability or AE judge reliability. Surgery and falls were the most common causes of AEs in this population of hospital patients. An Australian study of more than 14,000 admissions, using a different methodology, found AEs in 16.6% of admissions, of which 51% were judged preventable.[36]

The U.S. Office of the Inspector General used a sample of 780 patients in 2008 to examine AEs in Medicare beneficiaries. On the basis of this study sample, the report projects that 1.5% (15,000 per month) of Medicaid beneficiaries experience a preventable medical error that contributes to their death and that 13.5% experience AEs resulting in temporary harm.[37] Another non-peer-reviewed study also using administrative data found that 79,670 Medicare patient deaths from 2007 to 2009 were preventable using 13 safety indicators. Hospital-acquired bloodstream infections cost the federal government $1.22 billion from 2007 to 2009 for Medicare patients.[38]

Methodological issues greatly influence the results of AE studies. For example, prospective observational studies find higher rates than retrospective studies of patient records. This makes sense since observers can see patients, health-care providers, and interactive and situational factors as health care is delivered; much of this activity is not recorded in medical records. For example, Andrews et al. conducted an observational prospective study of 1047 Chicago patients and found that 46% had an AE and that 18% had at least a temporary disability as a result. Approximately 16% of AEs had interactive causes, such as communication errors. Although liability is often cited as a major concern for failure to disclose errors, in this study, while 18% of patients experienced serious AEs causing longer hospital stays and increased patient costs, only 1% of the patients made claims for compensation. A major contributing factor to errors was time in the hospital. Patients with longer hospital stays were more likely to have AEs, so that the probability of an AE increased by 6% for each day in the hospital.[39]

Donchin et al. conducted a thorough 24 hour/day prospective observational study over 4 months in 1989 in a six-bed intensive care unit (ICU).[40] This study found 1.7 errors per day out of an average of 178 activities per patient day (1%).

In a six-bed ICU, there were severe or potentially detrimental errors made twice a day; 29% of errors would have been severe if not discovered and corrected quickly. Errors were defined from a process flow or engineering perspective, that is, a deviation, an addition, or an omission of actions related to standard conduct. Unlike in other studies, medical decisions were not evaluated retrospectively for error. In addition to ergonomic factors, unit design, and paper flow issues, Donchin et al. found interactive and communication issues within the ICU to be major contributors to errors. Nursing errors peaked at change of shift when new nursing staff came on duty. Although physicians provided a small fraction (less than 7%) of the total ICU activities, they were involved in a disproportionate percent of errors (46%). Communication issues are crucial. For example, verbal exchanges between physicians and nurses were recorded in 37% of errors although such exchanges made up only 2% of the total recorded ICU activities. The study found that nurses conducted over 87% of the health-care activities in the unit. The authors recommended that nurses be included in physician's rounds and have a formal role in this information exchange as a way to address the need for better doctor–nurse communications.

Sample size also influences the results of studies of medical error. Lessing et al. examined 158 studies of AEs and found that larger studies find lower error rates. Very large studies generally report AE rates of less than 1% of patients. Lessing found small studies to have wider variation in rates and very large studies to be more reliant on administrative data sets with less opportunity for chart review. Also, many studies with higher error rates involved high-risk patients. Based on this multistudy review, Lessing calculated median rates of 8.9% for AEs and 4.9% for preventable AEs.[41]

Weingart et al. have written an excellent review of the epidemiology of medical error; they note that most studies underestimate medical error rates since they count errors as those mistakes causing injury. Since many mistakes are caught in time and patients are resilient, many errors do not cause harm.[42] Medical errors are costly. Van Der Bos reports that medical errors cost $17 billion per year in the United States, with 1.5% of hospitalization admissions resulting in injuries and 0.15% of outpatient encounters resulting in injuries.

INTERVENTIONS TO PREVENT AEs FOLLOWING SURGERY

Gawande estimated that there are 50 million operations per year in the United States, with 150,000 deaths following surgery and 300,000 infections following surgery, resulting in another 8,000 deaths from infections.[43] Postoperative infections following surgery are the single most expensive category of medical error, costing $3.6 billion per year.[44]

Meeks et al. estimates 500,000 postsurgery site infections per year, of which 60% are preventable. These preventable events provide opportunities for improvement to reduce hospital stays, costs, and unnecessary mortality. Meeks conducted a record review for 517 elective surgeries and found compliance with antibiotic guidelines in only 62% of patients studied. Meeks noted that emergency, nighttime, and weekend cases were more often noncompliant.[45]

Surgery is a basic element of health care; approximately 11% of the disease burden worldwide could be treated surgically. While surgery is practiced worldwide and the germ theory of disease is widely accepted, studies generally find poor compliance with safety guidelines. Eight hospitals around the world volunteered to participate in a pilot surgical patient safety study. Before intervention, these hospitals missed at least one basic precautionary safety step in most surgeries.[46] After studying sources of errors and infections, researchers devised a deliberately simple surgical checklist. Implementing this surgical safety checklist with an emphasis on better communication with surgical team members has proved to be an effective tool at preventing surgical complications, infections, and deaths. In this multicountry, multihospital trial, implementing a 19-item surgical checklist reduced complication rates 63% and death rates 50% following surgery.[47] Adherence to six measured safety steps went from 18.6% before implementation to 50.7% afterward.[48]

One goal of preoperative communications briefings and reviewing checklists is to familiarize team members with one another, learning each other's names for example, before the surgery begins so that when a crisis arises, the team members can communicate more easily. These preoperative briefings improve communication among team members, reducing observed communication failures from 3.95 to 1.31 failures per surgical procedure and reducing the communication failures with visible negative consequences by 64%.[49] Implementing operating room briefings also led to reductions in delays during surgeries,[50] less nursing staff turnover,[51,52] higher percentages of appropriate preoperative antibiotic use,[53] and reduced costs.[54] Furthermore, it has been demonstrated that changes in the safety attitudes of healthcare providers are positively correlated with improvements in postoperative complications. While 20% of those who used surgical checklists felt the checklists took a long time to use, 93% would want the checklists used if they were undergoing surgery.[55]

Improving administration of preoperative antibiotics is crucial for improving patient outcomes following surgery. This is achievable. For example, while a 2003 study of elective colorectal surgery found that only 5% of patients received appropriate antibiotic preoperative treatment,[56] Forbes et al. demonstrated an intervention that improved preoperative antibiotic administration from 5.9% to 92.6%.[57]

Infections in central line catheters are common and costly medical errors, ranking fifth among high-cost errors.[58] Leape estimates that 2 million people per year receive central line venous catheters, resulting in 9.7 million patient catheter days per year. These cause 48,600 central line infections, which are fatal in one-third of cases.[59] Since Provonost et al. have proved that these infections are completely preventable in 100 Michigan hospitals,[60] Leape challenges the remaining U.S. hospitals to follow this example.

Berenholtz et al. demonstrated in one hospital that a five-step intervention including (1) educating the staff, (2) creating a catheter insertion kit, (3) asking providers daily whether catheters could be removed, (4) using a checklist to ensure adherence to evidence-based guidelines, and (5) empowering nurses to stop procedures if they observed a violation of the guidelines, together reduced infection rates from 11% to 0%, saving eight deaths and $2 million.[61] Penprase et al. suggests that nurses should take leadership to champion preoperative briefings.[62]

Progress is measurable in surgical safety. Using a National Hospital Discharge Survey, Weiser et al. found that death rates following surgical hospitalizations decreased from 1.64 % to 1.14 % during the decade from 1996 to 2006. The number of hospital-based surgeries increased during this period from 12.25 to 13.69 million.[63]

ADVERSE DRUG EVENTS OR DRUG ERRORS

Four-fifths of adults in the United States take some drug, vitamin, or herbal remedy at least once per week. There are more than 10,000 legal prescription drugs and over 300,000 over-the-counter products on the market in the United States. In 2004, spending on prescription drugs exceeded $200 billion; drug spending has increased faster than other health-care costs and the gap in rates will likely continue to increase.[64] Drug usage is widespread and fully integrated into the practice of medicine. For example, 75% of outpatient visits involve either initiating or continuing some form of pharmaceutical treatment.[65]

Shrank et al. reviewed the quality of pharmacologic care in the United States using a representative sample of 3457 people and found that participants received 62% of recommended pharmacologic care. The quality of care was lowest for education and documentation: 46% received recommended care, 55% received recommended monitoring, and 63% met guidelines for avoiding underuse of medications and 84% met guidelines for avoiding overuse. With medications, as in the case of health care generally (McGlynn et al. 2003), those aspects of patient care such as education and monitoring that depend on direct communication with patients tend to receive less emphasis and as a result provide lower quality than those aspects of care that depend on the medical practitioner alone.[66]

Adverse drug reactions (ADRs) are reactions to the drug itself, as distinct from adverse drug events (ADEs), which include errors in diagnosis or ordering. Lazarou et al. analyzed 39 prospective studies and concluded that 1 million patients experienced ADRs in 1994, causing 4.7% of all hospital admissions. Over 100,000 people die per year as a result of ADRs, making it a leading cause of death in the United States.[67] According to the IOM report, ambulatory (outpatient) care drug errors cost at least $0.8 billion per year, while drug errors for hospital patients cost $3.5 billion per year. Hospitalized patients can expect to experience one medication error per day.[68]

Bates et al. reviewed ADEs in 4031 hospital admissions and found 6.5 ADEs per 100 admissions. Of these ADEs, 1% were fatal, 12% were life threatening, 30% were serious, and 57% were significant.[69] A smaller New Zealand study of 520 admissions found higher ADE rates, 12.9 per 100 admissions, while finding a similar proportion of ADEs (15%) to be life threatening or disabling.[70] A thorough study in Australia noted that ADEs were reported in 1% of hospital admissions and that 2%–4% of all initial hospital admissions were themselves medication related.[71] Such errors are costly in time and treasure. Another Bates et al. study found that ADEs in hospitals caused patients to spend approximately two extra days in the hospital and cost $2400 per incident.[72]

Bates et al. found that drug errors were most often made at the ordering stage by physicians. Another study by Barker et al. focused solely on nursing administration

of medications and found 19% to be in error. The largest category of error observed (43%) was administering drugs at the wrong time, 30% of errors were omitting the dose, and 17% were administering the wrong dose. In evaluating the consequences of these observed errors, 1% was categorized as potential ADEs.[73] A study of ADEs in ICUs found that ADEs were more common in ICUs than in other hospital settings. However, when adjusted for the number of drugs ordered, the ICU had similar ADE error rates to general care units.[74]

Rates of ADEs for hospitalized children are generally lower than for adults.[75–77] Part of the explanation may be due to the different reasons why children are hospitalized, that is, different ratios of injuries to chronic diseases. For example, 40% of the 6 million pediatric hospitalizations per year begin in emergency departments.[78] Fontescue et al. reviewed 1020 pediatric admissions to evaluate ADEs; this study also found most errors were made errors at the ordering stage.

STRATEGIES TO PREVENT ADEs

Fontescue et al. identified three interventions that would be helpful: (1) improved communication among doctors, nurses, and pharmacists, (2) more ward-based clinical pharmacists, and (3) greater use of computerized physician order entry with clinical decisions support.[79]

Van Lave et al. reviewed eight studies and reported that ADE occurred in from 0.7% to 6.5% of all hospitalized patients and that 5.7% of medication orders have an error (before the drugs are administered). Their proposed solutions include computerized ordering, greater participation of pharmacists in drug ordering, creating a climate of learning from mistakes, appreciating health-care team members ideas, and focusing on small steps for improved delivery.[80] Lefkowitz and Zarowitz offer a list of 10 items as a conceptual basis for organizing a safer hospital or practice-wide drug delivery system (including a clutter- and interruption-free work environment).[81]

The IOM 2006 report acknowledged that at least 1.5 million preventable ADEs occur each year in the United States, costing $4.3 billion per year. The IOM recommendations for preventing medication errors are summarized next.[82] Technologically based changes:

- Use more computerized provider order entry with clinical decision support systems (prevent errors at the ordering phase).
- Use more electronic prescribing (avoid handwriting errors).
- Use bar coding to match drugs with patients from ordering to delivery.
- Use smart intravenous infusion pumps.

Improved communication:

- Communicate better between medical staff team members when patients change locations, or during shift changes, or during other changes in responsibility (i.e., handoffs between practice specialties).
- Improve communication with patients; respect for patients rights.

Systems changes:

- Use pharmacists more to (1) supply high-risk medications, (2) participate in patient rounds, (3) provide pharmacist counseling, and (4) review medications on an on-call basis.
- Choose medications more for safety than for low cost.
- Create a culture of safety; view mistakes as learning opportunities.
- Shift from provider-centered to patient-centered model of health care.
- Improve drug labeling; make drug educational information more readable.

ADEs AMONG THE ELDERLY IN HOSPITALS AND NURSING HOMES: ISSUES AND STRATEGIES FOR PREVENTION

Page et al. evaluated inappropriate drug prescribing in hospitalized elderly patients and presented several screening tools that can help evaluate and choose appropriate medications. They question the tendencies of both patients and providers to rely too heavily on pharmacological interventions when other interventions such as psychotherapy may be more appropriate.[83]

Nursing home populations present special challenges in terms of preventing medication errors. There are 1.6 million residents in nursing homes (i.e., long-term care facilities) who take approximately twice as many medications as the general population; 61% take more than nine medications per day. The risk of ADEs increases with the number of medications.[84] Annually, 1.9 million ADEs occur in nursing home facilities. These events have serious consequences. For every dollar spent on drugs in nursing homes, $1.33 is spent on treatment of drug-related morbidity and mortality, resulting in costs of $7.6 billion per year.[85]

Crespin et al. found that three-fourths of North Carolina nursing homes reported drug errors during a 3-year period, of which one-third were repeat errors. Although drug errors in nursing homes caused less harm than drug errors in hospitals (0.8% of ADEs in nursing homes caused harm vs. 1.7% in hospitals), Crespin's team found that repeat errors were twice as likely to cause harm. Their strategies to prevent errors and harm are similar to the recommendations described by the IOM. They emphasize the need to focus on patients in transition, such as those moving in or out of nursing homes from a hospital, rehabilitation facility, or home, and recommend that nurses lead teams to improve safety processes, including reconciliation, labeling, and patient ID checks.[86]

Antidepressants and anticoagulants are among the drugs most commonly associated with ADEs among the elderly. Gurwitz and Field followed 490 elderly long-term care residents that were taking warfarin, a common anticoagulant, and measured 1.5 warfarin-related ADEs per patient over a 1-year period. Errors were most often made during prescribing and monitoring.[87] Fields reported improvements in warfarin management using a standard protocol for facilitated telephone consultations between doctors and nurses.[88]

Antidepressant prescribing in nursing homes rose from 19.6% in 1996 to 47.5% in 2006. This rising use of antidepressants is significant, first because 35% of ADEs in nursing homes are caused by psychotropic medications, of which 63% are

preventable[89] and second, because overuse of psychotropic medications increases the risk of falls by a factor of 1.7–2.0.[90] Hanlon et al. found that nursing homes with a higher ratio of nurses' aides on staff tend to use more antidepressants, while those with more medical directors on staff tend to use less.[91]

Marcum et al. examined 18 randomized studies of interventions to improve pharmaceutical treatment of nursing home residents and summarized their intervention strategies.[92] Successful strategies often involved greater use of pharmacists. For example, (1) pharmacist educational interventions for doctors, nurses, and nurses' aides led to decreased use of antipsychotic drugs and improved mental function for patients; (2) pharmacist review of medications leading to a 62% decrease in falls among the intervention group; and (3) several studies reported that increased use of pharmacists led to decreased numbers of medications per patient.

Peron et al. reviewed studies on medication mishaps in the elderly published in 2010 and reported on two studies that reduced drug errors in the elderly by one-third; one involved comprehensive patient assessments and the other provided 1 week of education for health-care providers. A third, more technology-based intervention using a computerized decision support system reduced drug errors by 16%.[93] Once again, a similar theme emerges; that is, focusing on the people involved, either the providers through education or the patients through assessment, was more effective than a more technology-based, computerized decision support system at reducing improving patient outcomes.

STRATEGY TO PREVENT MEDICAL ERRORS: CONDUCT MORE AUTOPSIES

Autopsies provide a useful tool to determine the accuracy of diagnoses and the appropriateness of treatment at the end of life. Thus, they can improve the quality of health care. The rate of discordance or disagreement between original diagnoses and the cause of death based on autopsy has held steady at approximately 40% since 1938. This discordance demonstrates how important autopsies can be, if we take the opportunity to learn from the experience of death. Through autopsies, we can learn more about the causes of death and how to provide more effective patient care. A major problem is that the rate of autopsy is falling. In 1998, it was less reported to be than 10% at nonteaching hospitals and less than 1% at nursing homes. Decreasing autopsy rates represent lost opportunities to learn from our mistakes. This is important since a Spanish autopsy study found that half the risk of death was from AEs resultant from clinical care.[94] Do falling autopsy rates represent a form of denial, a deliberate refusal to learn how to improve the practice of medicine? Lundberg has forcefully advocated for action to change this. Lundberg points out that 75% of deaths in the United States are Medicare patients, and this calls for the Health Care Financing Agency to require at least 30% of deaths to be autopsied for hospitals to be eligible for Medicare reimbursement. Similarly, Lundberg calls for the Joint Commission on Accreditation of Hospitals to require 25% of deaths to be autopsied in order to obtain or maintain accreditation.[95]

STRATEGIES TO PREVENT MEDICAL ERRORS: IMPROVE COMMUNICATION, COLLABORATION, AND TEAMWORK

There is compelling evidence that collaborative health-care teams produce better patient outcomes. Nursing perceptions of collaboration and teamwork are often linked to better patient outcomes. Manser reviewed 277 articles on teamwork in health care. Both retrospective and prospective studies found that "communication and teamwork issues are the most frequent contributing factors to adverse events." Manser calls for systems changes including (1) adaptive leadership in which senior leaders assign leadership tasks to other team members and (2) promoting open communication since this leads to better psychological health and safety.[96]

Good communication and collaboration are widely acknowledged to be crucial for patient safety. For example, the Joint Commission identified ineffective communication as one of the top three causes for sentinel events for 3 years 2009–2011.[97] Rosenstein and O'Daniel found that a majority of nurses report that they have experienced disrespectful conduct from physicians.[98] A survey of 4530 health-care workers found that most had witnessed disruptive behaviors (by physicians or nurses) and that such behaviors are linked with AEs such as medical errors and patient mortality.[99] One survey study found disruptive behaviors were most prevalent in attending surgeons.[100] Emanuel et al. state, "the Achilles heel of systems change (for patient safety) is dysfunctional relationships between clinicians and other workers."[101] Davenport et al. provide evidence supporting this assertion through a survey about collaboration involving 6,083 medical staff providing surgical patient care for 57,880 patients. Nurses were 56% of the surveyed group. This study found that reported communication and collaboration with attending doctors was inversely correlated with risk-adjusted morbidity.[102] In other words, better communication and teamwork lead to better patient outcomes. The quality of working relationships in health-care teams matters.

Baggs and Ryan identified sharp differences in how nurse and doctors perceive collaboration in two studies. Nursing perceptions of collaboration between physicians and nurses in a medical ICU were positively associated with positive patient outcomes when controlling for severity of illness. Negative outcomes were 16% when nurses reported poor collaboration and 5% when they reported full collaboration.[103] Another study of three ICUs notes that physician reports of collaboration are not correlated with patient outcomes, while nursing reports of poor collaboration were associated with poor outcomes such as readmission to the ICU and death.[104]

Lingard has shown that communication failures in operating rooms jeopardized patient safety in 10% of communication exchanges.[105] In subsequent reports, Lingard et al. showed that preoperative team briefings lasting 1–6 minutes (median 3.5 minutes) provide value to team members in terms of better understanding of case details, understanding concerns or ambiguities, team building, and decision making.[106] These preoperative discussions also improved clinical practice so that appropriate preoperative antibiotics were administered in 12% more of surgeries.[107] More structured formal teamwork training improves outcomes even more than short preoperative briefings. For example, Morey et al. reported how a 6-month formal training program for teams of emergency doctors, nurses, and technicians reduced clinical error rate from 30.9% to 4.4%.[108]

STRATEGY TO IMPROVE PATIENT CARE: FOCUS ON PATIENT NEEDS, ESPECIALLY ON HIGH-NEED PATIENTS

Gawande recently provided anecdotal evidence that focusing on high-use patients can improve health-care outcomes and save money.[109] High-needs patients are often struggling with multiple issues, of which health care is only a fraction. Gawande reports on a pilot program to assign coaches to these high-needs patients. These coaches are not medical specialists; they are motivated laypersons who can connect with patients and speak their language. The coaches work as part of health-care team to help the patients with their problems including housing, employment, and mental health issues; they encourage patients to take care of themselves, take their medications, and advocate for them. This pilot program has saved money overall, although some hospitals and doctors lost revenue because the previously high-need, high-use patients needed less treatment as their health improved. Gawande notes that a similarly successful effort has taken place on a larger scale in Denmark. Over a 20-year period, Denmark increased the quality and availability of primary care outpatient services. As examples of these increased outpatient services, doctors were paid to provide e-mail access and off-hours consultations, and nurses became case managers for patients with complex care. Largely as a result of these improvements, Denmark reduced the number of hospitals by 50% during this period.

Vermont has begun to implement a single-payer system with a goal to improve health care and making health care available to all Vermonters. Wallack, an advisor to Vermont's governor working on implementing this new system, expects that efficiencies from reduced administrative costs and improvements in primary care, preventive care, and chronic disease management will reduce the need for hospital care in Vermont also.[110]

STRATEGY TO IMPROVE PATIENT CARE: IMPROVE STAFFING AND WORKING CONDITIONS

Higher ratios of nurses to patients lead to better patient outcomes. In 2002, Needleman et al. reported on data from over 6 million medical and surgical patients discharged from hospitals to examine the amount of care provided by nurses and patient outcomes. This study found that the number of hours of care provided by registered nurses (RNs) was associated with better care for hospitalized patients. Numerous patient care outcomes were improved, including length of stay, rates of urinary tract infections, and gastrointestinal bleeding. A higher proportion of nursing hours provided by RNs (as opposed to licensed nurses or nurses aides) was associated with lower rates of pneumonia, shock, and cardiac arrest.[111] Although this 2002 study reported no association between nurse staffing and mortality, more recently, in 2011, Needleman and Buerhaus reported on data from 176,696 8-hour nursing shifts in which study authors found increased mortality when staffing was below a target level of care. The target level was not set unrealistically high since staffing was within the target level 84% of the time.[112] Higher mortality was also associated with higher rates of patient turnover because of admissions, transfers, and discharges. Using data

from the Veterans Health Administration, Sales et al. found that increased RN staffing was associated with 9% lower mortality risk in non-ICU patients.[113]

From a nurse's perspective, workload is measured by patient/nurse ratios. Aiken et al. studied more than 1,000 nurses and more than 230,000 patients and reported that each additional patient per nurse was associated with a 7% increased probability of a patient dying within 30 days of admission after adjusting for patient and hospital characteristics.[114] Other studies and review articles have confirmed and extended these findings.[115,116] Kane et al., for example, through a meta-analysis, found that nurse staffing of one RN per patient day was associated with lower hospital mortality. Each additional RN not only reduced mortality but also reduced other negative outcomes such as hospital-acquired pneumonia, respiratory failure, and cardiac arrest. Each nurse per patient day reduced the patient's length of stay in hospital, in ICUs by 24% and in surgical units by 31%.[117] Low nurse staffing in nursing homes is also linked to negative patient outcomes such as more deficiency citations for infection control.[118]

In a 2006 study, Needleman et al. examined the business case for increased staffing to achieve better patient care.[119] This study used a sample of 22% of all nonfederal hospitals to calculate costs and benefits of increasing staffing to the level obtained by the hospitals ranked at the 75% level for nurse staffing. In other words, at these levels, 25% of hospitals would have more nurse staffing and 74% of hospitals would have less nurse staffing. This study concluded that such an increase in staff for the hospitals that rank in the bottom 74% would save more than 4 million hospital days, 6,754 lives, and 44,773 urinary tract infections, and prevent 13,000 cases of hospital-acquired pneumonia at an increased cost of 1.4%. In a later study, Needleman acknowledges that because current reimbursement systems pay for disease treatment, rather than disease prevention, hospitals that made such changes to improve staffing would probably lose money.[120]

Cost concerns prevent other staffing changes that would improve patient outcomes. As another example, consider the long hours typically worked by medical residents during their training. Other industries such as aviation and trucking acknowledge the safety hazards involved in extra long shifts and require workers in these industries to have regular daily rest periods. Only the health-care industry operates in denial of the data showing that fatigue decreases efficiency and causes errors.[121] Stoddard et al. estimates that if hospitals implemented more appropriate work schedules and lost this source of cheap labor, this would cost hospitals between $1.4 billion and $1.8 billion per year.[122]

Understaffing also leads to burnout, decreased job satisfaction, and turnover among nurses. For example, Aiken et al. in a 2002 study of over 10,000 nurses found that after adjusting for patient and hospital characteristics, each additional patient per nurse was associated with a 23% increase in the chance of burnout and a 15% increase in job dissatisfaction.[123] Physicians too report feeling stressed and overworked. A survey of 422 family practitioners general internists found that time pressure is associated with decreased quality of patient care.[124] A national survey of U.S. surgeons, with a one-third response rate, found that 40% of those surveyed felt burnout, 30% screened positive for depression, and only 36% reported enough time for family and personal life.[125]

There is a general agreement that many workplaces remain understaffed, creating a nursing shortage. These vacancies create less than ideal staffing and poorer patient outcomes. Estimates of nursing job openings that remain unfilled range from 8% to 13%.[126,127] In nursing homes, the situation is worse than in hospitals. A 2002 government survey found that over 90% of nursing homes lack adequate staffing. RN positions are staffed at 50% of the recommended level. Nursing home patients should get 1.3 hours per day of nursing care from RNs or licensed practical nurses. Most nursing homes do not staff appropriately since this would cost $7.6 billion more per year.[128]

Spetz and Given examined this issue from a strictly monetary labor market perspective and estimated that nursing wages would have to double from 2002 to 2016 to fill the available and predicted job openings.[129] This line of strictly economic reasoning ignores extensive research describing the reasons why current nurses leave the workplace, many within the first 3 years of entry. Working conditions and job stress are crucial factors. Coomber and Barribal, in a review of nine articles on nursing turnover and intention to leave employment, found that job satisfaction was more important than pay. Lack of satisfaction with ineffective leadership and with the work environment was more important than or personal or demographic factors (age, etc.). Job stress had the most powerful impact on intention to leave, caused by lack of scheduling stability and lack of group cohesion.[130] Zangaro and Soeken using meta-analysis of 31 studies found that nursing job satisfaction was most correlated with job stress, followed by nurse–physician collaboration and autonomy.[131] Another survey of 1200 nurses, doctors, and health-care executives found that the quality of nurse–physician interactions influence both nursing morale and nursing retention; improving these relationships would improve both recruitment and retention.[132]

This research has a number of implications for patient care. For example, surveys of nurses and patients show that patients are more satisfied when nurses report adequate staffing, administrative support, and good relationships between doctors and nurses.[133,134]

STRATEGY TO IMPROVE PATIENT CARE: CHANGE THE SYSTEM OF PAYMENT

Many commentators have noted that current reimbursement systems that pay providers fees for tests, treatment services, and visits create incentives for unnecessary charges, treatments, and inflated costs. Shifting to a payment per patient removes the incentives to provide unnecessary or “upcoded” care, simplifies paperwork, and allows providers to focus on patient needs.

STRATEGY TO IMPROVE HEALTH-CARE DELIVER IN NOT-FOR-PROFIT SETTINGS

For-profit health-care institutions deliver inferior health-care quality. The evidence is clear. In 1989, Hartz showed that delivering health care in a for-profit context decreases quality of care. Hartz, using data from 3100 hospitals, found that patients in for-profit hospitals were 6% more likely to die than those at private not-for-profit

hospitals when controlling for severity of illness and hospital staff characteristics, training, and qualifications. In 1999, Himmelstein et al. studied health maintenance organizations (HMOs) representing 56% of all HMO enrollment and found that for-profit HMOs provided lower quality of care as measured by 14 quality indicators including such basic elements as immunizations, providing beta blocker drugs after myocardial infarction, providing eye exams for diabetics, pap tests, mammography, psychiatric hospitalizations, and prenatal and postpartum care.[135]

Hospital ownership status is strongly associated with preventable AEs. Thomas et al. examined a random sample of 15,000 hospitalizations in Colorado and Utah in 1992 to compare four types of hospitals: nonprofit, for-profit, major teaching government hospitals, and minor or nonteaching government hospitals. The study, after adjusting for patient and hospital characteristics, found that patients in for-profit hospitals get lower quality care than patients in nonprofit or major government teaching hospitals. Both minor government and for-profit hospitals delivered lower quality care. Patients in for-profit hospitals were 57% more likely (OR 1.57) to suffer preventable AEs, 2.63 times more likely (OR 2.63) to suffer preventable operative AEs, and 4.15 times (OR 4.15) more likely to suffer preventable AEs as a result of delayed diagnoses or therapies.[136] Patients in for-profit nursing homes also receive lower quality care and are cited more often for deficiencies in standards of care.[137,138]

For-profit health-care institutions deliver less care and charge more for care. Although for-profit hospitals spend less on personnel and charity care and provide shorter stays for patients, they are more expensive in total costs. For-profit nursing homes and hospices provide less care. For-profit rehabilitation facilities charged Medicare $4888 more per admission than similar facilities operated on a nonprofit basis.[139] The rate of Medicare spending increased faster among for-profit hospitals and in-home health-care providers than in nonprofit providers from 1989 to 1995.[140] A review of studies covering more than 350,000 patients found a pooled estimate demonstrating that for-profit hospital care costs 19% more than not-for-profit care.[141] The two largest for-profit hospital companies paid the federal government $2.2 billion in settlements for fraud. For-profit HMOs spend 46% more on overhead than nonprofit HMOs and six times more on overhead than the federal Medicare program.[142]

STRATEGY TO IMPROVE HEALTH OUTCOMES: PROVIDE HEALTH CARE FOR ALL

Our current system of health care leaves 15%–18% of the U.S. population under age 65 with no health-care insurance.[143] The IOM 2003 report on the uninsured calculated that 41 million people lack insurance coverage.[144] The report offers a useful conceptual illustration using a pyramid to show the effects of lack of insurance on health. At the bottom of the pyramid are consequences from the uninsured that impact on the most people. So, for example, people with insurance, who live in areas with a higher than average uninsured rate, are at risk for reduced availability of health care and overtaxed public resources. The 60 million uninsured in the middle of the pyramid have less financial security and more stress. These people get less preventive care and screening services and

often forego health care until they are severely ill, leading to poor health-care outcomes. Toward the top are the actual adverse health consequences for those who delay or do not receive care. At the peak are those who die prematurely because of lack of insurance.

Other researchers suggest that the numbers in the IOM report are too low. Wilper et al., for example, found that 46 million people lacked health insurance in 2009 rather than the 41 million reported in the IOM report. Wilper et al.'s study also found that the uninsured are 40% more likely to die than those with insurance after taking into account other effects that predict excess mortality such as health status, race, ethnicity, income, education, body mass index, smoking, exercise, and alcohol use. On the basis of this research, Wilper projected that 44,789 people die each year because of lack of insurance, making this a leading cause of death.[145]

The degree to which insurance coverage improves health-care quality is also illustrated by the changes in health status for adults when they turn 65 and are eligible for Medicare.[146] Card et al., for example, found that Medicare coverage decreased mortality by 20% for those admitted to the hospital from the emergency room.[147] McWilliams found improvements in health status for those without insurance as they transitioned and became eligible for Medicare. The health status of those with cardiovascular disease and diabetes improved. In others, most health status was unchanged although they improved in depressive symptoms.[148]

MEDICAL BANKRUPTCIES

Himmelstein et al. found that medical debt is the leading cause of bankruptcy in the United States, responsible for 62% of all bankruptcies in 2007.[149] This affects millions of people. On average, an estimated 700,000 families file for bankruptcy per year for medical reasons.[150] In two recent years, 2001 and 2010, 1.5 million people filed for bankruptcy each year.[151,152] Himmelstein et al. note that the proportion of bankruptcies as a result of medical reasons increased from 50% to 62% from 2001 to 2007. Those who filed for bankruptcy because of medical debts were actually deeper in debt than people who file for bankruptcy because of other problems. Three quarters of those who file for bankruptcy because of medical debt had insurance when their illness or injury began. Many lost their jobs as a result of illness and then lost their health insurance because they lost their jobs. The problem of medical debt may actually be worse than it appears since many medical bills are paid with credit cards and then these debts become more difficult to clearly identify as medical debt. Those who file for bankruptcy are only a fraction of those who suffer from excess medical debt. The number of nonelderly adults who report medical debts or problems rose from 34% to 41% from 2005 to 2007.

THE FEDERAL ROLE IN PAYING FOR HEALTH CARE

Total spending on health care was $2.4 trillion in 2008. Selden and Sing calculate that the government share of health-care spending to be 56%, not counting the military or prison populations.[153] Government paid for 55% of the care for the

"uninsured" through community health centers and tax subsidies for charity care. Woolhandler and Himmelstein estimate the government share to be 59.8% of total health-care spending and that private employers pay for 19% of health-care spending.[154] Government share of total health-care spending is probably larger than either of these calculations. For example, while health care for the military is considered public, payments that the federal government makes to insurance companies to provide health care for Federal Bureau of Investigation employees are considered private funds. A substantial fraction of total health care is unpaid. Seven million unpaid caregivers provide 70% of all long-term care.[155] These caregivers help the elderly and the disabled to stay in their homes.

Although the government pays for most care and we have the most expensive health-care system in the world, we have the largest proportion of people who lack access to medical care of any advanced country in the world. The public consistently supports a strong role for the government to ensure that all Americans have health coverage.

STRATEGY TO IMPROVE HEALTH CARE: IMPLEMENT A SINGLE-PAYER SYSTEM

Comparing the United States to Canada, which has a single-payer system and generally better health outcomes, Woolhandler et al. showed that the United States paid five times more per capita for insurance overhead, six times more for employer costs to manage health-care contracts, three times more for hospital administration, and three times more for administrative costs—overall, $1059 per person in the United States versus $307 per person in Canada. The percent of the health-care labor force that works in clerical and administrative work grew from 18% in 1969 to 27% in 1999. Total administrative spending in health care in the United States in 1999 was $294 billion.[156] Simpler models of health-care delivery save costs.

State-level studies of single-payer approaches in California and Massachusetts show that increasing coverage to include all residents would actually save 5% of costs overall in simplified administrative costs.[157] Vermont has begun to implement a single-payer system that will cover all residents and will switch from a fee-for-service to a per capita model for payment. This simplifies payment and prevents the perverse incentives built into fee-for-service models. It will be financed by employer and employee taxes and is projected to save 25% in health-care costs over 10 years.[158]

STRATEGY TO IMPROVE HEALTH-CARE OUTCOMES: REDUCE INEQUALITY

> In a state which is desirous of being saved from the greatest of all plagues, not faction but distraction—there should exist among the citizens neither great poverty nor again, excessive wealth, for both are productive of great evil … Now the legislator should determine what is to be the limit of poverty and of wealth.
>
> **Plato 427–347 BC.**

There is strong evidence that nations and states with greater equality of income experience more positive health-care outcomes. Wilkins and Pickett have published widely on this topic and recently made this research more widely available both online and in book form.[159] Contrasting societies with the greatest inequality and those with greatest equality, the most unequal societies have worse outcomes for infant mortality,[160] cardiovascular disease,[161] mental illness and drug usage,[162] violence, murder rates, imprisonments, obesity, overall health,[163] and life expectancy. These trends hold true even when comparing the level of equality among states in the United States and among countries with wide ranges of income, including rich and poor countries. Curiously, countries with more equality produce more patents and inventions. In addition, societies with more equality are associated with less materialism, more environmentally responsible behavior, and more trust.[164]

CONCLUSIONS

From a psychological perspective, our health-care system is shaped by multiple competing forces: (1) scientific curiosity or a desire to understand health and disease processes, (2) caring for others or a desire to comfort or cure those in distress, and (3) power or a drive to lead or control people and situations, and (4) greed. While accepting that these motivations will continue to shape our health-care systems, our challenges are to shift the balance of forces and (1) to embrace new forms of transformative leadership, (2) to develop systems and relationships that acknowledge the dignity and value of all health-care workers and patients, and (3) to shift our system's focus from a provider-centered to a patient-centered system.

Starr has discussed the historical roots of the tension between rationality and power in the history of U.S. medicine. The fascination with technology and pharmaceutical treatments that drives so much medical practice is an outgrowth of this marriage between scientific curiosity and power. The growing dominance of for-profit hospitals, nursing homes, insurance, and pharmaceutical companies over our health-care system has relegated prevention, caring, and curing to secondary roles. Himmelstein, Woolhandler, Thomas, and others have consistently demonstrated the destructive influence of for-profit medicine on patient outcomes. In spite of this convincing and irrefutable scientific evidence, public opinion has not caught up to this research. Most Americans mistakenly believe that for-profit health-care institutions deliver higher quality health care.[165]

On a more positive side, the public does see a need for change to deliver health care for all. Nine consecutive public opinion polls since 2000 show that most (59%–69%) Americans support government taking responsibility for all Americans to have health-care coverage.[166]

If we, who understand the research about causes and prevention of medical errors, and those who see the needs to improve working relationships among health-care workers, to provide better staffing, to replace profit-making as a dominant decision-making factor in health-care delivery, and to improve the availability and quality of health care can share our observations, personal experiences, data,

interpretations, and understanding with others, it is possible that one day, public opinion will demand quality health care for all from our political and health-care systems.

Winston Churchill has been quoted as saying, "You can always count on Americans to do the right thing, after they have tried everything else."[167] It remains to be seen how much "market-based" profiteering in the name of health care we can endure before we construct a rational health-care system that provides quality health care for all.

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3 Medical Errors

John H. Lange, Luca Cegolon, and Giuseppe Mastrangelo

CONTENTS

Received the Wrong Heart and Lungs, then Died

17-year-old Jésica Santillán died 2 weeks after receiving the heart and lungs of a patient whose blood type did not match hers. Doctors at the Duke University Medical Center failed to check the compatibility before surgery began. After a rare second transplant operation to attempt to rectify the error, she suffered brain damage and complications that subsequently hastened her death.

Santillán, a Mexican immigrant, had come to the United States three years before to seek medical treatment for a life-threatening heart condition. The heart–lung transplant that surgeons at Duke University Hospital in Durham, N.C., hoped would improve this condition instead put her in greater danger; Santillán, who had type-O blood, had received the organs from a type-A donor.

The error sent the patient into a comalike state, and she died shortly after an attempt to switch the organs back out for compatible ones failed. The hospital blamed human error for the death, along with a lack of safeguards to ensure a compatible transplant. According to reports, Duke reached an agreement on an undisclosed settlement with the family. Neither the hospital nor the family is allowed to comment on the case.

http://www.cbsnews.com/stories/2003/03/16/60minutes/main544162.shtml

SUMMARY

Medical errors have been recognized by the health-care professions for decades but recently have become an issue discussed by the general public. Historically, medical errors and adverse events (AEs) were presented as occurring only in the hospital environment. This certainly is not true since dramatic events can occur at any site having medical and/or clinical activities. Numerous studies are now being presented in the literature on medical errors, causes, prevention, and rates. Public awareness for these events became highlighted through several tragedies that happened to predominant members of society, such as Betsy Lehman and Dennis Quaid's twins (children). Lately, there has been great publicity over some of the "outrageous" events, such as amputating the wrong limb. What must be mentioned is these mistakes are just that—an error, not an intentional wrong and/or not representing incompetence. However, tragic as medical errors can be, those reported in the media are uncommon. The vast majority are less obvious, at least initially, but can over the long-term result in physical and emotional damage. Until recently, little information existed on the rates of errors. There appear to be differences in the type and number of errors both in practice location (setting) and geographically. However, it does appear that even with great attention to this subject there has been little change overall in reducing medical errors. Future modification will become more difficult as health-care costs become stagnant or are reduced. This will create greater pressure on workers not only to handle a higher volume of patients but to perform these tasks/activities more efficiently. Some have considered that one method of reducing errors is simply to redesign work systems; however, this alone cannot mitigate human error and in some cases creates information overload. This can become even more critical as the responsibilities and duties of health-care workers (HCWs) increase and care of patients becomes more complex. The commitment to manage medical errors is one involving all members of the health-care community, which becomes more critical with the inclusion of lower-tiered personnel in patient care. In some ways, the involvement of allied health-care personnel in actual medical care will increase certain forms of medical errors; however, proper education and training reduce other types of errors. What may be of greatest importance in medical error prevention is that everyone involved in patient care, both directly and indirectly, can influence the outcome. Lower-level HCWs can actually spend more time with patients and, if properly trained/experienced, may be in a better position to mitigate errors because of availability of time. Prevention is a multigroup/interdisciplinary activity with no one point of lesser importance than another. Understanding and realizing the important areas and the role each party plays in medical error prevention may be the most difficult lesson. Since medical errors are mostly systematic in nature, modification of the system structure is often necessary as a preventative practice.

INTRODUCTION

Medical errors have existed since the beginning of medical practice. It was not until recently, in the 1990s, that medical errors and related events became "well" known, especially to the public. However, medical errors have been recognized since the

beginning of medicine. This is illustrated through the Hippocratic statement (oath) of "first do no harm," warning about medical errors and mistakes. Disclosure of issues relating to medical errors to the public has been carried out through various notable media events, which were presented in newspapers and television reports. With the introduction of the World Wide Web, the Internet has made such events easily available and, as imagined, some of the more notable occurrences are continually recirculated. However, such reported events are usually the extreme cases and generally involve those in the public spotlight. What is not revealed is that these events (medical errors) are happening daily in all health-care settings and by all HCWs. Errors are not intentional but are a reality of human activity. As any activity becomes more complex and detailed, there is a greater likelihood of mistakes happening in the workplace. Since patient care involves multiple HCWs and combinations of interactions, error in information transfer becomes greater. Of course, then there is the classification as to what is a true error as compared to an AE from treatment and/or medication. In some ways, AEs can be predicted, at least for the population but not for the individual. This, in itself, is a form of risk-taking, with the idea that most will have a benefit rather than a deficiency from the therapy. The question becomes, "How are these errors and risks minimized, with the understanding they will never be totally eliminated?"

Explaining and implementing precautions against errors may be the most difficult of all; especially when considering human nature, all people, including HCWs, make mistakes. Overall, a system's goal is to reduce these errors as much as "humanly" possible. However, with this said, it is hard to explain to a person experiencing an error that some are fundamentally unavoidable yet can have such great consequences. This is really a dichotomy in contradiction but is true for many activities that are undertaken. Regardless, efforts must be and are being undertaken to reduce these risks; however, with health care developing a greater complexity and forming an institutionalized mindset that includes cost containment (cost restrictions), these efforts are becoming more difficult to control and monitor as well as becoming more bureaucratic in nature. Medical conglomeration and development of a bureaucratic system for health care may ultimately be the biggest hurdle to overcome in error prevention yet has not been well recognized by the health-care system itself. First, before even approaching these issues, there must be an examination of what brought to the forefront the discussion of medical errors or mistakes.

The occurrence of medical errors was heightened and illustrated to the public by the chemotherapeutic error that happened in 1995 to Betsy Lehman, who was undergoing treatment for breast cancer at the Dana Farber Cancer Institute (Voelker 1996). Lehman was a medical reporter for *The Boston Globe* and died from a massive overdose of chemotherapy (cyclophosphamide). This showed the public the "simplicity" in which medical errors can occur even at the best institutions.

Lehman took an active interest in her case, including writing in her newspaper column about her ongoing experience. As part of her treatment, she was undergoing aggressive cancer therapy with an anticancer drug before being reinfused with her own stem cells. This was an experimental therapy, and she was one of four patients being treated. Sadly, Lehman and another patient received massive doses of the cytotoxic drug (cyclophosphamide) used in this therapy. The other patient survived

but had heart damage as a result. Even more tragic, at autopsy it was learned that Lehman's cancer had been cured. Initially, the cause of her death was not known, but it was a result of the massive dose of the cytotoxic drug. This error was not discovered until 2 months later when a data entry employee noted the drug dosage was quadruple the appropriate amount. The overdose was never detected, and if caught, Lehman may have survived. Three pharmacists, seven nurses, and two physicians did not notice the prescribing error by an oncology fellow. In addition, this occurred when Lehman was being discharged, although she had an abnormal electrocardiogram and blood count along with vomiting and swelling.

This event highlights the ease with which medical errors occur. More importantly, this illustrates that most medical errors are multicausative in nature, in that no single person is directly responsible for the error, but rather the error is systemic. At the time of Lehman's death, support personnel were not considered equal in treating diseases or considered part of the medical team. Today no person should be afraid to suggest an error may exist, requiring reevaluation/examination of an order. No crosschecking of pharmacy orders occurred. In this case, the fellow's order was 4000 $mg/m^2 \times 4$ days, rather than 1000 $mg/m^2 \times 4$ days and was never checked or reviewed. Owing to the lack of communication, different parties were unaware of the true dosage the patient should receive. Because of this mistake, there are now many safeguards in place requiring multiple checks in drug delivery, especially for chemotherapeutic agents and pediatric dosages. These two areas, oncology and pediatrics, are especially "sensitive" to errors since doses are more critical than in other types of patients, making errors in these groups of greater importance. The sensitivity of oncology "treatments" is well illustrated in the Lehman case.

Up until this time, medical errors were infrequently noted in the public media although it was understood that they occurred. In many ways, medicine before this time was a mystical and mysterious arena and considered a science that was taboo in explanation and disclosure. The culture of how medicine was practiced also prevented others from examining the entire process, except for individual units. As seen in the Lehman event, others did not know or have ready access to the protocol, thus preventing any effective checking mechanism. In some ways, television and programs like the Discovery Channel and nature programming like *Nova* opened the world of science to the general public. This, in turn, has also provided an opening for the public to actively begin exploring medicine as a general topic. The Internet has also made information more readily available and in some ways much easier to understand. However, this form of information has also created fallacies and inaccuracies about medicine and science.

Other notable medical mistakes, such as the mistake that happened to the Quaid twins in 2007, have kept this subject in the public eye (CBS News 2011). In the Quaid event, actor Dennis Quaid's infant twins had a near-fatal overdose of heparin at a Los Angeles hospital. An adult dose of heparin was administered to the infants. They were given 10,000 international units (IU) of this drug rather than 10 IU. Both doses of the drug had similar-looking labels that were very difficult to read, resulting in the wrong concentration of drug being administered. This event resulted from someone misreading label(s)/information on the vial of heparin being administered, which can easily and commonly occur. In many ways, this story is

similar to the Lehman tragedy. Labels for adult and pediatric doses of heparin at the time had small lettering and were similar in configuration. Unfortunately, this is not unusual for many drugs, and when dispensing the medication at the pharmacy, this can result in an error (Bates 2007). Those administering the medication will often not recheck to see if it is the correct medication/dosage. Today, this is primarily due to a lack of time allotted for the type of activity and also a shortage of health-care personnel. In the Quaid case, litigation of a civil nature was initiated, but more recently, medical errors have been the focus of criminal actions. In addition, Quaid has created several short reports discussing medical errors called *Chasing Zero.*

In February of 2006, a pharmacist working at a hospital in the Cleveland, Ohio area approved a saline solution that contained medication (chemotherapy) for a young girl (2 years old), which was prepared by a pharmacy technician at a fatal concentration (Pharmacist Activist 2010). This error was overlooked by the pharmacist. As a result of this drug administration, the girl died from an overdose of the drug. The occurrence of medical errors, in this case a medication–pharmaceutical error, has been held to be criminal. The county prosecutor as a result of this medication error criminally charged the pharmacist with reckless homicide and involuntary manslaughter. Ultimately, in this event, this pharmacist pled guilty to involuntary manslaughter and was sentenced to 6 months in prison. Many health-care organizations, including those related to pharmacy practice, have considered this event a civil matter and not one of a criminal nature. However, this event has changed how medical errors are viewed and/or examined and emphasizes the extent and/or consequences of such an error. The real problem with this issue is that such errors commonly occur in the health-care environment. This is illustrated by a report on a 735-bed hospital that states that more than 44,000 errors occurred for about 6 million doses per year (about 0.7% errors) (Bates 2007). Out of this number, it was estimated 9500 errors had "the potential to harm patients" (Bates 2007). The "cross-check" instituted by the system discovered about one-third of these errors, with the remainder going undetected before administration. This illustrates the vulnerability of the system and suggests errors are not so much directly related to an individual but instead are a system-wide problem. This is illustrated in the Lehman and Cleveland–related cases, which were both actually a result of system errors. In some cases, there is a lack of proper training by personnel; thus, the problem becomes an issue of the cost and availability of qualified personnel.

Although all the events mentioned were tragic, occurrences of this nature throughout the health-care system are actually common but not well publicized. Mistakes and errors occur daily in all health-care systems. Recognition of these mistakes has now become so well known that law firms and lawyers advertise their services for medical errors. There have been on rare occasions criminal prosecutions of medical (pharmaceutical) errors, as mentioned. In many ways, this demonstrates concern for such errors, yet it is agreed they do commonly occur and all who practice in medical professions have made them. What makes this even more complex is the number of potential diagnoses and drugs available today (Kondro 2010). It has been suggested that there are now more than 6000 potential disease states (diagnoses) that can be made and greater than 4000 potential medications available for administration (Kondro 2010). This is compounded by drugs having similar names or different

names for the same drug and/or multiple generic versions. A study looking at infusion therapy revealed that 84 drugs were used in hospitals for this type of treatment and on average each drug had 8.5 different names. Thus, the same drug had about eight or nine generic names, potentially resulting in confusion at all levels of patient care (dispensing to administration) (Bates, Vanderveen, and Seger 2005).

According to the National Academy of Sciences, Institute of Medicine (IOM) Report "To Err Is Human," it has been estimated that between 44,000 and 98,000 patient deaths a year result from medical errors in the United States (Kohn, Corrigan, and Donaldson 1999; IOM 1999). Certainly, since this time, the number has increased. This report "formally" recognized the national and international problem with medical errors, making it more difficult for health-care providers or institutions to ignore these issues (Devers, Pham, and Liu 2004). However, the exact number of deaths and injuries is not known. When these estimated numbers are compared to other causes, such as motor vehicle deaths, breast cancer, and AIDS, it becomes clear that risk from medical treatment is not without its hazards (Swaminath and Raguram 2010). Included in the arena of medical errors, there are also consequences that will likely occur as a result of a medical procedure or act. These are usually called adverse effects/events (adverse outcomes), and they do not represent a "true" medical error. However, some reports may include these as medical errors although they are recognized as part of the treatment/action. AEs are detrimental to the patient and, from the patients' perspective, an error. In a Harvard Medical Practice study that revisited 31,429 patient records, there was a rate of 3.7% AEs, and out of this group, 43% experienced at minimum a moderate impairment from the AE (Cao, Taylor, and Vidimos 2010). Unfortunately, many of these errors, even those that are obviously AEs, as seen in the Lehman case, are not recognized, and little or no action is taken to prevent another occurrence. In some cases, other medication is given to "counter" an AE, leading to a multitude of drugs being taken by a patient. This results in the patient being treated for medications used in treating the original problem, commonly compounding the initial disease or event. Based on this, the actual number of unknown events is likely much greater than reported or recognized. Most in the medical community avoid presenting or discussing these "mistakes" because of liability, although there is a considerable discussion of this problem in the literature (Kohn, Corrigan, and Donaldson 1999; Mazor, Simon, and Gurwitz 2004; Swaminath and Raguram 2010). Although the actual number of patients harmed through hospital admission is variable and difficult to quantify, it has been suggested that 2.9% of those entering the hospital will actually experience harm (Encinosa and Hellinger 2008).

The importance of medical errors was placed in the national spotlight through the IOM report "To Err Is Human," along with subsequent media reports on the subject (Miller et al. 2007). This original report has been expanded further, identifying this overall problem (Bates 2007). However, such publications have frequently not provided information on the practical management of such errors or the rates at which they are occurring. It does appear that each type of medical practice or setting has unique criteria in identifying kind and cause of medical errors (Adubofour et al. 2004; Gandhi and Lee 2010). It is also likely that among different types of practices, the rates and kinds of errors vary. For

example, pediatric settings differ in the types of errors that occur, although there are commonalities even among various locations, such as prescribing errors (Zhang, Baicker, and Newhouse 2010). These varying factors make understanding medical errors difficult and expand their complexity beyond the fundamentals or basics of science. Understanding human behavior and interaction with the environment, in the clinical setting, must be considered in attempting to manage these errors. This is further magnified due to the biological diversity existing among patients along with interactions occurring during treatments (Taxis and Barber 2003; Kondro 2010).

In attempting to understand medical errors, it is necessary to have a good foundation in how health-care practices are undertaken related to each actual event and its science. Understanding that an error occurred may not by itself provide a full realization of the issue without a comprehensive review of the science involved in the treatment or prevention of the disease or drug related to the error. Some people may find the scientific aspect the most difficult to grasp. However, an interaction with social behavior and the psychology of man has to be considered and included with basic scientific knowledge. Activities and concepts of this nature may be the most difficult to study and learn. Many even consider such abilities to be learned from practice and observation. One problem existing with this process is those in science do not have the opportunity to obtain these skills, at least not effectively. This is in part due to the formal requirements of training scientists and the science programs presented to those in health care. Some in health care do obtain this experience but cannot or do not know how to convey these concepts to others. Thus, the complexity of the subject itself makes medical errors and prevention even more difficult. Errors associated with diagnosis have been suggested to be the most common. Sandars and Esmail (2003) reported diagnosis errors account for 26%–78% of identified errors. Those resulting in delayed or missed treatments are likely to be the most serious in nature. For treatment, delaying or inappropriate treatment errors accounted for 11%–42% of errors and can result in major consequences for a patient. However, these were identified as generally being preventable. One of the real issues in preventing errors is that up to 50% can be said to have no identifiable cause. In many cases, errors have multiple contributing factors or events, with none being a critical point in causation (Bates 2007). This can occur because of poor communication and coordination of care among health-care providers in both primary and secondary care settings (Moyen, Carmire, and Stelfox 2008). Some of these issues have developed as a result of preferred providers as required by insurance. In some cases, some providers are limited; that is, patients can only select certain ones, even within the same facility (e.g., hospital). Extreme cases can exist where a health-care provider one day may be within the patient's insurance system and the next day will not. Although discussed here is communication, changing status through insurance may also change the way communication is conducted or facilitated. There are also issues in patient communications. An obvious example is drug information provided to the patient. Such inserts are so complex that they are not understandable even sometimes to the extent that those with technical knowledge are also unable to comprehend the information. In other cases, this information may be in "small" print and pages in length, thus losing the patients attention span.

DEFINITION OF MEDICAL ERRORS

To understand medical errors and adverse effects and outcomes, these terms have to be defined and in some way described (Lisby et al. 2010). Definitions are difficult because no matter how carefully they are structured each will not totally encompass all concepts for which they were initially intended. When given loose criteria, activities, functions, and events would not necessarily be included through this definition and those that are may create confusion. Thus, any definition of medical error must be one that is a working phrase and requires adaption and modification over time and for events. This makes the term a living definition. In many cases, an adverse effect can be a medical error to the patient but is anticipated to at least some degree as part of the treatment or therapy.

Organism	Reference
Acinetobacter baumannii (B)	Slama (2008)
Burkholderia cepacia (B)	Lopes et al. (2007)
Clostridium difficile (B)	Chaudhry et al. (2008)
Group A streptococci (B)	Weinstein (1998)
Staphylococcus aureus (B)	Weinstein (1998)
Pseudomonas aeruginosa (B)	Weinstein (1998)
Escherichia coli (B)	Weinstein (1998)
Enterobacter spp. (B)	Weinstein (1998)
Enterococcus faecalis (B)	Arias and Murry (2008)
Klebsiella pneumonia (B)	Weinstein (1998)
Candida krusei (F)	Weinstein (1998)
Candida lusitaniae (F)	Weinstein (1998)
Aspergillus spp. (F)	Haiduven (2008)
Fusarium spp. (F)	Peman et al. (2006)
Scedosporium apiospermum (F)	Peman et al. (2006)
Herpes (V)	Weinstein (1998)

B = bacteria; F = fungi; V = virus.

The purpose of presenting a definition is to establish boundaries (Aronson 2009). As noted, there are different types of definitions, some of which are complex and have little practical use. However, definitions give a good starting point for understanding concepts and ideas. Any definition should not by itself limit expansion of concepts or ideas, but rather be a starting point. Care must be exercised when using any definition in its most strict form. A definition expands and grows as its context of use increases and expands.

OCCURRENCE, RATES, AND NUMBERS

The actual number of medical errors and injuries occurring a year in the United States is unknown, with only estimates available. Certainly, the actual number also

depends on what is defined as a medical error or injury. A vast majority of adverse effects and errors are not reported or identified. It has been suggested that only 30% of occurring adverse effects are reported for U.S. hospitalized patients (Sandars and Esmail 2003). This suggests there is a large underreporting of events and does not include ambulatory and outpatient settings. In one study of outpatients, discontinuation of care was suggested to result in one medical error for 49% of patients treated (Moore et al. 2003). This illustrates the importance of continuation of care. However, it must also be noted that up to 50% of the errors observed/reported had no identifiable cause (Sandars and Esmail 2003). This may be a result of how errors are categorized or reported, and they may not have a single point of causation but are multidisciplinary related. In other words, these errors are systematic in nature. This makes error identification and prevention even more difficult. IOM estimated there may be as many as about 100,000 deaths per year as a result of medical errors. It should be noted these are only the identifiable errors, with the actual number likely much higher—a fact commonly forgotten. It is suggested here that the actual number of deaths from AE is probably around 150,000 per year in the United States. For the world, this number could be in the millions. One method to obtain a better estimate of the true number would be through application of the capture–recapture method (CRM) (Lange and LaPorte 2003). Examination of rates using the CRM has shown that many notifiable events are greatly underreported and that medical errors would be no different. The concept of missing a large number of AEs is supported in the literature, showing that 90% of these events may be missed (Classen et al. 2011). Thus, medical errors can be considered highly underreported, making this issue more important than it was previously considered. Overall, it is obvious a better way of counting AEs is needed.

Direct medication errors alone have been suggested to account for 7000 deaths a year in the United States (Adubofour et al. 2004). For medication errors, the inpatient death rate has been suggested to be 1 in 854 and for outpatients 1 in 131 (Gianutsos 2008). The reason for the greater rate in outpatients is likely that these errors are not identified until manifestation reaches a critical stage, with this time period being critical in reversing the outcome. For dispensing errors, which are often evaluated separately, it has been suggested that 3% are potentially serious for inpatients (Allan and Barker 1990). Medication errors increased 2.5-fold for inpatients and 8.5-fold for outpatients over the time period of 1983–1993 and have likely continued to increase. For an ambulatory setting, dispensing error rates have been estimated between 1% and 24% of prescriptions. When patient volume increases, at least for an outpatient pharmacy, this may be as high as 12.4% (Gianutsos 2008). Much of this can be attributed to staff shortages and overwork. However, in some settings, ethnic differences contribute to these error rates, such as having a multilingual population. Here, pharmacy personnel will have to speak more than one language as well as be able to translate instructions. Some may classify these rates of error as epidemic. It has been reported that 23% of patients discharged experienced an adverse effect because of some form of medical error. For heart failure patients, 20% are readmitted within 1 month of discharge (Kondro 2010).

In the outpatient area, it has been suggested that medication errors resulted in 116 million additional medical visits, resulting in an additional 76 million prescriptions,

17 million emergency room visits, 3 million admissions, and about 19,000 deaths (Gianutsos 2008). This may have a total cost of $76.6 billion. Overall, about 7% of all hospital admissions are related to a medical error or injury. What is of even greater importance is that these numbers appear to be on the rise, with some of this resulting from a higher number of additional visits to outpatient clinics.

Practices can be established or undertaken to reduce the rate of medical errors. For example, in anesthesia, deaths rates can be reduced from 1/10,000 to 1/200,000 through the application of appropriate technology. This technology involves the use of pulse oximeters, capnometers, and oxygen regulators/analyzers. Along with these technological advances, a raised awareness about patient safety helped reduce the number and rate of deaths in anesthesia (Massachusetts Medical Society 2007).

For adverse drug events (ADEs), it has been suggested that 770,000 people are injured each year with a cost of $5.6 million per hospital (MEDCEU 2009). However, this does greatly vary depending on the size of the hospital. Patients having ADEs were in the hospital an additional 8–12 days for each hospitalization. Incorporation of a computerized medication system has been suggested to reduce errors related to medication by 28%–95% and offers an overall saving(s) of about $500,000 a year (per hospital). In a 1998 study, "serious medication error" was reduced by 55% when computerized prescribing was initiated even though there was limited physician participation (Bates 2007). This resulted in an 83% reduction in overall medication errors, with an estimated cost saving per ADE of $6000. An incidence rate of ADEs has been placed around two to seven events per 100 admissions. It has been estimated that 9.7% of ADEs result in severe disability. The number of patients with ADEs resulting in death have been suggested to double as a result. Generally those that are older and sicker and go to multiple pharmacies appear to be at greatest risk. Overall, the most important ADE resulting in life-threatening consequences occurs in the intensive care unit (ICU), which makes sense since this is where the most critically ill patients can be found. However, there does not appear to be a relationship between type of medication and ADE, although antibiotics and narcotics/analgesics tend to stick out as the most frequent contributors to AEs.

The largest number of errors appears to be related to dosing, then wrong drug or wrong patient, frequency, and finally administration even with a known allergy (Gianutsos 2008). For dosing, this likely results from, in part, staff shortages and poor mathematical skills possessed by allied, medical, or health-care personnel. Observation in algebra classes suggests most health-care-related students are not prepared well enough to efficiently perform mathematical skills to proficiently calculate dosages. In these classes, it is not unusual that 75%–80% fail or are unable to successfully complete the class. When conversion of the metric system is included in these calculations, the number of errors dramatically increases. It may be prudent for health-care-related workers to complete a health science– or pharmacy science–related mathematics course as part of in-house training as a way to reduce dosage errors. However, the danger here is many may not be able to pass such a class. In part, this illustrates a problem in health care and its training of personnel.

Pharmacy errors have been the focus of many studies relating to medical errors (Moyen, Carmire, and Stelfox 2008). Often the focus is on the pharmacist and others

in this settings; however, mistakes related to drugs are not limited to this specific group but extend to all aspects of drug delivery and administration to patients. Most errors related to drugs occur at administration and are actually not related to the pharmacy. Physicians contribute to pharmacy error by prescribing the wrong medications and the improper dose along with not monitoring side effects. However, when care becomes a multiple-discipline approach, for example by including a pharmacist to aid in managing drug therapy, reduction in errors has been shown to occur (Tam et al. 2005).

Mechanical errors account for 86% of liability claims (Gianutsos 2008). Mechanical errors occur during the processing preparation of a prescription, for example the drug's dosing, labeling, and directions. As related to litigation, 2% of these errors were a result of the wrong drug being dispensed, although the dosing may have been correct. A survey of 1000 community pharmacists in 1996 found more than half had made dispensing errors in the past 60 days (Gianutsos 2008). This rate breaks down to most making 2.5 errors in a 60-day period, with 8% of pharmacists believing this could actually be 6 or more in the time period. However, from studies involving CRM in other areas, it is believed that the true number is most likely much higher. What is even more important is that many believe the rate of errors is actually increasing. The biggest contributors to these errors are a large volume of phone calls, too busy that day, and too many customers. In identifying errors, about 50% are by the pharmacist and 36% by the patient or family, with these values varying depending on study and setting (Gianutsos 2008). Workload appears to be an important contributor to these errors, with 47% of those dispensing less than 100 prescriptions a day reporting an error, whereas for more than 100 prescriptions, this rate increased to 60%.

COST OF MEDICAL ERRORS

Medical errors can result in tragedies to the patient and his or her family and friends, as well as a high cost to the health-care system. Although financial costs are often discussed in managing medical errors, along with impact on patients, it must be remembered there is a cost, even sometimes financial, to the HCWs (Sirriyeh et al. 2010). Most medical facilities look at cost when evaluating performance, and medical errors can greatly contribute to losses in revenue. However, what we must really remember is the cost to the patient.

The IOM reported the estimated cost of medical errors in the United States annually is $37.6 billion, with $17 billion of this cost included directly as an expense to the health-care system. This equates to about $13,000 per error. In 2008, it was estimated that medical errors cost the U.S. economy $19.5 billion (Ledue 2010), although the cost may actually be greater when many of the incidental costs (e.g., returning to a clinic for follow-up treatment or therapy) for patients are included. Of the 6.3 million medical injuries, about 1.5 million were related to a medical error. Certainly not all can be avoided, but it has been estimated that 25% can be prevented (Ledue 2010). This equates to about 7% of the inpatient admissions having some form of identifiable medical injury, with about 2500 avoidable deaths, and more than 10 million missed days of work resulting from injury-caused

short-term disability. The most common medical errors involve pressure ulcers, postoperative infections, hemorrhages as a result of operative complications, and mechanical causes. This list is not exhaustive, as there are a few other recognizable errors as well. Most medical errors/injuries are not addressed as much in the public media as events like operating on the wrong site during surgery (e.g., amputation of the wrong limb), mostly because they are less recognizable to the public as an event and incident. Someone that dies from a systemic error associated with a medication is not as dramatic of a news event as a person having the wrong limb amputated. It is also more difficult to identify the causative factors related to a systemic error since this type of event usually occurs over a longer period of time.

It has been reported that each preventable error resulted in $8750 in additional cost for the hospital stay. Historically, these costs were absorbed by the insurance carrier or provider (e.g., Medicare), but as time goes on and errors are better recognized, there is a resistance to providing insurance coverage. This figure does not include costs and/or losses after hospital discharge. In addition, the loss of future earnings by the patient may be even greater, especially for those events that result in disability or a long-term event. These costs do not include costs incurred by family members and caregivers taking time to assist the impacted patient while at home or elsewhere. The total costs associated with medical errors cannot be clearly qualified, but they are large and appear to be increasing. Many of the costs incurred are not easily seen or recognized, and some (e.g., pain and suffering) may even be impossible to establish or quantify. It is recognized that the magnitude of such mistakes is great and they require attention by the health-care community (Miller et al. 2007).

The rate of errors varies dramatically among studies, although commonalities exist for the different health-care systems (e.g., the United States and the United Kingdom, as examples) (Sandars and Esmail 2003). The rates of errors can also differ depending on what type of error is reported and how the data are collected and the reporting is conducted. For example, in a study of North Carolina hospitals, internal reviewers reported a higher rate of errors compared to external reviewers (Landrigran et al. 2010). This alone provides insight as to the difficulty in identifying an actual medical error and from this identification determining which constitute a hazard to the patient.

For medication errors, patients experiencing an ADE were hospitalized for approximately 8–12 additional days, resulting in an additional cost of $16,000–24,000 (Gianutsos 2008). Nationally, the total cost of ADEs has been estimated to be $1.56–5.6 billion dollars a year. Patients who suffer the most severe ADEs (e.g., seizures) on average were in the hospital for 20 days, while those experiencing a less severe event were hospitalized for 13 days. In comparison, patients that did not have an ADE were in the hospital for an average of 5 days. Costs for these patients dramatically varied: from $38,007, $22,474, and $6,320, respectively. This illustrates the financial burden created by medical mistakes (MEDCEU 2009). Even minor ADEs such as itching due to a drug reaction can result in almost $700 in additional cost. Although an event such as itching is minor, these costs can accumulate and, as mentioned, result in billions of dollars in additional expenses for health care across the board.

CATEGORIZATION AND CLASSIFICATION

Medical errors as a single subject are difficult to identify and define. The definition of this term is broad and somewhat complex to "clearly" describe and categorize. However, medical errors, as a subject, must be separated from adverse effects. An adverse effect in a patient results from medical management and is not related to the disease state of the patient. The disease state alone can contribute and have a negative impact on a patient suffering an AE. This can make a medical error difficult to identify since disease can result in some undesirable effects (e.g., nutritional state due to an infectious disease). Further, from a patient's perspective, adverse effect and medical management can have a negative impact and result in additional financial costs.

Errors, as a defined event, can be prevented (Jacobson et al. 2003). In some cases, adverse effects will occur because of treatment and are "formally" recognized, as in the case of chemotherapy. Alternatively, some AEs may be prevented by informing the patient of side effects and/or events to look for and report. This can be accomplished through instruction by specially trained personnel, such as pharmacy technicians, on AEs of certain diseases and treatments. In the Lehman case, such information may have prevented her death. Thus, if planned or anticipated, these events would not be strictly classified as errors, although this definition may have overlapping characteristics. Injury to a patient, whether planned or unplanned, is still harm and would be considered an error. Drug therapies with a narrow range of tolerance are of greater concern since they would be more prone to a potential error or adverse reaction, compared to those with a wide range. Traditionally, this range was identified for pharmaceutical agents (e.g., drugs) but can be expanded to include other types of "actions," like surgery. For example, the removal of part of a lung may be necessary due to disease, if, for example, the patient develops a pneumothorax, yet after surgery this may cause an adverse effect for that particular patient's well being. Here, the benefit of stopping disease may ultimately be viewed by the patient as an adverse effect on their overall quality of life. Knowing the patient's tolerance for errors or at least its estimate may allow classification of "activities/substances" as being more or less likely in causation of a medical error. Such a categorization may enable providers and those administering therapy to be aware of potential errors. However, this alone adds to the burden of health care and will require a higher level of training than currently exists. Obtaining such information will also require practitioners to spend more time with a particular patient, increasing the cost of care. This can create a bigger demand on an already stressed system.

ERRORS: PLANNING AND EXECUTION

There are two major types of human errors: planning and execution. Execution errors are slips, where the correct action does not proceed as was intended by the person. Planning errors are mistakes in which the original intended action is not correct. This presentation will discuss four types of slips: caption, description, associative activation, and loss-of-activation (Zhang 2010).

Errors can arise as a result of a wrong diagnosis. This can cause harm and be categorized as an error. In this scenario, a different type of medical error emerges

than traditionally discussed. This becomes a preventable error with subsequent effects that have adverse effects on the patient. Thus, actual differences in medical errors are not likely defined in practice. A distinction between execution and planning failures does exist and can be both distinct and overlapping. In a wrong diagnosis, the failure may by itself be a planning error, yet the subsequent administration of a "wrong" drug extends it to an execution error, resulting in multiple failures in recognizing a mistake. A common planning error in health care is giving the correct medication to a child but in the adult dosage. However, some of these errors are categorized as execution failures and may be due to "lapse" or "slip" type of occurrence. A slip is identified as "failure" of attention, whereas a lapse is a failure of memory (Jacobson et al. 2003).

Caption slips result from automatic activation of a well-learned routine that overrides the current intended activity (e.g., driving home directly instead of picking up a prescription on the way home). Description slips are due to incomplete or ambiguous specification of intention that is similar to a familiar intention (e.g., inserting a zip disk into a floppy drive). Associative activation slips are due to the activation of similar but incorrect schemas (e.g., picking up the desktop phone when the cell phone rings). Loss-of-activation slips are due to a loss of the activation of current intention (e.g., forgetting an idea for a symposium proposal after answering an interruptive phone call).

Slips are errors of execution in which the correct action does not proceed as intended. A simple example is putting salt in your coffee instead of sugar. Depending on the circumstances and/or setting, a minor slip-type error can result in a drastic event. In some cases, this minor slip can lead to unintended consequences later that may not be realized because of a previous error. Slips occur at decision points where selecting the appropriate action is not predicated on the immediate previous action and/or activity; rather, this new action is based on information related to the entire task or activity. This requires the decision maker to pay attention at the decision junction, with the actual junction not being clearly obvious. Slips may simply occur because of failure of an attention check at the decision point (Botvinick and Bylsma 2005). This can result in some activity or action being done the wrong way.

Execution and planning can occur because of rule errors associated with treatment guidelines in protocols. The rule of guiding treatment may be "inadequate" for a specific patient yet when applied would be considered correct. This can result because of the diversity of treatments and actual biological differences in patients along with interactions from the planned event. Mostly, these adverse reactions are known, yet cannot be predicted. Effects of this nature may be recognized and considered part of the planning. The question is when does this "known" or "anticipated" event(s) become an error? Many of the adverse effects from drugs, especially those that are severe, can be categorized as errors, particularly from a patient perspective. This can be extended to nondrug-type activities (e.g., occupational and physical therapy).

MEDICATION ERRORS

One of the most recognized forms of error is associated with medications (Fred 2005). Medication errors can be related to any HCW in the delivery system, although most presentations focus on pharmacists and their role in drug safety. However, even

if the drug is properly prepared and dispensed, this is only part of the delivery system to the patient or end user. In some cases, drug errors can be extended to over-the-counter medications. As the role of pharmacists changes to encompass more direct health care, drug delivery is beginning a shift to many of the allied-health professions (e.g., pharmacy technicians), and this is changing the landscape of how medications are provided and dispensed to patients (Elston et al. 2009). This requires an expansion of the concept of medical/medicinal error to a larger population of HCWs. Pharmacists are keenly aware of these types of errors although, in some cases, they have no direct interaction with the mistake (e.g., administration of the wrong drug to the wrong patient). Errors related to the pharmacy greatly vary but can be placed in some generic categories. These categories are somewhat arbitrary yet provide a format for discussion and presentation. In some cases, these categories overlap or be multicategorized (e.g., wrong prescription and delivered to the wrong patient) (Maidment, Lelliot, and Paton 2006). In addition, categorization is not limited to just the hospital setting and can be extended to all aspects of patient care (Elder and Dovey 2002).

- Impetigo
- Staphylococcal scalded skin syndrome or Ritter disease
- Toxic shock syndrome
- Cellulitis
- Abscesses
- Carbuncle
- Bedsores
- Septic phlebitis
- Sepsis
- Endocarditis
- Osteomyelitis
- Pneumonia
- Urinary tract infection
- Food poisoning disease
- Septic arthritis
- Conjunctivitis

CAUSES OF ERRORS

The cause of an error can be divided into those that are "medical" in nature, such as amputating the wrong limb, an injury, like a fall, and lastly pharmaceutical, as in dispensing the wrong drug. Some medical errors overlap into all three groups, for example the wrong drug is dispensed and as a result of this medication the patient falls. As such, these three arbitrary classifications are grouped as medical errors. Probably the most difficult to recognize are those of a medical nature, which are collectively called practice errors. Each area of medical practice, using the broadest sense, involves or incorporates some form of this error. However, many of the

services provided by HCWs commonly overlap and do not encompass those actually providing "strict" medical services to a patient, but may extend to include auxiliary personnel as well.

There are a variety of medical-related errors (practice errors) with the classic example being operating at the wrong site or amputating the wrong limb (Stahel et al. 2010). Although this is generally uncommon, it often receives great publicity. These mistakes can take on multiple forms including operating on the wrong site or body part, leaving objects inside the patient after a surgical procedure or related device(s) type errors, and even operating on the wrong patient (Neily et al. 2009). Operating on the wrong location/limb can even occur after it was correctly marked. In one case, this occurred due to the transfer of the ink mark to the other limb, likely a result of the patients crossing their legs after marking (Knight and Wedge 2010) Although this is a case study, such reports are well noted in the literature but are fortunately rare (Robinson and Muir 2009). Meinberg and Stern (2003) found through a survey of 1000 hand surgeons that 21% had operated on the wrong site with another 16% acknowledging preparation of the wrong location. Factors contributing to these errors include multiple surgeons, time constraints, and the characteristics of the patient. A reason commonly cited for not wanting to mark the site of surgery is a risk of infection from the marker (pen), which does not appear to be valid (Burton et al. 2010). Stahel et al. (2010) reported on a population of 127 events, 25 involved the wrong patient and 107 were for the wrong site or procedure. Out of this population, 5 wrong patients and 38 wrong sites or procedures experienced a significant harm, with one patient dying as a result of site or procedure error. For wrong-patient errors, the primary cause was mistakes involving communication and diagnosis. Nonsurgical auxiliary personnel were suggested to have some responsibility in causation of wrong-patient events. This suggests there is no one group involved in practice errors, especially as related to surgery, and this group also includes other types of practice errors. Patients experiencing wrong site or procedure was attributed to errors associated with judgment and lack of time taken to ensure correctness. In some ways these errors can be identified as systemic in the process of treating the patient.

Studies are beginning to appear in the literature concerning microbial transfer from marking pens, which has been suggested to be a concern regarding the spread of microbial infection. Marker pens that are alcohol-based have been suggested to exhibit antimicrobial action quickly (within minutes) (Ballal et al. 2007). However, it appears that water-based pens can carry the risk of microbial transfer. In addition, there is a limited lifespan of pen use on multiple patients (Cao, Taylor, and Vidimos 2010). Thus, it appears marker pens that are alcohol-based will not transfer bacteria as long as the use of a single pen is limited to a few patients. This suggests that alcohol is acting as a "limited" disinfectant.

For operating room procedures, the largest percent of errors (AEs) occurs for the eye, followed by leg/foot and then pelvis (Neily et al. 2009). The greatest contributor to these events is communication problems followed closely by failing to take the time to identify the location (time-out problems). In nonoperating room scenarios, wrong patient, followed by wrong side and then wrong site, are the most frequent errors. Wrong procedure accounts for about 5% of these nonoperative errors.

Neily et al. (2009) reported that invasive radiology had the largest number of wrong-patient events, followed by ophthalmology. Ophthalmology was reported to have the highest number of wrong-site events, closely followed by urology, whereas general surgery was predominate for the wrong site. These data suggest that practice errors in both surgical and nonsurgical activities are well distributed throughout medical specialties. Further, not all events are reported or identified, making these numbers much higher. Reported events do not include the more common adverse effects such as infections.

Overall, such errors can be avoided by careful identification of the surgical location and accurate identification of the patient. Many facilities have established standardized protocols and procedures to follow in attempt to eliminate such errors. Yet, as noted by Robinson and Muir (2009), these mistakes are still occurring on an ongoing basis.

One of the most common errors related to surgery is inadvertently leaving items (retained sponges and instruments [RSI]) inside patients (Greenberg et al. 2008; Regenbogen et al. 2009). It has been noted that 62%–88% of RSI occur even when there is evidence of the correct count being recorded in the patient's medical record. Greenberg et al. (2008) suggested that discrepancies occur in one out of eight operations, and that 59% are actually a misplaced item and 42% are human error in the final count. In terms of operating time, this is one inaccurate count for every 14 hours of surgery. Sponges are miscounted and remain in patients after surgery in about 12 out of 100,000 patients. Although this number is "small," the ultimate cost per event is large and can greatly increase the cost of health care. The cost of an RSI-related event is more than $60,000, and with the cost of litigation included it escalates to around $150,000 (Regenbogen et al. 2009). If newer technologies were applied in detecting these errors, its cost has been estimated to be about $26 per operation. Even with the cost of these mistakes as compared to that which would eliminate or at least reduce occurrences, RSI events are still common, at least from the total perspective of patient care. These occurrences show how vulnerable the health-care industry is to mistakes and the costs incurred by such mistakes. More important, it illustrates benefits of implementing modern technology in medical error prevention. However, to have this benefit, there must also be a capital investment. Even with technology intervention, there can be no complete elimination of human errors and interaction based on such activities.

There are some less clear errors related to surgery. For example, an Australian study reported (Kable, Gibberd, and Spidelman 2002) that technical errors accounted for 52% of performance errors, followed by skill-based errors (slips and lapses) at 18%. Surgical errors were also higher than those observed in the categorization as medical, 21.9% and 13.3%, respectively. However, for these errors, disability did not last 12 months for 83%, while permanent disability was reported for 13% and death for 4%. It was also noted that 47.6% of medical (surgical) errors were preventable, with other referenced studies providing a generally higher value (52%–74%). Kable, Gibberd, and Spidelman (2002) did indicate that an important factor related to these errors was age. Possibly of importance in this study was a suggestion that 11% of the errors were systematic in nature and not the fault of an individual.

Diagnostic errors are also an important type of medical error and occurred more frequently than surgery at a wrong site. It has been suggested that a diagnostic error

occurs for 0.4% of hospital admissions (Zwaan et al. 2010). These errors, however, are associated with a higher rate of mortality as compared to other adverse errors (29.1% vs. 7.4%). In family practice (general practice [GP]), diagnostic errors/mistakes constitute the greatest number of litigation claims for in both the United States (34%) and the United Kingdom (63%) (Kostopoulou, Delaney, and Munro 2008). Such errors included misdiagnosis, delayed recognition or evaluation of test results or proper diagnosis, and failure to conduct the appropriate test or tests. Proper diagnosis appears to be related more to proper formation of hypotheses than to follow-up evaluation (Kostopoulou, Delaney, and Munro 2008). For GPs, error rates have been suggested to be in the range of 5–10 per 100,000 consultations, with poor communication cited as a contributor (Sandars and Esmail 2003).

LABORATORY ERRORS

Medical errors are not limited to practice or patient clinical settings. Errors occur in the laboratory arena as well (Howanitz 2005). Many do not consider laboratory testing to be very prone to errors and have commonly dismissed the actual rates (Goldman et al. 2010). These types of errors are not limited to those of a chemical-related type test but include anatomic/surgical specimens as well. For anatomical analysis, there appear to be dramatically different rates of error among pathologists, yet the real problem in evaluating this error is determining the correct result (Renshaw and Gould 2007). Some of these mistakes, such as with transfusion, can result in death, although these errors are usually not that common (Valenstein and Sirota 2004). Errors regarding laboratory practice can occur in one of three areas: preanalysis (preanalytic; sample collection and processing), analysis (analytic), and postanalysis (postanalytic; reporting results) (Nakhleh 2006; Tekkesin, Kilinc, and Keskin 2010). Although the areas of laboratory mistakes are separate, an error can occur in a sample in more than one category. Many forms of laboratory testing routinely are not believed to experience errors, but when the types of testing conducted are considered, the potential for AEs and errors becomes great. Some are not commonly considered when evaluating medical errors. When considering these errors, what is not commonly discussed is patient injury, which can occur during laboratory sampling. For example, Astion et al. (2003) found that in preanalysis 5% of patients undergoing phlebotomy experienced an injury. Some types of laboratory testing include:

- Clinical chemistry
- Blood banking (e.g., blood typing)
- Genetic
- Antibiotic sensitivity
- Histology
- Immunoassays
- Blood glucose analysis (meter and laboratory)
- Anatomic pathology
- Hematology
- Microbiology

Genus and Species	Reference
Mycobacterium tuberculosis	Addo et al. (2007)
Mycobacterium bovis	Addo et al. (2007)
Mycobacterium africanum	Addo et al. (2007)
Mycobacterium avium	Dhungana et al. (2008)
Mycobacterium kansasii	Dhungana et al. (2008)
Mycobacterium xenopi	Thaunat et al. (2004)
Mycobacterium chelonae	Hsieh et al. (2008)

Laboratory errors can be detected through many different mechanisms (Plebani 2009). However, in some cases, the results are wrong or are provided for the wrong patient. For either of these scenarios, the end user will not recognize that a mistake has occurred. Overall, the frequency of laboratory errors has been reported to be in the range of 0.1%–9.3% (Tekkesin, Kilinc, and Keskin 2010). Astion et al. (2003) reported rates of error (distribution) for each category, which were 71% preanalytic, 18% analytic, and 11% postanalytic. When evaluating cause of errors related to the laboratory, noncognitive was most frequent, constituting about 73% of those preventable, and cognitive constituted around 30% (Astion et al. 2003). Astion et al. (2003) went on to suggest that physicians appear to disagree on the problem of these types of errors because of the concept of them being unpreventable. The impact of these errors has not been well investigated; however, Astion et al. (2003) found that 5% of the incidents observed resulted in a specific injury. This demonstrates that such errors are not without consequence. A patient may even be admitted to a hospital as a result of being assigned someone else's laboratory results. This could ultimately result in an AE for two patients, one admitted and the other not receiving treatment.

Probably the best-recognized AEs are those associated with transfusions. Although reported rates greatly vary (1 in 238 for misidentified transfusion specimens in the United Kingdom and 1 in 54,000 for New York state), the consequences can be enormous (Valenstein, Raab, and Walsh 2006). For example, about 25 transfusion deaths occur a year in the United States (Valenstein and Sirota 2004). Much of this is related to misidentifying patients. These values do not include the number injured or close calls that may occur.

Preanalytic mistakes can occur because of a number of reasons or events. The most predominate is related to specimen transport (Astion et al. 2003). Other types of errors within this category include contaminated blood draw, wrong labeling, labeling mistakes (e.g., information on type of sample), mismatched patient, improper handling, inappropriate preservative, wrong storage, and incorrect tube/container (Tekkesin, Kilinc, and Keskin 2010). An important factor contributing to these types of errors is nurse and personnel turnover, which may result in staff not understanding or being familiar with the institution's procedures and practices. In addition, many samples have a larger volume of material obtained than needed.

Pathological errors exist and have been evaluated in the literature (Valenstein and Sirota 2004). Generally, these types of errors can be categorized as transfusion and anatomic pathology. These types of errors are those looking at patients and their care. There are also many well-known mistakes related to these activities, such as

Organism	Time Period	Reference
S. aureus	11 days, on plastic patient chart	Huang et al. (2006)
	9 days, table top	
	9 days, cloth curtain	
	18 days, glass coverslip	Jawad et al. (1996)
	21 days, cotton fabric	
	56 days, dry mop in hospital	Oie and Kamiya (1996)
Acinetobacter	>4 months,[a] on dry surfaces	Wendt et al. (1997)
	6 days, dry filter paper	Allen and Green (1987)
	13 days on formica	Musa et al. (1990)
	18 days, glass coverslip	Jawad et al. (1996)
C. difficile	3 hours, moist surfaces (vegetative)	Jump et al. (2007)
	Months, spores	Jump et al. (2007)
Enterococcus faecium	>4 months[b]	Wendt et al. (1998)
	>90 days, cotton fabric	Neely and Maley (2000)
E. faecalis	33 days, cotton fabric	Neely and Maley (2000)
E. coli[c]	>28 days, stains steel surface	Wilks et al. (2005)
Serratia marcescens	10 days, glass coverslip	Jawad et al. (1996)
M. avium	90 days in deionized water	Archuleta et al. (2002)
Yersinia pestis	2–4 hours, dry stainless steel	Rose et al. (2003)

[a] Survival is highly variable depending on strain tested.
[b] Under dry conditions.
[c] *E. coli* O157:H7

in forensic pathology (Sturner 1998). However, the application of forensic science to clinical practice can provide insights in to medical error occurrence, allowing follow-up as a method of future prevention (Ermenc 1999).

In New York state, it was reported that out of 104 "serious" transfusion errors, 92 were due to the wrong patient receiving incorrect blood (Valenstein and Sirota 2004). From this group, 54 received incompatible ABO blood, with 12 of these being identified as a preanalytic error. Although these rates are low (1 in 19,000 transfusion), the risk of an AE is high when such an event occurs. Plus, these rates do not tell the entire story. Kaplan (2005) reported that there are 339 close calls for every 1 actual harm. The main preventive measure used in transfusions is multiple cross-checking. The error rate for blood banks has been placed at 15%, which is high, with some of this as a result of multitask requirements (Kaplan 2005).

Anatomic pathology errors are considered to be critical because of the potential harm (Valenstein and Sirota 2004). One issue with these types of samples is that analysis may not be very determinative, with disagreement existing among reviewers. This makes evaluating actual errors difficult and subjective (Renshaw and Gould 2007). These types of samples also suffer from unrelated errors in analysis, such as misidentification. The error rate for anatomical pathology has been reported to range from 0.1% to 0.8%. Others have suggested that this rate is much higher (7%–10%) (Elston 2008). Most of the mistakes reported are actually disagreements over how

the sample/tissue/histology is categorized and thus would not represent true errors. However, it appears that the highest number of errors is associated with the breast and gynecological tracts (Renshaw and Gould 2007).

Malignancy as a disease likely exhibits the highest number of errors in misdiagnosis or missed events as compared to other disease states and diagnoses (Elston 2008). Elston (2008) reported that the frequency of misdiagnosis relating to cancer varied among facilities but ranged up to 11.8%. General pathologists are less efficient in recognizing dermatological cases and events as compared to dermatopathologists, suggesting that some types of samples are best evaluated by specialists. Errors have been shown to decrease when more than one pathologist makes an evaluation.

There are many factors contributing to errors by pathologists. Workload has been discussed in the literature as a contributing factor in errors (Renshaw and Gould 2007). However, there have not been enough adequate studies evaluating this factor, mostly because pathologists do not think it is important. A response to the paper by Renshaw and Gould (2007) suggested that errors may increase with low numbers of cases, while such an increase in "mistakes" may also be observed for very busy facilities (Vollmer 2006).

INFECTIOUS DISEASE

Misdiagnosis and medical errors also occur in the occurrence of infectious disease. These errors, scientifically, can occur because of misdiagnosis of an infection, a laboratory-related error, delayed treatment, inadequate resistance testing, causation of another disease event, and identification of the wrong organism. Mistakes related to infectious disease are not commonly discussed as a medical error, primarily because most receive only limited training in this area of science. In some cases, such as for necrotizing otitis externa, occurrence is generally restricted to patients with a specific disease or condition, such as insulin-dependent diabetes (Jacobsen and Antonelli 2010).

Errors associated with infectious disease are more commonly reported, at least in the literature, for parasitic infections. Some of these reports are case studies where actual identification of the cause of disease was discovered at autopsy, at least in the United States (Alunni-Perret et al. 2010). These events are a result of lack of familiarity with parasitic/tropical diseases and nonspecific symptoms. However, in almost all cases, patients do have a history of travel to a region where such diseases are common. Malaria is a common example of a misdiagnosed disease (Stoppacher and Adams 2003). Yet, even for this type of disease, especially since it is the most common parasitic form of disease worldwide, there are few cases observed in the United States. Newmann et al. (2004) reported about 1500 cases of this disease observed in the United States each year. Most of these originate from travel outside the United States, since there are few endemic cases. Stoppacher and Adams (2003) reported for the United States during 1979–1998, 118 deaths as a result of this disease, and when compared to the rate of disease events provided by Newmann, the approximate death rate is around 0.8%. This number alone makes the disease unlikely to be recognized by most practitioners, leading to a high likelihood of misdiagnosis. Even antemortem

cases of fatal malaria are missed (Stoppacher and Adams 2003). Low rates of common diseases, at least elsewhere in the world, can enhance the rate of probable misdiagnosis. This is enhanced by the few cases seen in laboratories, especially those that do not have availability to a multitude of specialized personnel.

Although cases related to infectious disease–type errors focus on the United States, other locations in the world where these unusual diseases are more common, at least from an infectious disease point of view, are not exempt from these types of mistakes. In a reported case in Asia, scrub typhus was transmitted through a needlestick injury (Kang et al. 2010). This case is indirectly related to misdiagnosis; the occurrence of such errors does appear to be common even in locations where the disease is endemic (Olson and Bourgeois 1979). These errors are not limited to events in the laboratory but also depend upon what type of analysis the laboratory is instructed to perform. An error of this nature becomes a practitioner error and not one associated with laboratory medicine.

Errors are not limited to unusual diseases but also occur for other more common infectious agents, such as bacteria. There are a myriad of issues and errors that can occur; most are discussed in case studies (Weissert et al. 2009). In the case study presented by Weissert et al. (2009), bacterial analysis was conducted through an automated system and missed the bacterium *Burkholderia pseudomallei*, which was causing an abscess in the head area of a patient. This report suggests locations where the disease is not endemic may commonly misdiagnose or misidentify the organism and may have inadequacies in antimicrobial sensitivity testing. This is likely a more systemic-type error since most health-care personnel are not familiar with these diseases.

In a study of severe sepsis, treatment errors were identified in 30% of cases (Huggan 2011). Huggans (2011) reported that in 2003 in New Zealand the incidence of severe sepsis patients requiring admission to an ICU was 0.77 per 1000 people entering the hospital (population). A similar investigation in Canada reported this rate was 1.1% for the time period 1999–2003. These data illustrate the extent of sepsis and its importance as a medical problem, yet suggest there is a high rate of error associated with treatment. Since this type of microbial infection has a high rate of mortality mitigation, the quick onset of effective treatment is essential and imperative errors are to be kept to a minimum. Errors associated with sepsis have been suggested to be related to not diagnosing the events or not doing so in a sufficient period of time, delay in administering antibiotics, and lastly failure to begin antimicrobial therapy even after information on sepsis has been received from the microbiology laboratory.

Communication has also been identified as an important factor in errors in sepsis cases handled by an interdisciplinary team approach. When guidelines and education for clinical staff were instituted, an 8% reduction in sepsis patient–related errors was reported. Huggans (2011) suggested education was the most important element related to reduction of sepsis or infectious disease errors. This suggests that with specific intervention, measures can be undertaken to reduce errors associated with infectious disease and its treatment.

One issue patients may have is actually finding or talking with the person in charge. This usually occurs only when a problem or issue arises. In some cases, a

Substance	Effect
Chlorine	Halogen, highly electronegative, can strip electrons, denature enzymes and oxidizes sulfhydryl groups; effective against bacteria, spores, fungi, and viruses; commonly used due to its low toxicity and effectiveness; related to iodine
Phenolics	Carbolic acid; degrades and denatures proteins and cell walls/membranes; effective against vegetative cells, fungi, and most viruses, not effective against spores and hepatitis B
Alcohols	Hydrocarbons with one or more hydroxyl groups (–OH); ethyl and isopropyl are applicable as antimicrobials, methyl is not effective, and isopropyl is generally most effective; denatures (coagulation) proteins, dissolves lipids, and damages membranes, needs some water for effectiveness; most solutions are 70% alcohol; effective (but low level) against vegetative cells, fungi, and some viruses; most effective against enveloped rather than nonenveloped viruses; not effective against bacterial spores
Hydrogen peroxide	Inhibited by organic matter; effect is direct and indirect action with oxygen (electronegative effect); effective against bacteria (vegetative), viruses, fungi, and, at high concentration, spores
Detergents	Soaps are detergents, and this is a polar molecule that acts like a surfactant; anionic detergents have limited effectiveness; cationic detergents are most effective; disrupts cell membrane; vigorous rubbing increases effectiveness
Formaldehyde	Formaldehyde (CH_2O), inactivates nucleic acids and proteins, dehydrates the cell; effective disinfectant but toxic; effective against bacteria, fungi, viruses, and spores; alkylating agent—disrupts DNA with a mechanism of donating an alkyl group to another compound; disrupts proteins
Glutaraldehyde	Effective against bacteria, fungi, viruses, and spores; disrupts proteins and enzymes (cross linking); alkylating agent
Ethylene oxide (ETO)	Disrupts proteins and nucleic acid; alkylating agent; effective against bacteria, fungi, viruses, and spores; ETO sterilizer is a chemoclave; exposure can be toxic
Chlorhexidine	Organic with chlorine and two phenol rings; effective against cell membranes and denaturation of proteins; effective against vegetative cells (bacteria) and some fungi and viruses; not effective against spores; exhibits low toxicity
Quaternary ammonia (QA)	QA contains NH_4^+ and is generally a good disinfectant; although hard water may make this less effective, G– bacteria can grow in the preparation and these agents are not effective against nonenveloped viruses and fungal and bacterial spores; effective against enveloped viruses and G– and G+ bacteria, and is a cationic biocide; mechanism of action is disruption of membranes; limited effectiveness against mycobacteria; commonly used in the food industry; can cause irritation to mucus membranes and respiratory tract

[a] The terms “disinfection” and “sterilization” are often misunderstood. Disinfection is the reduction of viable microbes, while sterilization is the elimination of all microbes. In some cases, a disinfectant will act as a sterilization agent when a sufficient amount of time is allowed. A sanitizer is used to kill microbes that are important in disease causation and are commonly used in the food industry.

patient's family will be shuffled around from various "providers" or HCWs while attempting to get an answer to a difficult question. This is even more evident when a medical error occurs, in that no one wants to provide an answer or own up to an error that has occurred. Some states and countries (e.g., Australia) have provided legal protection or discussed at least having an apology related to mistakes be initiated, especially for pharmacists (Mastrianni et al. 2010). Open disclosure has never been fully recognized or discussed in medicine but is now becoming an important issue (Lazare and Levy 2011; Studdert, Piper, and Iedema 2010).

PEDIATRIC ISSUES

Medication errors in pediatric settings can be of greater concern than for most adults because of a more narrow tolerance range (Gonzales 2010). One review (Miller et al. 2007) suggested that there are 100–460 prescribing errors per 1000 patients. The categorization of these errors vary, but the errors have been reported to break down approximately 3%–37% for prescribing, 5%–58% for dispensing, 72%–75% for administrative, and 17%–21% for documentation (Miller et al. 2007). Although these ranges are great, it indicates that there is a tremendous variation in the categorization of medical errors for children with no single "functional" area being a predominate contributor. However, from this, it does appear, at least for children, administration is an important activity associated with medication errors and likely other forms of medical mistakes. As mentioned, increased requirements in patient care and reductions in staffing are probably the most important causes of medical errors. Shorter stays in hospitals and increasing outpatient treatments may also be contributing to administrative and other types of errors. Epidemiological studies on these types of errors can assist in identifying rates and categories or locations where errors are likely to occur. One issue, with many of the studies, is a lack of the severity related to occurrences. This evaluator may be an important factor that is not recognized in the pediatric epidemiology of medication errors (Miller et al. 2007). Thus, just classification of an error alone may not provide a good evaluator of whether an event is a true hazard to the patient. These studies do not provide the overall number of near misses or mechanisms in place that prevented these events. There is also a lack of information on the quality of personnel, that is, who is more responsible for errors and who is actually preventing or contributing to the reduction in errors.

There is a lack of a definition that clearly identifies terms in pediatric errors. In turn, however, definitions would assist in epidemiological studies of medication errors at all levels. This can also confound comparisons between epidemiological studies. Note, problems of this nature may also be contributing to reporting errors. Thus, there may be higher reported rates of medical errors because of definitional categorizations rather than error occurrences.

One of the cited reasons for errors in pediatric populations is a lack of standardized dosing. Most drugs for pediatric patients are provided on body weight (bw), such as mg/kg-bw, and this can increase the likelihood of error. Children also have a different metabolic rate than adults and often cannot communicate issues with medications and treatment. They are also smaller, allowing less error in dosing.

Gonzales (2010) in a review reported an ADE for children of 6 per 100 admissions and 7.5 per 1000 patient-days. For these ADEs, it was suggested that 24% were serious or life threatening, which appears to be much greater than those observed in adult populations (MEDCEU 2009). It was suggested that the most common drugs associated with errors are antibiotics and sedatives. The most common type of error has been suggested to be dosing, which was discussed in the Quaid case. This also is associated with the issue that many drugs were evaluated for adults yet used in pediatrics as an off-label issuance. Reasons for pediatric drug errors include distracted personnel, interruptions, inadequate nursing staff, incorrect amount of medication being administered, failure to adequately check the drug and dose (some resulting from auxiliary staff having inadequate mathematical skills), poor communication, handwriting issues, and unfamiliarity with the drug being delivered (Stewart et al. 2010; Gonzales 2010). Even improved technology will not prevent some of these problems or errors. In many cases, the error does not originate with the person who administered the agent but in the process of obtaining the agent. In addition, those with a longer hospital stay have the highest number of errors. Much of this is due to having more medication administered during their hospital stay.

Methods have been proposed to prevent these types of errors. It has been suggested that pharmacy monitoring could eliminate 81% of the errors (Stewart et al. 2010). A computerized ordering system can also reduce errors (Walsh, Kaushal, and Chessare 2005). However, ultimately much of the burden in preventing these types of mistakes exists with the nurse. Focusing much of patient care on one party may be one of the biggest unrecognized issues, especially as many hospitals have inadequate or undereducated support staff and are often understaffed.

GEOGRAPHIC VARIATION

There have been suggestions that the quality of care varies geographically (Zhang, Baicker, and Newhouse 2010). Not only is there variation among the types of settings and over time, but regionally as well. It has been reported that there are more "misadventures" in urban hospitals as compared to those set in a more rural setting. It has been suggested that the reason for these differences is a result of patient volume, with those in an urban area often being busier. However, there is a high rate of complications in rural facilities because of medication mishaps. Those being discharged from an urban setting have a larger number of adverse effects, especially related to surgical and medical procedures done in teaching hospitals as compared to others. Most of these variations in events are due to the type and/or structure of the facility. In part, this may be due to the fact that more complex procedures are performed at teaching facilities as compared to nonteaching institutions. It may be possible to configure a facility into a structural relationship that looks like those providing the best care for each category. However, the issue with this structured configuration is cost. In addition, it will require a great deal of flexibility and open mindedness.

It appears that there is a geographical relationship for medication, prescribing practices, and disease prevalence (Feifer and James 2010). Some of this may be related to specialization and its distribution in the region. These patterns may

also exist for medical errors. Possible cross training and experience from facilities located in different regions may provide an answer by providing institutions with new ideas and initiatives.

SOLUTIONS FOR PATIENT SAFETY

Since medical errors occur on a regular basis, there is a need for solutions to mitigate such errors. Solutions are being developed and formulated to resolve these mistakes. One of the problems with attempting to control these errors is that they are time-consuming and costly. Most of the costs related to the prevention of medical errors involve the implementation of new technology, education, and HCW time and activity. Today, the biggest deterrents to preventing medical errors are increased workload and reduction in reimbursement. Solutions to prevent errors often involve additional time requirements for each patient, procedure, and medication administered. Although, in general, there are many implemented solutions, such as name changes for drugs due to similarities and computerized systems, these all require well-trained personnel and additional time. Vantage Professional Education (2011) identified "patient safety solutions" as referenced in the Internal Steering Committee of the Joint Commission. Although this is a somewhat comprehensive list, it may not include all potential categories because the list is in a continuous state of change and development. This list incorporates issues and problems identified from a range of studies, including case reports, that impact patient errors from mistakes/AE/ADE.

One of the most efficient mechanisms of preventing disease is hand washing. The solution to this issue is simple in that people need to more frequently and effectively wash their hands; however, this takes time and effort. With current shortages in personnel and time constraints, these simple practices often take a backseat to other activities. Studies have shown that HCWs are frequently contaminated (or become contaminated) with microbes (Cao, Taylor, and Vidimos 2010). Errors take place when HCWs do not wash their hands between patients or activities, thus putting others at risk. However, the availability of hand sanitation has been shown to reduce nosocomial disease rates; thus, there is a functional solution to this problem. In this case, the inclusion of alcohol-based hand "soap" is effective in reducing microbial loads, including methicillin-resistant *Staphylococcus aureus*. It should be noted that this "soap" is not effective against all microbes, especially spore-forming bacteria like *Clostridium difficile* (Cao, Taylor, and Vidimos 2010). Possibly of greater importance is effective hand washing by physicians. This may be one of the most deficient areas of leadership in medicine, with top physicians not following good practice and being a model for others (Bolon 2011). Thus, hand washing itself is a preventable error.

Falls are another concern that is commonly overlooked as a medical error. Although this can result from various causes, some arise because of treatment or medication (e.g., nitrates). These events can be prevented by with an more auxiliary personnel available to assist patients, especially for those with an impaired gait.

Probably one of the most important solutions is communication with the patient and other HCWs. Traditionally, a focus on communication involved not

Agent/Effectiveness	Bacteria	Nonenveloped Virus	Envoloped Virus	Bacterial Spore	Fungi
Chlorine (I–H)	X	X	X	X	X
Phenolics (L)	X		X		
Alcohols (I)	X		X		X
Hydrogen peroxide (H)	X	X	X	X	X
Dtg (L)	X				
CH_2O (I–H)	X	X	X	X	X
Glut (H)	X	X	X	X	X
ETO (H)	X	X	X	X	X
Chl (L)	X				
QA (L)	X		X		

Note: CH_2O = formaldehyde; Dtg = detergents; ETO = ethylene oxide; Glu = glutaraldehyde; Chl = chlorhexidine; and QA = quaternary ammonia. H = highest; I = intermediate; and L = low are levels, which are how extensive this agent is against a wide variety of microbes. The highest level (H) is most effective against all organisms, while low (L) is the poorest. Prions are not discussed and constitute a unique requirement for disinfection. Concentration of agent and time of exposure must always be considered when evaluating disinfection/sanitation.

using abbreviations, writing clearly, not mislabeling, and standardizing practices. However, this can be extended to communicating with others associated with patient care and checking systems to ensure it is the right patient, right medication or procedure, right route, and right dose or location (four Rs). These errors can even occur as part of a physical examination (Fox 2008). Patients must also be aware of their responsibilities in treatment. This includes following directions and alerting providers to unexpected events. In some ways, distributing information about their diseases and related outcomes can educate consumers and make them an intricate part of the team. Such a communication may also provide more specific information for diagnosis and effective treatment, thus leading to better patient outcome.

SUMMARY

Medical mistakes or errors can never be eliminated. However, the concept of basic practices, such as hand washing and having a double check system, can be implemented to prevent errors and establish the idea of prevention along with forethought. In controlling these mistakes, there must be financial input, time allocation, and adequate training of personnel. Many of the causes of medical errors are not individuals but the systemic nature of medicine. The culture and nature of institutionalized medicine make prevention difficult and creates a pattern of resistance. This process of preventing errors is not a one-time adventure but a continuing process. In many ways, medical culture is similar to that seen in the airline industry at one time. It took horrific events, such as the poor and stifled communication among a flight crew resulting in the collision of two planes at Tenerife North Airport (Canary Islands) and 583 deaths. This became a classic example of an autocratic decision-making

processes becoming unchecked. Thus, medicine can borrow from other industries practices, procedures, and lessons for medical error recognition and prevention. As medicine changes, so will preventive practices and procedures. In addition, this is not the concern of only one group but all individuals who are all involved in health care. Lastly, the ancient concept established by Hippocrates of Con in "first do no harm" may be the cornerstone of medical error prevention.

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4 Nosocomial Diseases
A Discussion of Issues and Prevention

John H. Lange, Luca Cegolon, and Giuseppe Mastrangelo

CONTENTS

SUMMARY

Nosocomial infection(s) (NI), which are commonly called hospital-acquired infection(s) (HAIs) or in this chapter, hospital-borne disease(s), have existed as major overall concerns in the health-care industry and community since the inception of antibiotics. Rates of these infections are increasing along with severity and complications. A rise in antibiotic resistance, including multiple resistances, has magnified the effects of nosocomial diseases. Today, NIs are not only impacting patients in hospitals and other facilities but health-care workers (HCWs) as well. As organisms become more resistant, issues related to NIs will become greater and more acute. Microbial resistance is resulting in the need for more complex treatments and increased costs. Aspects of NIs are also being magnified by the "types" of patients affected in hospitals and related institutions as compared to the past. NIs now extend beyond the traditional hospital setting and include community and ambulatory settings as well. Also, as patients spend more time convalescing at home, many of the risks associated with NIs are now seen in the home environment and other locations. Today, resistance is no longer contained to bacteria and is also

occurring in other microbes such as fungi and/or viruses. Therefore, these changes are impacting patient health along with HCWs. Because the cost containment is a major issue in health care, the rise in NIs will have a negative impact on the financial stability of many institutions. These issues and concerns have resulted in a greater effort to minimize NIs. Emphasis is now being placed on effective and efficient cleaning techniques (disinfection), hand washing, and monitoring practices. Also, increased rates of vaccination have helped minimize some NIs in HCWs and patients, as seen with hepatitis B vaccination. However, currently there are some agents for which no vaccination or cure exists (e.g., hepatitis C). Understanding the ecology of these infections will also assist in the reduction of NIs as seen in the application of probiotics.

INTRODUCTION

HBDs have emerged as a major cause of mortality and morbidity in the world (Pittet, Taraara, and Wenzel 1994; McFee 2009). Nosocomial comes from the Greek word *Nosokomeian*, which means a place from which disease is carried. Traditionally, NI was a result of infectious diseases being acquired and/or transmitted within a hospital setting. This definition has been extended to include other forms of health-care facilities such as physical and occupational settings. As a result of resistance, there are now community-acquired infections, which can even include events associated with athletic activities (McNitt and Petrunak 2009). However, other locations related to health care also carry risk of contracting NIs, such as physical therapy facilities. NIs are becoming more acute in these various settings because of an increased frequency of antibiotic-resistant microbes, especially those that are multiresistant (multidrug-resistant organism [MDRO]), along with a higher percentage of immune-suppressed patients in the population. Emphasis of out-of-hospital care has moved NIs to locations not considered traditional health care or classical HBD. Another concern that has arisen is the increase of those who are not fully vaccinated. Concern for vaccination traditionally existed for HCWs but now extends to others, including caregivers and, in some ways, the community in general.

As resistance increases and care settings expand, treatment of what was previously considered basic infections is becoming more difficult, thus resulting in longer durations of illness and poorer patient outcomes. This is specifically noted for acute diseases that are now becoming chronic (e.g., acquired immunodeficiency syndrome [AIDS]). As these diseases become more complex, their spread is increasing and now often occurs outside the traditional hospital environment. Antibiotic resistance is also beginning to accumulate in the true opportunistic pathogens (*Acinetobacter*), and many historical infectious diseases like *Mycobacterium tuberculosis* (tuberculosis, or TB) are becoming frequently multidrug resistant (MDR). Issues of resistance will become even more critical as fewer new antibiotics are being produced and/or developed. For some diseases, such as TB, resistance may even give rise to sanitariums as a result of no drug treatment being available (extensively drug-resistant TB [XDR-TB]). Fundamentally, there may soon be a shift to the "old" treatment

procedures (e.g., sanatariums) that existed before the availability of antibiotics as a result of resistance.

Since hospital stays are becoming shorter and patients are now convalescing at home, those contracting NIs in health-care facilities are moving these agents to the community. Overall, these events are adding to the caseload of NIs and making treatment more difficult. It is also shifting the type and form of concern for HAIs. Not only are traditional HCWs at risk, caregivers, patient families, and those in home health care are also now at risk. In some ways, the community at large may become at risk (Gardam 2008). Rapid modes of transportation have also magnified potential spread of disease in ways that were not previously considered, at least historically (Sampathkumar 2007). Travel of this nature, as has been suggested for TB, may be a common form of disease spread, especially as related to MDRO, yet has not been fully recognized (Webster 2010).

The transmission and occurrence of infectious disease in nontraditional locations have raised concerns with the general public and are becoming major news events (Gardam 2008; Berens and Armstrong 2008). These cases have drawn considerable attention to the spread of disease in what was considered at one time not to be an at-risk association or activity (e.g., athletic events) for infectious diseases (Decker 2010). Today, infectious diseases, such as methicillin-resistant *Staphylococcus aureus* (MRSA), are commonly discussed at local meetings and schools and in the general media (e.g., newspapers). However, it appears that few have a good understanding, at least scientifically, of these NIs and how they can be prevented and avoided (Berens and Armstrong 2008).

Not only patients in the hospital, but HCWs as well, are at risk from these infections and those that come in contact with infected patients (e.g., family members and those in the community in general) (McNitt and Petrunak 2009). This may be most critical for an aging population. These exposures now extend to the whole community and may be more widespread than previously considered (File and Marrie 2010). This population now includes those with immune suppression and partial or incomplete vaccination to commonly occurring diseases (e.g., caregivers without a hepatitis B vaccination). What is not frequently discussed is that family members and others may also be experiencing decreased resistance (e.g., immune deficiency) at the time they are caring for those that are sick. Other scenarios are also emerging, as seen with the rise of pertussis (whooping cough or *Bortetella pertussis*). This disease was historically associated with children but is now being seen in older adults that were either not immunized or lost their immunity (Rittle 2010). This type of disease is of importance because of its "longer" incubation period and communicability (3 weeks and 5 days with antibiotic therapy) (Heymann 2004). What is being observed for this infectious agent may be occurring for others as well but has yet to be clearly recognized.

Generally, an infection is considered nosocomial if it is acquired 48–72 hours following a hospital admission. However, with the increased spread of these infections and the rise in resistance, this time period may no longer be as applicable as defined. Since NIs include other health-related locations (e.g., physical therapy facilities, athletic training facilities, and dialysis), this definition extends to where treatment, therapy, or other actions/activities are undertaken, including ambulatory-related

facilities. This may become even more critical with the rise of instant health clinics throughout the United States in various types of "stores." The impact of these types of settings on the spread of NIs is still not known.

The prevention of infectious diseases for HCWs can be broadly categorized as fomite-related (spread through nonliving objects such as table tops), airborne transmission, or puncture-related injuries. Direct contact also exists although this is, in part, minimized by the use of universal precautions and partially falls into the categorization of fomite-transmitted, at least in this discussion. For the general public, there are other modes of transmission (e.g., waterborne, direct contact); however, the four mentioned (fomite, aerosol and puncture/needlesticks, and foodborne) can be considered primary in nature for HCWs. Fomite prevention involves "cleaning" surfaces or items, mostly through disinfection and sterilization. Overall, hand washing has been considered a critical practice in preventing transmission/spread of microbes and is basic in breaking the chain of transmission (chain of infection). This chain has often been viewed as the basic model for preventing disease transmission in health-care settings. Disruption at any step will prevent continuation of the disease. The steps consist of etiological agent, reservoir, portal of exit, method of transmission, portal of entry, and susceptible host.

Airborne transmission is a little more difficult to prevent and commonly involves the use of respirators; however, application of enhanced airflow and ultraviolet (UV) radiation (light) has been reported to be effective (Conroy et al. 2010). Puncture injuries in the transmission of disease (HBD) are most critically related to hollow-bore needle events (Salehi and Garner 2010). In many ways, this is at the heart of the blood-borne pathogen rule(s) established by the U.S. Occupational Safety and Health Administration. Implementation of universal precautions has helped prevent the spread of disease (e.g., human immunodeficiency virus [HIV]) and has made HCWs more aware of the risks. Universal precautions are designed to prevent exposure through any route (e.g., skin, parenteral inoculation, and mucus membranes) to potentially pathogenic materials. These precautions are based on the concept that all blood and body fluids are contaminated and presumed to be infectious. Exposures are "controlled" through barrier methods (precautions), which are intended to break the route of transmission. In some circumstances, these precautions have been shown to be inadequate in providing protection, as seen for hepatitis B and patient exposure/activity related to oral surgeons as an example (Reingold, Kane, and Hightower 1988). Thus, these practices have limitations, which are sometimes forgotten.

Failure by the health-care industry (HCI) to fully recognize how important these preventive practices are in controlling NIs has allowed a continuum of the status quo. Basic measures would greatly reduce the rate of NI in health-care settings but until recently were mostly given priority in words and not through practical actions (Huang 2009). Historically, hospitals were paid to treat all infections including those that were nosocomial (hospital acquired) in nature; thus, there existed little incentive to prevent what they would ultimately be paid to treat. In this scenario, health-care providers were actually rewarded for more NIs. However, this was not advantageous for patients that experienced or succumbed to these infections. Therefore, historically, there was little reward for aggressively preventing NIs. This scenario is now changing in that there is a decreased incentive because they are no longer being

re-reimbursed for these infections (i.e., HAIs) (Brown, Doloresco, and Mylotte 2009). However, 100% elimination of NIs is not possible. Further, this has become even more complicated through efforts to establish cost containments in workmen's compensation, especially as related to NIs in HCWs.

HAND WASHING

Hand washing has been considered the most fundamental mechanism for preventing disease transmission, including those that are nosocomial HCW-related (Bolon 2011). This practice is commonly forgotten by HCWs and the general public, with frequent relearning required at all levels (Boyce and Pittet 2002). Transmission of microbes through hand contact can occur not only from HCW to patient, but from patient to patient and patient to HCW. Visitors and family members can also transmit diseases. The concept of infectious diseases was first suggested in the 1500s by Girolamo Fracastoro (1478–1553) but was rejected in favor of the miasmic theory. Around 1822, a French chemist and pharmacist named Antoine Labbarraque first suggested regular hand washing as a way of removing odors from those conducting autopsies. It was not until Ignaz Semmelweis and Oliver Wendel Holmes Sr. that a major effort was undertaken to establish hand washing as a standard practice. Overall, Semmelweis is given the greatest credit in formulating this concept although it appears that Holmes was the first to actually devise or emphasize this practice. The importance of hand washing originated before the introduction to the germ theory by Louis Pasteur in 1864.

Semmelweis observed that there was a much higher rate of deaths from puerperal fever (a form of septicemia) in obstetric wards run by physicians as compared to midwives at the Vienna General Hospital (Bencho and Schejbalova 2006). Puerperal fever is caused by the gram-negative organism (bacteria) *Streptococcus pyogenes*. To mitigate this disease, he required physicians to wash their hands with a chlorinated lime solution before treating patients, and as a result there was a reduction in the rate of "infectious" disease. These infections were classic HBDs, which have changed today with the expansion of health care and are now mostly replaced by organisms that are MDR. This rate, by physicians, soon mirrored that seen with midwives. Semmelweis emphasized the concept of cleanliness along with hand washing, which was fundamentally ignored. This cleanliness includes "disinfection" practices throughout the hospital, including cleaning instruments, bedding, and the like. Today, the real issue related to Semmelweis is that disinfection is forgotten in practice and remains a major "route" of disease transmission (McFee 2009).

The key to Semmelweis's understanding of this problem was based on basic epidemiological methods. He concluded from observation that some agent was being transmitted from cadaverous materials to patients. At the time, medical students, but not midwives, would conduct autopsies before treating patients. The concept of spreading disease ran against current medical training and thought, which was still influenced by the humors of the body. Semmelweis even recommended cleaning be extended to instruments and the hospital itself. Today, the importance of proper cleaning is still being learned, especially with recent findings that common instruments (e.g., stethoscopes) and even white coats carry contamination (Pandey et al. 2010).

Semmelweis's concept was published in an *Austrian Medical Journal* in December, 1847 and was considered by some to be as important as that of Edward Jenner's discovery regarding the smallpox vaccine. Even with this acknowledgement, his concept was not widely accepted and in most cases ignored. The real tragedy of this lack of acceptance is that Semmelweis's ideas are still being learned and explained today. Studies (Jump, Pultz, and Donskey 2007) have shown that incomplete cleaning of hospital rooms and most likely other areas are important sources of HBDs, especially for some microbes like *Enterococcus* and *Clostridium difficile*.

INFECTION RISK

Approximately 50% of the major hospital health complications are associated with NIs. It has been estimated that 2 million people in the United States contract NIs while in the hospital, which equates to 1 in 20 hospital admissions, and if other of types facilities are included (e.g., physical therapy), this would be even higher. Klevens et al. (2008) reported that in 1995 there were 99,000 deaths and a cost of $4.5 billion in the United States as a result of NIs. This translates into one death every 6 minutes. Infections of nosocomial origin are the leading cause of death in this group with a median age of 57 (Curtis 2008). It has been suggested that the elevated rise in NIs is due to the increasing age of the population, a larger number of immunocompromised patients, more invasive procedures, poor hygienic practices, and overuse of antibiotics (MacGowan 2008). Hospitals that are "large" have a greater mixture of types of patients (case mix), and those patients with longer hospitalizations exhibit higher rates of NIs (Sax, Pittet, and Swiss-NOSO Network 2002). The highest number of NIs is found in adult and pediatric intensive-care units (ICUs) (Huskins et al. 2011; Lee et al. 2011). Patients at the greatest risk are those with invasive vascular catheters and various associated monitoring devices (Chittick and Sherertz 2010). In general, urinary tract infections (UTIs) are predominately nosocomial (Qureshi 2009) although other site locations are also of importance (e.g., skin) (Reygaert 2009).

It has been shown that smaller hospitals that have instituted good infectious disease controls can dramatically reduce their rate of NIs (Hermanek 2005). This is illustrated through a small hospital in Alaska, Central Peninsula General Hospital (CPGH), which reported an NI rate of 0.19/100 patient days while the national average at the time was 0.50/100 patient days. The newspaper article by Hermanek suggested that this is a result of good hygienic and infection control practices. Part of the program at CPGH included implementation of the guidelines provided by the Centers for Disease Control and Prevention (CDC) for "hand hygiene." In addition, new employees also undergo training regarding hand hygiene, which is also conducted annually. There is also a smaller turnover of personnel in hospitals of this size, and these personnel are more stable in performing similar job functions each day. In the smaller hospitals, it is more likely that the same people will be in these positions and that there is little if any student involvement that distract from primary duties.

Besides the contamination of microbes in the environment, a major source of these organisms is from those that are colonized (McNitt and Petrunak 2009). There

is a clear distinction between colonization and infection. Infection is when the person is being harmed by the microbe. Colonization on the other hand is when the microbe takes up residence but does not cause harm, at least not to a noticeable degree. In most cases, the person is not aware that they are colonized. However, a colonized person can spread these organisms, and such events are not limited to patients but can also include HCWs. People that are colonized can act as reservoirs for NIs (Wolvers et al. 2010). Colonized people can also add to the bacterial load at various "high risk" locations in hospitals (e.g., ICUs) and act as unrecognized sources of these microbes. In many cases, the identification of a colonized person can be difficult with no one occupation being exempt from this type of event. However, due to cross-contamination, where the contamination began may be difficult to identify.

Surfaces and objects can also act as sources of infectious materials. Although these are not truly colonized, surfaces and/or materials can act this way. Thus, even after effective and efficient cleaning, locations can be reinoculated and act as reservoirs for infectious agents (e.g., *C. difficile*). Today, the inclusion of metals in surface materials has been shown to reduce microbial levels, and they are now being commonly incorporated as part of medical components (Grass, Rensing, and Solioz 2011).

Not all patients are at equal risk for infection by nosocomial agents. Patients with invasive devices are at greatest risk for infection by coagulase-negative staphylococci. The most commonly encountered bacterial genus in this group is *Staphylococcus*, and generally the most virulent species (spp) is *S. aureus* (Reygaert 2009; Cowan and Talaro 2006). *S. aureus* is a gram-negative organism, and the drug-resistant form of greatest concern at the present time is MRSA (Ali, Abbasi, and Mirza 2007; Rubin et al. 1999). Other forms of antibiotic resistance are emerging, such as vancomycin-resistant *S. aureus* (VRSA) (Centers for Disease Control and Prevention 2004). Fungal UTIs are also becoming common as a result of extensive application of broad-spectrum antibiotics, with the most frequent organism being *Candida* spp. (Nicoletti et al. 2009). However, these are not the only microbes of concern. Others that are commonly seen today associated with NIs include *Acinetobacter baumannii*, *C. difficile*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis*, *Enterococcus faecalis*, and *E. faecium* (Chen et al. 2011; Curtis 2008; Ercole et al. 2007; Jensen et al. 2005). Today, all of these organisms can carry resistance to multiple antibiotics (i.e., MDRO) and be responsible for NIs. The increase in MDRO is becoming one of the biggest issues related to NI. There is now a growing list of microbes (e.g., mycobacteria) that are becoming resistant to all known antibiotics. A partial list of nosocomial agents and identified site(s) are shown in Table 4.1.

There are some bacteria (*M. tuberculosis*) that evolved "functional" resistance to all known applicable antibiotics (Sangare et al. 2010). The real issue associated with MDRO occurrence is that it is no longer rare but becoming common among a variety of organisms (*A. baumannii*) (Allen and Green 1987). Infections by MDRO increase the cost, length of hospital stay, and complications for patients. These patients also increase risk of infection to other patients and HCWs, and recently this is being extended to others (e.g., caregivers) previously not considered an at-risk group.

TABLE 4.1
Nosocomial Infectious Disease Agents and Identified Site(s)

Name of Organism	Example Site(s) (Location)	Reference
A. baumannii (B)	Intra-abdominal infection (IAI)	Nicoletti et al. (2009)
Aspergillus spp. (F)	Skin	Vonberg and Gastmier (2006)
Bacteroides fragilis (B)	IAI	Nicoletti et al. (2009)
Burkholderia cepacia (B)	Lung	Lopes, Goulart, and Starling (2007)
Candida spp. (F)	IAI, skin	Nicoletti et al. (2009)
Candida krusei (F)	UTI	Weinstein (1998)
Candida lusitaniae[a] (F)	UTI, wound	Sanchez et al. (1992)
C. difficile (B)	Digestive	Chaudhry et al. (2008)
E. faecalis (B)	Digestive	Arias and Murry (2008)
Enterobacter spp. (B)	Digestive	Weinstein (1998)
Enterococcus spp. (B)	IAI	Nicoletti et al. (2009)
Escherichia coli (B)	IAI	Nicoletti et al. (2009)
Fusarium spp. (F)	Skin	Peman et al. (2006)
Herpes (V)	UTI	Weinstein (1998)
Hepatitis C (V)	Liver	Mailliard et al. (2009)
K. pneumoniae (B)	IAI	Falagas and Karageorgopoulos (2009)
P. aeruginosa (B)	IAI	Nicoletti et al. (2009)
Scedosporium apiospermum (F)	Lung	Peman et al. (2006)
Serratia marcescens (B)	Brain abscess	Hirooka et al. (2007)
S. aureus (B)	IAI, lung (pneumonia)	Nicoletti et al. (2009)
Staphylococcus epidermidis (B)	Skin	Otto (2009)
Norovirus (V)	Gastrointestinal	Johnansen et al. (2008)
Pantoea agglomerans (B)	Blood system	Liberto et al. (2009)
P. aeruginosa (B)	UTI	Weinstein (1998)

Note: B = bacteria; F = fungi; V = virus

[a] Commonly amphotericin B resistant.

CREATION OF ANTIBIOTIC-RESISTANT ORGANISMS

Antibiotics were formally discovered in the late 1920s by Alexander Fleming, who observed that the fungi *Penicillium notatum* inhibited *S. aureus* on a petri plate (Evolution of Antibiotic Resistance 2009). This resulted in the development of penicillin and later other antibiotics. Today, this term can be extended to those substances that inhibit or kill any type of microbe, including viruses. Although viruses are not susceptible to antibiotics, there are now antiviral agents, and viruses are beginning to become resistant to these substances (Weinstein 1998).

In 1941, all staphylococcal bacteria were susceptible to penicillin, yet 3 years later resistance emerged and remains today. Antibiotic resistance develops through

an evolutionary process. When antibiotics are present, there is selection of resistant mutants. Although the rate of mutational change is small (about 1 in 5,000,000 bacteria), the number of bacteria that exist and their rapid generation time often result in a good likelihood of a resistant mutant occurring (Trun and Trempy 2004). After a mutation occurs, this genetic resistance can be shared with other bacteria through three possible mechanisms: conjugation, transformation, and transduction.

Conjugation (gram-negative bacteria) involves the "sexual" transfer of genetic information through a pilli(us). This is bacteria's way of having sex. A copy of the genetic information is transferred through the pillus, and when inside the new bacterium, beneficial changes are incorporated into its DNA. Transduction occurs through a bacterial virus that incorporates this mutational information and carries it to the bacterium, and in transformation the uptake of DNA is through the bacterial membrane, allowing a genetic modification. In transformation, a donor microbe can be "dead" and its remaining DNA is incorporated to another bacterium, conferring resistance to the recipient (Trun and Trempy 2004). Because of transduction and transformation, even if the bacteria are killed through disinfection, resistance may occur through these genetic exchange mechanisms. This makes these two mechanisms powerful in allowing antibiotic resistance to continue even after the destruction of microbes. Transformation has been known since 1944 when this "mechanism" was experimentally demonstrated by Oswald Avery, Colin MacLeod, and Maclyn McCarty. Their publication (Avery, MacLeod, and McCarty 1944) is often considered the beginning of molecular biology.

Recent studies have shown that bacteria frequently exchange genetic information among genera and species (Trun and Trempy 2004). Thus, if antibiotic resistance emerges in one organism it can quickly be transferred to other microbes outside its species (horizontal gene transfer, the transfer of genetic information to another organism that is not its offspring; also called lateral gene transfer) (Woo et al. 2003; Barlow 2009; van Reenen and Dicks 2011). This becomes magnified with the overuse of antibiotics and supports the transfer of this resistance to other bacterial species. Antibiotic resistance is not new in biology and is also occurring in other ecological communities, such as with insects (most notably leaf-cutter ants) (Traniello, Rosengaus, and Savoie 2002; Clardy, Fischbach, and Currie 2009). Thus, there are lessons that can be learned from other organisms that have dealt with resistance longer than we have. Preventing resistance is a constant vigil and evolutionary game between man or the organism affected and microbes. The process of resistance is one of basic evolution that was first identified by Joshua and Ester Lederberg (Burke 2003). These researchers demonstrated that resistance involves selection of spontaneous mutations for the antibiotic(s) in question. Thus, even when antibiotics are not present, mutants are emerging because of naturally induced genetic mistakes (natural selection).

NOSOCOMIAL INFECTION SITES

NIs can occur at any site in the body; however, the most common locations are urinary; respiratory; skin; gastrointestinal (GI); ear, nose, and throat (ENT); and blood systems (Ogbolu et al. 2011; Gorkiewicz 2009; Zhanel et al. 2008; World Health

Organization [WHO] 2002; Heymann 2004). About 40% of these infections are in the urinary tract (UTIs), which also includes catheter-related infections (Chenoweth and Saint 2011; WHO 2002). Of these, it has been estimated that approximately 80%–95% of all hospital-related UTIs originate from the application of catheters (Curtis 2008). A UTI is defined as positive when there is more than 100,000 ($>10^5$) microorganisms/ml with a maximum of two isolated organisms. Although this is the clinical microbiology definition, patients usually become aware of such infections by experiencing pain upon urination or through pelvic discomfort. Initially, this is usually expressed as a minor complaint and is often overlooked by clinicians. Types of microbes associated with this site include *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus* spp., Staphylococci, and *Pseudomonas* (Qureshi 2009). Most Staphylococci associated with these infections are either VRSA or MRSA (Schito 2006; Ali, Abbasi, and Mirza 2007). From principles of natural selection, mutants are constantly occurring whether the agent (antibiotic) is present or not (Trun and Trempy 2004). One of the biggest sources of infection for the urinary tract is the contamination of catheters from bacteria residing on the patients skin (Bleasdale et al. 2007). High levels of multidrug resistance are also occurring for enteric bacteria with isolates existing at various locations on patients (Ogbolu et al. 2011). Observation of this nature demonstrates the difficulties emerging from MDRO.

For the respiratory system, major nosocomial organisms include respiratory syncytial virus, influenza, *P. aeruginosa*, *Serratia* spp., *E. faecalis*, *Haemophilus influenza*, and *Klebsiella* spp. (Morrow and Kollef 2010; Curtis 2008; Weinstein 1998). There are a number of risk factors for respiratory NIs, including obesity, age, inadequate hand washing, lung disease, aspiration, tracheotomy, intubation, mechanical ventilation, and respiratory distress (Joseph et al. 2010; Curtis 2008). If a patient has pneumonia, a NI increases the risk of death two- to tenfold (Feldman 2005). The incidence of respiratory NI (hospital acquired pneumonia) has been reported to be 5–10 cases per 1000 admissions (Isakow, Morrow, and Kollef 2007). Respiratory-related infections are most predominant in long-care facilities and can increase the hospital stay by 7–30 days and add $12,000–$40,000 in additional cost per patient (Isakow, Morrow, and Kollef 2007).

Common forms of NI related to the skin are cellulitis (Cowan and Talaro 2006; May 2009), abscesses (boils) (Xu et al. 2010), and furuncles (Lawrence, Golik, and Davidson 2009). *S. aureus* causes the largest percent of these infections, with the other major pathogen being *Streptococcus pyogenes*. In general, *Staphylococcus* outnumbers Group A *Streptococcus* about 2:1 for this "disease" (Chira and Miller 2010). Cellulitis is an infection in the underlying layers of the skin and can result from a scratch or cut that allows the bacteria to enter. The most common locations for this type of infection are arms and legs. Symptoms associated are generally redness, swelling, and pain, similar to necrotizing fasciitis. Staphylococci can also cause blood infections and pneumonia (Tacconella and DeAngelis 2009). Colonization can also occur in some people. The vast majority of these infections involve MRSA, although the most serious are VRSA. The cost of treating a MRSA infection has been reported to be 6%–10% higher than methicillin-sensitive *S. aureus* (MSSA) (Rubin et al. 1999). What is of greatest concern is that MRSA and VRSA NIs are appearing in community settings, and there may even be a distinction in their genetic

"qualities," but this line is now blurred (Hawkey and Jones 2009). These events are making headlines in the public media and are now spreading through community and sporting events. This concern has become so great studies have been conducted on the survivability of bacteria on artificial athletic fields (McNitt and Petrunak 2008). Transmission commonly results from contaminated hands. This supports the importance of hand washing. Infections can last from a few days to years, with treatment forming a chronic condition requiring years of therapy.

However, other microbes can be of concern. There have been recent reports of necrotizing fasciitis occurring due to *A. baumannii* (Charnot-Katsikas et al. 2009). There appears to be apparent shift from polymicrobial to monomicrobial causation of this disease (necrotizing fasciitis) (Gurdal et al. 2010), with *Acinetobacter* becoming an illustrative example. This makes the classification of some infectious diseases more complex, as in the illustration of *Acinetobacter.* What makes of *Acinetobacter* such a problem is its compilation of antibiotic resistance (e.g., pandrug resistance, XDR) even though it is generally not highly virulent (Mihu and Martinez 2011). Here necrotizing fasciitis can no longer be strictly identified as "acute streptococcal gangrene" since there are a number of microbes capable of its causation (Table 4.2). Abscesses are formed at the location of infection (site of injury) and are commonly associated with pus. Generally, the area around an abscess will be swollen, red, and painful.

One of the major microbe-related "disorders" of the GI tract is a result of *C. difficile*. This genus of bacteria is a spore former, and this makes it resistant to most disinfectants (Jabbar et al. 2010; Cowan and Talaro 2006; Jump, Pultz, and Donskey 2007). NI associated with this organism generally involves diarrhea and colitis (Bobo and Dubberke 2010; Thomas, Stevenson, and Riley 2003). Since the organism is resistant to most agents, at least in the spore form, spread occurs easily through an oral–fecal route. This makes disinfection much more difficult and allows the organism to be easily transmitted from person to person. Settle and Wilcox (1995) reported that patients infected with this microbe (hospital-acquired disease [HAD] or HBD) had a hospital stay that was about 3 weeks longer than noninfected

TABLE 4.2
Examples of Microorganisms Reported to Cause Necrotizing Fasciitis

Organism	Reference
A. baumannii	Charnot-Katsikas et al. (2009)
A and B streptococci	Charnot-Katsikas et al. (2009)
P. aeruginosa	Hefney et al. (2007)
Enterobacteriaceae	Book and Frazier (1995)
Staphylococci	Gabillot-Carre and Roujeau (2007)
Bacillus cereus	Hutchens et al. (2010)
K. pneumoniae	Kohler et al. (2007)
K. oxytoca	Greer-Bayramoglu et al. (2008)
S. marcescens	Curtis et al. (2005)

patients. Most of these cases are acquired while in the hospital by patients with a history of antibiotic therapy; age is also a major risk factor. Since diarrhea is a common symptom associated with this organism, spread easily occurs and, without prevention, it can result in the infection of other patients.

NIs of the ENT are similar to that seen with the skin. MRSA is a commonly reported NI for this location (Ali, Abbasi, and Mirza 2007; Raja et al. 2005). Historically, vancomycin-resistant enterococci (VRE) infections were not commonly seen at these sites but are now becoming more frequent (Sader, Farrell, Jones 2010; Tacconella and Cataldo 2008). These types of microbes are most prevalent in buccal abscesses. Although these NIs are seen in adults, pediatric patients are at greatest risk.

Blood-related NI has been most commonly associated with coagulase-negative staphylococci, enterococci, fungi, *Enterobacter* spp., and *Pseudomonas* (Japoni et al. 2009; Curtis 2008). These infections result from direct and indirect routes. Direct routes involve needlesticks, while indirect transmission can occur through breaks in the skin. The biggest hazard with these infections is antibiotic resistance, especially if the patient is immune suppressed (Karam and Heffner 2000).

ROUTES AND SOURCES OF INFECTION

Traditionally, the primary route or source of infection for NIs is a surface or structure. Surfaces or structures become contaminated from patients, visitors, and/or HCWs that are infected or colonized. Microbes are commonly transferred from hands, catheters, intravenous lines, and surgical incisions. Sources of microbial contamination vary and include medical and surgical equipment (Call et al. 2009). Hand washing is considered the cornerstone of infectious disease control and is commonly related to hand hygiene (Bencho and Schejbalova 2006). Although this was first recognized as a form of odor control in 1882 by Labarraque, a French pharmacist, it is now a primary tool in infection control. Not only it is effective in reducing disease rates in health-care settings and as a preventative measure for HCWs, but it is applicable in reducing transmission in environmental settings. Here, frequent hand washing can reduce the rate of infectious disease in the general population. What is commonly forgotten is that visitors and members of a patient's family can contract or become colonized by MDRO that exists at a health-care facility. These groups can also transmit disease to patients and HCWs. Visitors and patients' family members have not been fully recognized as sources of infectious disease and may be of great importance. This may be of a critical nature for those organisms that are transient in nature (e.g., *S. aureus*) and "highly" infectious (e.g., influenza, pertussis).

Hand washing is considered the primary method of preventing NIs and has been recognized as one of the most practical methods of prevention (Bencho and Schejbalova 2006). The biggest problem with this practice is getting everyone to actually wash their hands effectively. To be effective, it is necessary to wash with soap and water vigorously for at least 20–30 seconds. An alternative to this practice is to use an alcohol-based disinfectant (ABD). In many ways, an ABD is easier to use and can be employed almost anywhere. ABDs are now even being placed in schools and public locations. However, the only problem with these disinfectants is that they

are not effective against spore-forming bacteria (Jabbar et al. 2010). This is probably the major limitation of ABDs; however, it is commonly used in health-care settings. To be effective, it is necessary to wash hands for at least 15 seconds while using an ABD (Curtis 2008). Adequate "scrubbing" of the hands does not commonly occur with an ABD, with most, especially HCWs, undertaking only a partial hand-cleaning activity. In many ways, the concept of this type of sanitation as being "effective" even with brief application has become entrenched in the health-care environment and is continually reenforced through these misconceptions. Unfortunately, these misconceptions have now been transferred to the community, where such practices have become a "fact" that really has no scientific basis. When hands are soiled, soap and water cleaning is necessary before using an ABD. It must be emphasized that an ABD will not completely replace soap and water "washing." In many hospitals, in an attempt to reduce NIs, there are continuous training programs on hand washing.

Medicated soap is commonly used for disinfection of the hands (antiseptic and surgical hand wash). Agents frequently used in soaps include chlorhexidine, triclosan, and hexachlorophene. Probably, chlorhexidine is the most commonly used agent and is typically in a concentration of 0.5%–4%. Triclosan is frequently used at a concentration rate of 1%–3%. Hexachlorophene is no longer used since it has been shown to be absorbed through the skin, may affect newborns, and is a potential toxicant (Mancini 2004; Kampf and Kramer 2004). Antibiotic resistance has been reported for chlorhexidine, especially for gram-negative bacteria (e.g., *E. coli*) (Weber, Rutala, and Sickbert-Bennett 2007). Resistance has also been demonstrated for *Candida albicans* along with acquired resistance for *S. aureus*. This agent has also been shown to cause skin irritation (irritative contact dermatitis) and dry skin (Kampf and Kramer 2004).

Tricloran is a phenol-based agent that has been shown to be bacteriostatic at low concentrations. Resistance has been demonstrated for gram-negative bacteria and *S. aureus* (Birosova and Mikulasova 2009; Braoudaki and Hilton 2004; Kampf and Kramer 2004; Russell 2002). This has become a concern since triclosan is commonly added to household cleaning products as an antibacterial agent. Although allergic reactions and irritation have been reported with this agent, such events are uncommon (Kampf and Kramer 2004).

Hand washing can break the chain of organism transfer, but this requires frequent application. Most people do not wash their hands long enough to be highly effective; this has been one of the long-term problems with this form of preventive practice. As was shown by Semmelweis, when hand washing is properly performed, NI rates can be dramatically reduced.

What has to be emphasized in hand washing is its primary importance in disease prevention. This is commonly forgotten, even by those that would be recognized as experts in infectious disease (e.g., microbiologists). Failure to adequately wash hands can spread disease not only to patients but to other HCWs as well. ABD and partial hand washing often create a false sense of security for people, including HCWs. Constant reminders along with demonstrations help enforce the importance of disease prevention mechanisms. Often cultural practices become greater than scientific information and hamper disease prevention, and in many cases, this appears to occur for hand washing. Some of this is due to economic pressures and inadequate time

TABLE 4.3
Terminology Applicable in Controlling Infectious Disease Agents

Sanitization	Activity to reduce the level of microbes that is generally safe for purposes of public health. Microbes will remain but are at low levels.
Disinfection	Destruction (killing) of pathogenic organism, usually those in a vegetative state; however, some microbes will remain. Ideally, this will also destroy spore formers, but this is not always the case. When this practice is directed or applied to living tissue, it is called antisepsis with the chemical/substance/agent being an antiseptic "agent."
Sterilization	Total destruction of microbes. This can be accomplished by autoclaving, as an example. These methods will also kill spores (endospores).

allotted to HCWs to be able to effectively complete tasks. This can be illustrated by the common requirement of health-care providers having the necessity of attending a certain number of patients a day or unit of time. Increased demands often result in shortcuts in activities like hand washing.

There has been discussion about the effectiveness of bar soap as compared to liquid form. Bar soap can be used or shared by many people to wash their hands. It is possible that this could be a source of cross contamination. There have been some literature reports of this potential; however, one published paper suggests that this is a low-to-nonexistent risk (Heinze and Yackovich 1988). A more recent study (Hegde et al. 2006) suggests, on the other hand, that bar soap may be a reservoir for microbes, especially if heavily used. This study's conclusion is that heavily used bar soap can be a source of infection and thus results in the spread of infectious agents. It appears based on these studies (Hegde et al. 2006) that "heavy" use is an important factor for "contamination." Thus, there is potential in a large workplace for soap to be a source of contamination; there, bar soap would not be a good method of disinfection. The best form of soap would be in a liquid form. Agents have been described as to how well they "inhibit" microbes and are generally categorized into three groups (Table 4.3).

PREVENTION OF NOSOCOMIAL INFECTIONS

The two primary routes of exposure to infectious diseases that are of concern for HCWs are related to fomites (including, in this discussion, direct contact with people) and airborne transmission although cuts/injection (e.g., needlesticks) is also commonly mentioned. Both of these routes can be initiated by a carrier. The most effective method for eliminating microbes is sterilization. This generally involves the use of moist heat, that is, 15 pounds of pressure per square inch (psi) for 15 minutes at 121°C. Although these practices are of great importance, one of the most critical is hand washing. There are

other routes that can be of importance. Waterborne organisms can be of concern in certain circumstances, such as with the organism *Legionella*. Overall, this route is of lower importance in health care as compared to public health. Controlling fomite transmission involves cleaning surfaces and "items" and taking universal precautions. Almost anything can serve as a reservoir or be contaminated, including curtains and medical instruments and devices (Gastmeier et al. 2003). Infectious disease agents associated with fomites can be controlled through disinfection and sterilization. In many cases, sanitization is performed, although some will categorize this as disinfection (Table 4.3).

Airborne transmission is more difficult to prevent for HCWs and generally involves the application of respirators; however, it has been shown that adjustment of airflow and use of preventative methods such as UV light can be effective in reducing the transmission of airborne microorganisms (Conroy et al. 2010). Reports have shown that respirators are effective in reducing the rate of infectious airborne diseases (Lange 2003). These reports suggest that to obtain such effectiveness the respirator must include a high-efficiency particulate air filter (Lange 2003). Failure by the HCI to fully recognize how important these preventative practices are has allowed a continuation in the status quo and has thus maintained current levels of NIs in these facilities. Basic measures will greatly reduce the rate of NIs in health-care settings but until recently were mostly given priority in words and not in a practical way. Historically, hospitals were paid to treat all infections, including those that were nosocomial in nature; thus, there existed little incentive to prevent what would they would ultimately be paid to treat. From this scenario, health-care providers were actually rewarded for more NIs. However, this was not advantageous for patients that experience or succumb to such infections. Therefore, there was little reward for aggressively preventing NIs. This scenario is now changing in that there is a decreased incentive through lower or no reimbursement for those infections that are nosocomial in nature (Brown, Doloresco, and Mylotte 2009). Hand washing has been considered the most fundamental mechanism for preventing disease transmission, including those that are nosocomial-related (Bencho and Schejbalova 2006). This practice is commonly forgotten by HCWs and the general public and requires frequent relearning at all levels. The concept of infectious disease was first suggested by Alī Sīnā Balkhi (c980–1037), who presented the idea of contagious disease, and again later by Fracastoro in about 1546. From this, others considered that there was some microscopic agent that entered the body and caused disease although the miasmatic theory remained.

There were numerous indications (observational and experimental) that the miasmatic theory was not correct. In some ways, this started with Antoni van Leeuwenhoek (1632–1723), who observed various types of microbes. During this time period, it was realized that various microbes existed, but the relationship of these newly discovered organisms was not associated with disease. It would not be for another 200 years that the association was established by Louis Pasteur around 1864. The association of infectious agents was noted in silkworms by Agostino Bassi around 1835 but was not extended to human disease. This idea of the germ theory of disease was incorporated into aseptic practice by Joseph Lister through the use of disinfectants in preventing surgical infections. It has to be questioned today, "Are there other unknown 'microbes' or entities that are causing disease but not

recognized?" The discovery of prions and the existence of transmittal cancer, as seen in the Tasmanian devil, should encourage continued thought into such possibilities.

Since most NIs in hospitals are associated with the urinary tract, catheters should be employed only when necessary. Catheters should not be employed longer than required and should be removed as soon as possible (WHO 2002). Practices of this nature can reduce the rate of these infections by 40% (Curtis 2008). Hand washing is also important in these infections and may be the cause of up to 15% of NI events.

Employment of proper cleaning practices has been shown to significantly reduce the risk of NI (Woodland et al. 2010; Huang, Datta, and Platt 2006). Evaluation of effectiveness has been performed using a fluorescent marker solution technique (Carling et al. 2008). This study evaluated 13,369 surfaces and found that on average, there was only 49% effectiveness in cleaning standardized surfaces, with less than 30% effectiveness for more critical surfaces (e.g., toilet hand holds, bedpans cleaners, room door knobs). However, even vigorous cleaning twice a day has not been shown to be effective in reducing the rates of UTIs. In general, one of the identified problems is that hospital cleaning personnel receive little or no training on good cleaning practices. The most effective method, overall, for preventing NIs is effective hand washing. However, even with effective hand washing, more effective cleaning practices are needed (Podnos et al. 2001).

It has been shown that application of silver/alloy/silver hydrogel-tipped catheters is effective in reducing the number of infections. This metal alloy has been suggested to be effective in both short- and long-term applications. What is of importance is that none of the bacteria or fungi associated with these devices has acquired resistance to sliver (Curtis 2008). However, resistance to silver has been shown to occur on a frequent basis with some strains of MRSA, suggesting such events are possible (Loh et al. 2009; Percival, Bowler, and Russell 2005). Catheters coated with nitrofurazone have also been reported to be effective in reducing urinary NI. One of the most effective practices in preventing catheter-related infections is early removal and good cleaning, especially in the urinary meatus area (end opening of the penis), which has been suggested to be a major contributor of infection (Curtis 2008).

For blood-related infections, the application of barrier systems, such as gloves, gowns, masks, and drapes, has been shown to be effective in reducing NI (Curtis 2008; Forbes 2008; Slaughter et al. 1996). Certainly, this was the purpose of establishing universal precautions and blood-borne protection rules. Multiple barriers have been shown to be more effective than just gloves alone. Although the initial cost of these barriers is greater than gloves alone, when these costs are evaluated against the number of additional NIs, these practices are cost-effective and prudent. Central venous catheters (CVCs) are placed at numerous locations for administration of fluids into the blood system. It has been shown that application into the subclavian (shoulder location) results in a lower rate of NIs. When antiseptic chlorhexidine solutions are used on the area of application, rates of NIs become even lower, especially when compared to other practices (Curtis 2008). The employment of multiple preventive practices at the same time, which is termed "blunting," has been suggested to be the best strategy in reducing CVC-related infections. In one study, using blunting practices resulted in a change from 7.7/1000 CVC-related blood infections to 1.4/1000 (Curtis 2008).

Most of the NIs related to the respiratory system involve the use of ventilators (Koenig and Truwit 2006; Vincent 2004). Practices that have been commonly employed to reduce ventilator-related nosocomial infections (VRNIs) include application of nontracheal methods whenever possible, putting the patients in a semierect position so they have a less chance of aspiration, application of "kinetic bed therapy," employment of "subglottic secretion drainage," use of moisture and heat exchangers rather than humidifiers that are heated, use of chlorhexidine for oral decontamination, and employing enteral feeding instead of parenteral (Curtis 2008). When these practices are used along with education programs, VRNI rates can be reduced by almost half (8.75 to 4.75/1000 "ventilator days") (Babcock et al. 2004).

For surgery, there are numerous factors related to NIs (Xu et al. 2010). There are higher rates of infection when surgical procedures take more than 2 hours. Scrubbing for surgery also appears to be a risk since in some cases this is inadequate. Historically, patients were shaved for procedures, but now it appears that clipping hair is better because it does not leave small nicks in the skin. Although traditionally antiseptics (i.e., iodine, chlorhexidine) were used in the preparation (cleaning) of sites for surgery, studies have found that bathing with soap and water is slightly more effective (Curtis 2008; Webster and Osberne 2006). Warming patients before surgery has also been reported to be effective in reducing NI. This appears to be due to better circulation and likely results in an increased effectiveness of the immune system (Curtis 2008).

HEPATITIS

One hazard for HCWs is needlesticks, and from this comes the risk of hepatitis, although transmission has occurred through other routes (Perry, Pearson, and Jagger 2006). Hepatitis can be transmitted through various routes, including oral–fecal (hepatitis A [HAV]), sexual (hepatitis B [HBV]), and blood-borne (hepatitis B and C). Currently, there is a vaccination for hepatitis B but not C. Fundamentally, the difficultly with hepatitis C (HCV) vaccine development is that there are numerous genotypes (at least six) and the virus has a high rate of mutation. Although a virus will retain its genotype, there is enough mutation to confuse any immune response that would be developed through vaccination. In addition, until recently, there has not been an effective model available to study HCV for vaccine development. The lack of a model has also greatly hampered investigation into vaccine research for HCV, although other approaches are being investigated (e.g., DNA vaccines) (Yu and Chiang 2010). These viruses have some resistance to environmental conditions, with hepatitis C probably the most sensitive and hepatitis A the most resistant. As a general rule, these viruses can survive in the environment for a few hours to a day or so. There are other hepatitis viruses as well, although they have not been commonly discussed in regard to HCWs. However, these organisms overall are of great importance to patients and contribute to disease.

The incidence of HBV has dropped in the United States from about 14/100,000 in the mid-1980s to around 3/100,000 in 1998. However, the number of people infected is around 1.25 million, making this a common chronic disease (Lin and Kirchner 2004). HBV is a member of the Hepadnaviridae family, with the entire virion called

the Dane particle. Vaccination for HBV consists of a three-injection series that induce seroconversion in 95% of children and 90% of adults. For those not responding, revaccination will result in 30%–50% of this population seroconverting (Lin and Kirchner 2004). Administration of this vaccine is through intramuscular injection with the second and third administered 1–6 months after the first. Ideally, injections should be about a month apart. There are various groups at risk to these viruses in a health-care setting. Generally, they can be categorized as perinatal, children/adults, chronically ill, and HCWs. Risk of horizontal infection during adulthood is less than 5% (Zhang and Zhang 2010).

For hepatitis B and C, the risks for HCWs are mostly related to needlesticks, especially hollow-bore needles. This commonly occurs during recapping of needles (Salehi and Garner 2010). It has also been suggested that blood-borne exposures are underreported by possibly fourfold (Goob et al. 1999). This alone suggests that the risk is greater than traditionally considered. Goob et al. (1999) reported that 4.4%, 4.4%, and 7.1% of patients in their study were positive for HIV, hepatitis B, and hepatitis C, respectively. Puro, Petrosillo, and Ippolito (1995) found that for blood-borne injuries, 51% were from hollow-bore needlesticks, 16% from sutures needles, 13% from sharp objects, and 19.5% resulted from skin contamination. Out of this group (646 injuries) there were four HCV seroconversions, which made up 1.2% of the events. Friedland and Klein (1987) reported the rate of seroconversion after accidental percutaneous exposure to HBV and HIV to be 12%–17% and 0.03%–0.09%, respectively. However, today a higher percentage of people would be vaccinated for hepatitis B (Simard et al. 2007; Dannetun et al. 2006). This is supported in a recent finding that there were no HCWs seroconverting for HBV in 449 events of exposure to blood-borne pathogens (Kuruuzum et al. 2008). More recently for HCV, an Italian study of 4403 exposed HCWs observed 14 that seroconverted (0.31%, confidence interval [CI], 0.15–0.48 [HCV]) after accidental contact with "hollow-bore blood-filled needles" (De Carli et al. 2003). This investigation suggested that the highest risk is associated with deep injuries. Variation in rates for HBV may be related to the increase in those receiving HBV vaccination. Such preventative practices are effective in reducing transmission of disease to HCWs. Although clusters of HBV cases have been reported, especially historical transmission from HCWs to patients, this does not appear to be frequently occurring, at least in the United States (Gostin 2000). There have been cases reported in which transmission occurred among patients, most notability in hemodialysis, especially through shared medical equipment.

Overall, hepatitis C is not considered to be effectively transmitted by needlestick in comparison with hepatitis B. However, with the increased rate of vaccination against the hepatitis B virus, seroconversion for those with a needlestick has dramatically decreased, at least for relative numbers (Lanphear 1997). Overall, this suggests that at least for hepatitis, the major risk exists from HCV today (Michelin and Henderson 2010). However, as mentioned, other infectious agents can be transmitted in blood and fluid (e.g., HIV) and exhibit a risk. Traditionally, these risks were evaluated for HCWs, but anyone handling sharps, including those associated with disposal, can be at risk. As risks shift, there will be a greater urgency for a hepatitis C vaccine.

NUTRITION AND PROBIOTICS

Many patients in hospitals, especially long-term facilities, are malnourished (Kubrak and Jensen 2007). Kubrak and Jensen (2007) reported that for hospitalized patients, 13%–78% suffer some form of malnutrition. This rate is even higher in the elderly, and has been reported to be 42%–91% (Kubrak and Jensen 2007). Based on this study, malnutrition is a major risk factor for infection, especially associated with acute illness. One factor causing nutritional problems is the inability to eat on a regular basis by the oral route.

Probiotics are microbes that are intentionally taken for purposes of colonizing the GI tract, especially in adhering to the mucosal surfaces (Isakow, Morrow, and Kollef 2007). There is no one microbe that serves all beneficial aspects, but a variety confer positive characteristics. One purpose of these organisms is to out-complete pathogens and prevent occurrence of infections and colonization and to "metabolize" nutrients. The most acute situations in the GI tract, especially for patients, are those that have result from long-term antibiotic therapy. Beneficial microbes not only act through their microbial ecology in the gut but also provide vitamins (vitamin K), protection against allergies and ulcerative colitis, and the breakdown of nutrients (Isakow, Morrow, and Kollef 2007).

Adding to nutritional problems are infections associated with the GI tract, most notably *Clostridium difficle* and VRE (Gorkiewicz 2009; Raja et al. 2005). Administration of probiotic bacteria can assist in the treatment and prevention of these NIs, especially if the patient is being treated with antibiotics (McFarland 2011). Treatment with active yogurt, *Saccharomyces boulardii*, *Lactobacillus* spp., and *Bididobacterium* spp., has been shown to lessen and reduce nosocomial GI-related disease events. If the patient is taking antibiotics, administration of probiotics has been suggested to reduce the incidence of diarrhea (Isakow, Morrow, and Kollef 2007). However, data are limited on the effectiveness because of the lack of applicable clinical trials. Small trials have shown probiotics to be safe and effective as preventive agents. Probiotics have been suggested to be most effective for preventing *C. difficile* diarrhea–related events. Having a *C. difficile* infection has been suggested to increase mortality by 10%–30% (Rohda, Bartolini, and Jones 2009).

Human flora plays multiple roles in providing protection. A healthy flora provides a defensive barrier against pathogens and virulent opportunistic organisms. Flora has been shown to be important for maintaining and developing immune function, the integrity of the system, digestion, metabolism, and in controlling inflammatory mediators. Colonization or infection by pathogens can alter these conditions, with antibiotic therapy damaging the normal flora. Antibiotics, especially those that are broad spectrum, contribute to the overgrowth and expansion of pathogens (Rohda, Bartolini, and Jones 2009).

Antibiotic-associated diarrhea occurs when an imbalance in the normal flora develops. There are a number of microbes that are associated with diarrhea, including *Pseudomembranous colitis*, *Clostridium perfrigens*, *S. aureus*, *Candida* spp., *Salmonella* spp., *Klebsiella oxytoca*, and *C. difficile* (Gorkiewicz 2009; Ayyagari, Agarwal, and Garg 2003). However, the most important pathogenic organism appears to be *C. difficile*. One study (Ayyagari, Agarwal, and Garg 2003) reported

that over 25% of all antibiotic-associated diarrheas were due to *C. difficile*. In the United States, this organism causes infections in about 1.2% of all patients, with an increased health cost of over $1 billion (Isakow et al. 2007). This NI has become of even greater concern with the occurrence of outbreaks in hospitals. In Quebec, an outbreak resulted in an absolute mortality for those greater than 90 years of age of 14%. Even after treatment, it has been shown that this organism has a relapse rate of about 15% (Mylonakis, Ryan, and Calderwood 2001).

CONCLUSION

NIs are becoming of greater concern in the HCI and general community. These types of infections are of concern because of an increase in their rates and a higher number of MDROs. It appears that the rate of NI will continue to increase in the future and will further spread in the community environment. For the HCI, the costs associated with these infections are now becoming critical, and NIs are a major issue in cost containment.

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5 No More Preventable Deaths

Hospital-Acquired Infections in Canada and One Union's Campaign to Stop Them

Jonah Gindin and Michael Hurley

CONTENTS

Measuring the Effect of Enhanced Cleaning

Researchers from East Kilbride, Glasgow, UK, recently presented their results of a study saying that only one extra cleaner in a hospital working Monday to Friday can reduce the number of methicillin-resistant *Staphylococcus aureus* (MRSA) infections.

The study, presented at the European Congress of Clinical Microbiology and Infectious Diseases, aimed to evaluate the effect of one extra cleaner using microbiological standards based on aerobic colony counts and the presence of *S. aureus* including MRSA.

The team of researchers introduced one extra cleaner into two matched wards from Monday to Friday, with each ward receiving extra cleaning for 6 months in a crossover design. Ten hand-touch sites on both wards were screened weekly using standardized methods and patients were monitored for MRSA infection throughout the year-long study. Patient and environmental MRSA isolates were characterized using molecular methods in order to investigate temporal and clonal relationships.

Results: Enhanced cleaning was associated with a 32.5% reduction in levels of microbial contamination at hand-touch sites when wards received enhanced cleaning ($p < 0.0001$: 95% CI 20.2%, 42.9%). There was little effect on environmental MRSA/*S. aureus*. Near-patient sites (lockers, overbed tables, and beds) were more frequently contaminated with MRSA/*S. aureus* than sites further from the patient ($p = 0.065$). Genotyping identified indistinguishable strains from both hand-touch sites and patients. There was a 26.6% reduction in new MRSA infections on the wards receiving extra cleaning, despite higher MRSA patient-days and bed occupancy rates during enhanced cleaning periods ($p = 0.032$: 95% CI 7.7%, 92.3%). Adjusting for MRSA patient-days, and based upon nine new MRSA infections seen during routine cleaning, we expected 13 new infections during enhanced cleaning periods rather than the four that actually occurred. Clusters of new MRSA infections were identified 2–4 weeks after the cleaner left both wards. Enhanced cleaning potentially saved the hospital up to £70,000.

Conclusion: Introducing one extra cleaner working Monday to Friday produced a measurable effect on the clinical environment, with apparent benefit to patients regarding MRSA infection. MRSA strains originally identified from hand-touch sites were later found in patients. There is scope for further research on hospital cleaning as a cost-effective component in the control of hospital-acquired infection.

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A truck pulls a trailer with "Report Hospital-Acquired Infections—Call 1-888-599-0770" emblazoned on the side through beautiful and sparsely populated northern Ontario. This 8000 mile, 15-community trek is another leg of a 7-year campaign, which calls for systemic changes to Ontario's health-care system in order to drive hospital-acquired infection (HAI) death rates down. Inside the trailer is a theater set of a hospital room.

This stage of the campaign will visit isolated communities as small as Hornepayne (population 360) and Richard's Landing (population 600). Everywhere the tour touches down it catches attention and earned media, thanks to interest in a leading cause of death, a compelling narrative, and a visually interesting display. In every community, the campaign also touches the hearts of people personally affected by the tragedy of the death or illness of a family member that was perhaps preventable.

When the trailer arrives in a community, the three hospital workers on tour with the portable room set it up. When erected, the hospital room set is complete with two walls, a door, and a floor and is equipped with a hospital bed, bedside tables, and electronic equipment. It is this backdrop that catches the interest of the media and allows the campaign to reach a wide audience.

One person is designated to follow up on media advisories—sometimes by satellite phone—calling and visiting local media and inviting them to the demonstration. If the media are too stretched to participate, often the case with downsized newsrooms, the hospital workers will write up their presentation and send photos. Inevitably there is coverage. In smaller communities, the story and photo are often on the front page. Photographers and videographers are particularly drawn to the display.

The presentation involves a nurse talking about antibiotic-resistant bugs such as MRSA, vancomycin-resistant enterococci (VRE), and *Clostridium difficile*—what they are, how virulent they are, how they can be killed, and five key demands of government that, if acted on, would significantly drive down HAI-related deaths. A hospital cleaner demonstrates how a room must be cleaned on discharge in order to kill any pathogens.

It takes an hour to set up the display and another to take it down. Then the teams get into their vehicle for an 8- or 10-hour drive to the next community. The hospital room has been used for 150 presentations on HAIs. The northern Ontario tour will be followed 1 month later with a tour of eastern, central, and southern Ontario.

This campaign is being waged by the 30,000-member Ontario Council of Hospital Unions, funded by its parent union, the Canadian Union of Public Employees. It is unique in blending theatre with activism and science. The campaign is dogged. Its operating theory is that change will come through effort spent over many years to change public and media perceptions about HAIs.

THE STATE OF HAIs IN CANADA

HAIs are a serious and growing problem in Canada. They account for significant disease, death, and expense; are distressing to patients and their families; cause loss of wages/productivity; and extend patients' length of stay in hospital. Yet federal and provincial governments have been slow to respond, and in many cases, these governments are pursuing health policies that are actually making the problem worse.

Current rates for Canada of all HAIs and HAI mortality do not exist.[1] The most often cited estimate used a combination of U.S. and Canadian data from the 1980s and 1990s to estimate that HAIs affected 220,000 Canadians, cost the health system $1 billion, and caused 8,000–12,000 deaths.[2] A 2002 study by Canada's public health agency found an overall prevalence of HAIs of 10.5%,[3] which is slightly higher than similar surveys conducted in other countries.[4] Using these figures, we estimate that by 2002 HAIs were affecting 320,000 patients per year, costing nearly $1.5 billion, and killing between 12,000 and 18,000 people. That makes HAIs the third leading cause of death in Canada, behind only heart disease and cancer.[5]

Studies estimate that up to 70% of HAIs are preventable.[6] Nonetheless, rates of antibiotic-resistant HAIs today are many times more prevalent and many times more deadly than they were 10 years ago. MRSA increased threefold between 2001 and 2009,[7] VRE increased tenfold in the same period,[8] and mortality resulting from *C. difficile* quadrupled between 1997 and 2005.[9]

THE COST OF HAIs

In addition to causing significant pain and suffering, disability, and sometimes death, HAIs are a direct financial burden on the health-care system. Studies estimate that HAIs increase the cost per patient anywhere from $1,909 to $38,656 and increase length of stay in the hospital by 4.3–15.6 days.[10]

Between the late 1990s and 2009, the cost of treating MRSA rose from approximately $40 million to nearly $340 million.[11] The trend with VRE is the same, with treatment costs rising from $32 million to $460 million by 2009.[12] Given that the cost of treating MRSA and VRE is almost $1 billion today, despite only representing a small proportion of all HAIs,[13] the cost to Canada's health system is certainly in the billions. This need not be the case. There is a substantial literature detailing the cost-effectiveness of HAI prevention.[14] One 2006 study calculates the cost of preventing MRSA to be less than $20 per case prevented.[15] By this estimate, the cost of preventing MRSA is less than 1% of the cost of treating it.

Despite the enormous cost-benefit of preventing HAIs, to date the political will to do so has not prevailed in government. Instead, key elements of infection prevention and control in hospitals have actually been cut back as hospitals and health ministries look to reduce health-care costs, at the expense of quality care.

In the wake of the 2004 SARS epidemic in Ontario, which killed dozens and affected hundreds of patients and health-care workers, the Ontario Ministry of Health convened an expert panel on SARS and infectious disease control. The panel identified providing proper resources as essential to infection prevention and control.[16] Ontario's best practices guidelines for infection prevention and control echo the SARS panel's emphasis on resources.[17] Yet a 2005 study found that hospitals in Ontario and across the country "continue to fall short of expert recommendations with respect to the intensity of surveillance and control activities and infection control program human resources."[18] Why are we underfunding infection prevention when we have seen the devastating consequences? What is driving Canada's health policy if not "first, do no harm"?

Increasingly, it appears the answer to that question is cost saving. This is a direct result of the increasing reach of markets into public services, known as neoliberalism. Neoliberalism sees the role of government as limited to facilitating the smooth operation of private markets. In other words, governments should not be taxing citizens and then spending that money on public services for the benefit of everyone. They should butt out, and let the market decide who gets what and how.[19]

As the neoliberal project has been applied to health care, it has shifted the orientation from quality-of-care to financial "rationalization."[20] Emphasizing "efficiency" and "value-for-money," the logic of this system is rarely questioned despite growing evidence that running hospitals as corporations has negatively impacted patient outcomes.[21] This should come as no surprise to us, for as Bayle and Cal point out, "the marketplace has no interest in looking after the health problems of citizens, but rather only in assuring the profitability of its investments."[22] Predictably then, cuts to nursing hours have been shown to increase mortality (by as much as 7% per patient added to a nurse's workload),[23] cost-saving reductions in length of stay have increased adverse events,[24] and cuts to beds and cleaning budgets have increased the spread of HAIs.

OVERCROWDING: PAVING THE WAY FOR INFECTION

In 2009, the Organization for Economic Cooperation and Development (OECD) noted that since 1995, the number of acute care hospital beds in OECD countries has decreased on average from 4.7 per 1000 population to 3.8. In Canada, the change

has been more dramatic. In 1986, Canada had 6.6 hospital beds per 1000 people. By 1995, however, the number of beds had decreased to 4.1, and today that number has fallen further to 2.7, making Canada one of the bottom five countries.[25] So fewer beds per person means that hospital occupancy rates are very high, which leads to overcrowding. Of all 30 countries in the OECD, Canada has the highest occupancy rate, at 89%.[26]

Ontario's trajectory mirrors the national trend. In 1990, Ontario had 50,000 hospital beds staffed and in operation, but throughout the 1990s and 2000s, provincial governments steadily slashed beds, leaving just 30,000 today.[27] That is a cumulative cut of 38% in 20 years. Over the same period, Ontario's population has grown by 28%.[28] While in 1986 Ontario had 5.4 beds per 1000 population, today there are just 2.4—less than half that number—and the fewest hospital beds per person of any province in Canada.[29]

With no accompanying surge in healthfulness to reduce the need for beds, hospitals are often operating over capacity right across the country. "We're often over [capacity] in many facilities," says Dr. Bonnie Henry, a specialist at the British Columbia Centre for Disease Control, "and I think that's a contributing factor for a lot of issues, particularly when you get things like *C. difficile* outbreaks." Reducing overcrowding would be "the single most important thing we could do to prevent infections in health-care facilities," she says.[30]

The literature linking hospital overcrowding and HAI transmission supports this assertion.[31] Kaier et al. show that the incidence of *C. difficile* correlates directly with high occupancy rates.[32] Orendi argues that if hospital occupancy rates could be kept below 82%, "most health-care-associated infections currently seen would be prevented, including those caused by MRSA and *Clostridium difficile*."[33] In a study of MRSA rates in Northern Ireland, Cunningham et al. conclude that "the problem of MRSA cross-infection is related to overcrowding and rapid turnover of patients in acute settings."[34]

Not only does overcrowding lead to higher HAI transmission directly, it also undermines infection control practices such as hand hygiene, patient cohorting (grouping infected patients together to avoid cross-contamination), and environmental cleaning.[35] HAI outbreaks, in turn, have been shown to extend patients' length of stay, further increasing overcrowding and leading to a vicious cycle.[36]

In Ontario, the cost of hospital overcrowding has become devastatingly clear. In May 2006, Joseph Brant Memorial Hospital (JBMH) in Burlington, Ontario saw the number of cases of *C. difficile* jump threefold. The hospital's attempts to contain the outbreak failed. They also failed to acknowledge the outbreak publicly until October 2007—nearly a year and a half after it began. In November 2007, JBMH finally hired an external infection prevention and control team to investigate. By the time the outbreak abated in April 2008, over 91 people had died, 76 of them "directly," "strongly," or "likely" as a result of acquiring *C. difficile* in the hospital.[37]

In a private report by the external infection control team, obtained through the Freedom of Information and Protection of Privacy Act, occupancy rates are listed as one of the primary causes contributing to the outbreak.[38] According to the report, "JBMH often operates at 105 per cent capacity … [which has] likely contributed to the perpetuation of the CDAD outbreak by creating an environment of constant

overcrowding."[39] HAI outbreaks of this magnitude "require time and financial resources to address."[40]

In outbreak scenarios, once the damage has been done, hospitals often receive emergency funding from government to bring HAI levels back down to "acceptable" rates, before this funding evaporates again. But preventing the significant suffering and death caused by HAIs necessitates a systemic solution. The responsibility for HAI prevention rests ultimately with governments, who must provide funding for adequate numbers of acute beds and adequate nursing staff to accommodate unforeseen fluctuations in patient load.[41]

SWEEPING HAIs UNDER THE RUG? THE IMPORTANCE OF ENVIRONMENTAL CLEANING

Environmental cleaning is another key component to infection prevention and control and another victim of health-care cuts. The literature demonstrates that infectious agents can survive in the hospital environment,[42] that these infectious agents can be transferred from the environment to hands,[43] that exposure to a contaminated environment is associated with colonization,[44] and that environmental cleaning can reduce the risk of infection.[45]

One recent study specifically examined the problem of VRE contamination of the hospital environment with the objective of discovering whether persistent contamination was the fault of cleaning personnel, products, or procedures.[46] The study found that "surface contamination with VRE is due to a failure to clean rather than to faulty cleaning methods or products."[47] This "failure to clean" is a direct result of cuts, leaving hospital cleaners understaffed, without proper equipment or sufficient training.[48]

The consequences of underresourcing hospital housekeeping came to the fore in Canada during an inquest into the deaths of 16 patients at a Quebec hospital in 2006. An outbreak of *C. difficile* at Honoré Mercier Hospital in Saint Hyacinthe, Quebec, resulted in 16 patient deaths.[49] In her report, coroner Catherine Rudel-Tessier notes, "The way to avoid an outbreak is to prioritize cleanliness and hygienic measures in every facility … Those charged with preventing and controlling infections must have the personnel and the resources necessary to do their job."[50] Yet as Rudel-Tessier notes, Honoré Mercier reportedly had understaffed housekeeping for some time prior to the outbreak. "As of January 2005, it was shown that cleaning was not always done between the departure of one patient and the arrival of another patient," a recipe for infection transmission.[51] According to the coroner, "Honoré Mercier Hospital lacks the necessary resources for preventing and controlling infections," and operates "in a context where there is a staff shortage for the workload at every turn."[52] The outbreak was only contained when the hospital hired an additional 10 cleaners to contain the outbreak and prevent further transmission.[53]

Yet, despite instructive cases like Honoré Mercier, politicians and hospital management continue to downplay the importance of hospital cleaning, viewing it instead as a source of potential cost savings. Shortly after the SARS outbreak, George Smitherman, then the minister of health for Ontario, suggested hospital cleaners should be paid the same as hotel or bank cleaners, saying "just because it's

a public health-care system doesn't mean that we … should expect to pay more to sweep the floor in a hospital."[54] Gordon Campbell, then-Premier of British Columbia, agreed, complaining of "rigid union contracts [put] ahead of patient care." The solution according to Campbell's government was to "increase flexibility, and enable tendering of contracts."[55]

Blaming unionized public-sector workers for service cuts has a long pedigree in Canada, and elsewhere. As health ministries try to control health-care spending (without stepping on the toes of pharmaceutical companies, for example),[56] hospital support workers have become a favorite target. They are generally the lowest-paid health-care workers, a majority are women, and they are frequently workers of color.[57] "The cleaning function is at the bottom of the hospital hierarchy," notes Karen Messing in "Hospital Trash: Cleaners Speak of Their Role in Disease Prevention" (1998). "The perceived distance of cleaning (along with laundry and food services) from the central mission of hospitals is shown by the fact that these services are increasingly subcontracted out."[58] The result is that a major pillar of infection prevention and control in hospitals is being eroded. And as more and more hospitals look to outsource their cleaners as a cost-saving measure, the problem is only getting worse.

In British Columbia in 2003, the government of Gordon Campbell unilaterally removed job security and no-contracting-out provisions from the collective agreements of hospital support workers. Less than a year later, over 8500 unionized hospital support jobs had been lost.[59] Since 2003, the proportion of cleaning budgets in British Columbia diverted to private contractors has jumped from 3% to 60%.[60] Privatization nearly halved wages for British Columbia hospital cleaners, rolling them back to pre-1968 levels.[61] Those working for private contractors are now the lowest-paid health services support workers in all of Canada, earning 26% below the national average.[62]

Two case studies of the British Columbia experience have captured the danger that outsourcing poses to patients. Both studies found that privatization of hospital cleaning services has resulted in a precipitous decline in working conditions, chronic understaffing, insufficient cleaning materials, insufficient training, and high turnover. In a study by Stinson et al. (2005), 75% of participants reported having been understaffed in the previous month and 38% reported always being understaffed.[63] Over one-third of surveyed cleaners regularly performed work for which they were not trained.[64] Many contractors reported they were specifically advised by management to avoid contact with patients and other hospital staff.[65] In an indication of how far some private companies will go to maximize their profits, participants in the Stinson study reported being limited to one pair of disposable gloves per shift.[66] This violates common sense, never mind best practices, as it increases the likelihood that cleaners will spread pathogens from one part of the hospital to another.

Zuberi and Ptashnick (2011) also found a high turnover of cleaners and supervisors as a result of privatization.[67] Chronic understaffing was endemic, with over two-thirds of interviewed workers reporting there were insufficient staff to provide adequate quality of service.[68] Understaffing contributes to overwork, which in turn results in a higher incidence of workplace injuries. Low wages, the existing danger

of the work (exposure to infection, sharps, biohazards, etc.), and the additional risk of injury as a result of overwork have resulted in high turnover and chronic labor shortages.[69] Forcing cleaners to rush to complete the work of two to three people often results in a reduction of quality, leading to an increased risk of disease transmission through the environment.[70] Zuberi and Ptashnick also found that privatized cleaners were often assigned tasks for which they had not been trained and that training was reported to be minimal, often occurring "on the job."[71]

High turnover of health-care workers and fragmentation of previously integrated hospital ward teams have been shown to be highly detrimental to quality of care, leading to increased HAI transmission.[72] The above studies conclude that contracting-out of hospital cleaning has undermined quality, with serious implications for occupational and patient safety, in particular, the transmission of HAIs through the environment.

The experience of one Vancouver Island hospital serves to further illustrate the deadly consequences of outsourcing and underresourcing hospital cleaning. In the summer of 2008, the Nanaimo General Regional Hospital (NGRH) experienced an explosive outbreak of *C. difficile*. The Vancouver Island Health Authority (VIHA) failed to advise the public of the outbreak, with the *Nanaimo Daily News* reporting that NGRH patients and staff found out about the outbreak by reading the newspaper.[73] Two months after the outbreak began, VIHA requested help from the British Columbia Centre for Disease Control (BCCDC). The BCCDC's investigation found that Compass Group, the private contractor providing housekeeping services to NGRH, failed to provide adequate training to cleaners and sufficient cleaners to meet the agreed standards in the contract or to meet cleaning needs during the outbreak.[74] Most alarmingly, BCCDC investigators discovered that the contractor had provided cleaners with insufficient supplies and training, resulting in overdilution of the bleach (1:1000 instead of 1:10). This diluted cleaning solution was too weak to kill the *C. difficile* bacterium and, according to the investigators, was "clearly a contributing factor to the propagation of the [*C. difficile* infection] CDI outbreak."[75]

Even before calling in the BCCDC investigators, VIHA was apparently aware of the source of the problem, approving additional housekeeping funding in early August to combat the outbreak,[76] but by that time, the damage had been done. Over the course of the epidemic, 64 patients were infected, and 8 died as a result of their infections. Dr. Bonnie Henry of the BCCDC and one of the authors of the NGRH report notes that "the issue really came down to when the cleaning service had changed, the number of hours funded for cleaning had dropped considerably."[77] Echoing the findings in Stinson et al. (2005) and Zuberi and Ptashnick (2011), Dr. Henry says quality is "dependent on the training, the turnover, the amount of hours that are budgeted for staff."[78] In other words, they are exactly those aspects of hospital cleaning that are most detrimentally affected by outsourcing.

Even after the devastating experience at NGRH, Compass Group continued to violate the standards of their contracts. A year later, the Workplace Compensation Board of British Columbia cited Compass Group for eight violations of occupational and patient safety at different hospitals where it held cleaning contracts.[79] In response to the growing public pressure to abandon the incompetent (if not negligent)

Compass Group, VIHA finally relented in 2011. In a gross understatement, VIHA vice president of operations and support Joe Murphy acknowledged, "there's no secret that at times we weren't happy with the consistency and efficiency of the work."[80] In April 2011, VIHA signed a $50 million deal with British Columbia company Marquise to replace Compass Group. But in a grotesque twist, just 2 weeks after the announcement, Compass Group purchased Marquise, clinging on to those valuable contracts.[81] Thanks to the nature of private contracts, VIHA is apparently powerless to affect the quality of cleaning services in their hospitals. The Compass Group experience proves that the claim that outsourcing hospital cleaning does not affect quality is a lie.

Sadly, NGRH is not an isolated case. Since surveillance for MRSA infections began in 1997, the highest single-year increase comes in the Western provinces[82] in 2004–2005, immediately after British Columbia's privatization, when MRSA rates nearly doubled.[83] Since 2003, MRSA rates in the west have rivaled Ontario and Quebec, historically the epicenters of the disease.[84] Similarly, though Ontario had much higher rates of CDI than British Columbia/Alberta from the start of surveillance to 2005, since then British Columbia/Alberta has overtaken Ontario, and in 2008, British Columbia had the highest CDI rates in the country.[85]

THE UNITED KINGDOM

British Columbia's experience with privatization and HAI transmission parallels that of the National Health System (NHS) in the United Kingdom. In comparison to British Columbia's relatively recent experiment with the privatization of hospital cleaning, the United Kingdom made competitive tendering for hospital cleaning contracts mandatory in 1983. The result over the next 20 years was a dramatic decline in cleanliness, coupled with a significant rise in the incidence of HAIs.[86] As noted in the Department of Health's Revised Guidance on Contract Cleaning, "competitive tendering of cleaning services … had the effect of lowering quality standards."[87] In a 2004 assessment of hospital cleanliness by the NHS, results showed that employing private cleaners made a hospital twice as likely to get a "poor" score on cleanliness.[88] In 2008, the Royal College of Nurses called on the government to ban contracting-out of cleaning altogether, calling it dangerous and unsafe.[89]

As a result of public pressure to end the continuing deterioration of hospital cleanliness from contracting-out, the United Kingdom has taken a series of measures (in some cases, half-measures) to improve cleanliness:

- In 2001, competitive tendering was made voluntary (rather than compulsory as it had been before).[90]
- In 2004, the Department of Health acknowledged that privatization of cleaning promoted the lowest common-denominator, stipulating that private contractors must pay the same wages and benefits as in-house cleaners.[91]
- In 2008, the Department of Health earmarked £50 million to "deep clean" every hospital in the NHS.[92]
- According to government figures, the deep clean has resulted in a major reduction in rates of HAIs.[93]

SUCCESSFUL INTERNATIONAL EXAMPLES IN THE FIGHT AGAINST HAIs: THE NETHERLANDS AND SCOTLAND

The Netherlands has much lower rates of MRSA and *C. difficile* than Canada, the United States, or the United Kingdom.[94] In 2007, the Netherlands had a 6.2% prevalence of HAIs overall, much lower than Canada's 2002 rate of 10.5% (which must be even higher by now).[95] One important factor in this difference is the priority that the Netherlands has given to preventing HAIs. Starting in 1988, the Netherlands began implementing a "search and destroy" policy, seeking to identify HAIs, treat them, and disinfect contaminated areas before the infections have a chance to spread.[96]

The search and destroy policy involves strict isolation of patients suspected of carrying HAIs while tests are conducted and rigorous cleaning of the hospital room, including patient touch-sites, after discharge.[97] One study documented the success and cost-effectiveness of the search and destroy policy in a single hospital, concluding that it prevented 36 cases and 10 deaths and saved almost half a million euros.[98] Despite the successes of search and destroy,[99] it has yet to be adopted in Canada.

Another key factor in the Netherlands success is a low occupancy rate. At only 64%, the Netherlands has one of lowest hospital bed occupancy rates of any OECD country.[100] As detailed above, overcrowding in hospitals is a major contributing factor to the spread of HAIs. And again, occupancy rates continue to grow in Canada as more beds are cut every year.[101]

Scotland has also taken HAIs very seriously. In 2007–2008, there was a deadly *C. difficile* outbreak at the Vale of Leven Hospital in Scotland. An independent review of the outbreak concluded that poor hygiene at the hospital was one of the causes of the outbreak.[102] In response to the Vale of Leven outbreak, Scottish Health Secretary Nicola Sturgeon called on hospitals to bring all hospital cleaning back in-house. "I am keen to see the phasing out of existing contract cleaning in hospitals," Sturgeon said, "and I would want to see no more in the future, with cleaning kept in-house."[103]

While the United Kingdom continues to backpedal on contracting-out hospital cleaning without actually reversing course entirely, Scotland, Wales, and Northern Ireland have done just that. Governments in Wales and Northern Ireland have declared their intentions to bring all hospital cleaning back in house.[104] The Scottish government also added 1000 additional hospital cleaners and banned any further privatization. Health Protection Scotland (a division of Scotland's National Health Service) announced that 2010–2011 saw *C. difficile* infections decrease by 37% among patients aged over 65 years and 42% among those aged under 65 years. MRSA infections have also declined by 31%.[105] According to health secretary Sturgeon, improvements to hospital cleaning deserve the credit.[106]

In the same year that Parliament stopped contracting-out cleaners, they also launched the Scottish Patient Safety Programme (SPSP), a nationwide program to reduce inpatient mortality and hospital adverse events. At the program's halfway point, mortality was down 5%, and both *C. difficile* and central line catheter-associated bloodstream infections had dropped 50%.[107] The SPSP seeks to involve 80%–100% of health-care workers.[108] In order to do so, it has used "social-movement

thinking," to understand "what triggers participation and what helps to embed and spread change."[109] The contrast between Scotland and Ontario could not be starker.

WASHING OUR HANDS OF THE PROBLEM

During the outbreak of SARS in Ontario in 2003, many patients and hospital staff contracted the virus in hospital. Forty-four people died.[110] The SARS outbreak underlined the vulnerability of patients and staff to contracting disease in an environment that patients had assumed to be safe. The Ontario Ministry of Health and Long-Term Care (OMHLTC) endangered patients and hospital staff by minimizing necessary precautions and ignoring lessons and best practices from other jurisdictions. While hospital staff in China treating SARS patients wore Stryker suits that completely isolated them from patients, Ontario health-care workers were performing intubations without wearing goggles.[111]

From the vantage point of the chaotic management of the SARS outbreak, hospital staff observed a health system that minimized threat, generally avoided more expensive systemic solutions, and emphasized individual responsibility. As the Ontario Council of Hospital Unions paid more and more attention to HAIs, a pattern of systemic neglect became clear. The campaign "No More Preventable Deaths" began.

In the 10 years leading up to SARS, cuts to beds and cleaners took their toll. While Ontario was becoming the province with the fewest hospital beds per person in Canada, countrywide the proportion of hospital budgets going to cleaning was cut by 5.6%.[112] Given that more than 70% of support service budgets go to staff, these budget cuts translated into significant job losses.

Rather than learning from SARS that the cheapest solution is not necessarily the best one, Canadian governments have approached hospital cleaning as a center for cost reduction. In addition to cuts to cleaning budgets, an increasingly high proportion of hospital spending has been diverted to private contractors. The share of housekeeping spending that went to private contractors between 1999 and 2004 rose from 0.05% to 4.4% in Ontario.[113] While 4.4% is fortunately still much lower than in British Columbia (60%) or Alberta (11%), the trend is clear.

The "No More Preventable Deaths" campaign advocates solutions taken from Coroner's recommendations or from proactive measures implemented in other jurisdictions, including the following:

- Mandatory reporting by hospitals of death rates because of HAIs
- More resources for hospital cleaning and infection control
- An end to the contracting-out of hospital cleaning
- A significant reduction in hospital bed occupancy rates
- An end to the practice of patients sharing rooms and bathrooms

This ongoing campaign has pushed the Ontario government to require hospitals to report HAI rates and to increase infection control resources. But the primary emphasis of the Ontario Ministry of Health remains on individual responsibility: "Just wash your hands."

While other jurisdictions have taken meaningful action—and have dedicated considerable resources—to reduce HAIs as noted above, Ontario's slow progress means that thousands of lives are needlessly lost every year. The campaign will not stop until all of the demands have been met. In the absence of government leadership in Canada and in Ontario in reducing patient harm, all hospital workers have an obligation to current and future patients to campaign aggressively to reduce the death toll from HAIs.

ENDNOTES

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6 Hospital Epidemiology

John H. Lange, Giuseppe Mastrangelo, and Luca Cegolon

CONTENTS

> Medication errors are among the most common medical errors, harming at least 1.5 million people every year, says a new report from the Institute of Medicine of the National Academies. The extra medical costs of treating drug-related injuries occurring in hospitals alone conservatively amount to $3.5 billion a year, and this estimate does not take into account lost wages and productivity or additional health-care costs, the report says.
>
> *http://www.naturalnews.com/020515.html#ixzz1ReFrdpQk*

SUMMARY

Epidemiology is the study of disease occurrence. Today, it includes more than the traditional diseases, such as infectious agents, but extends to events like accidents and diseases from chemical exposures. Those in the health-care industry (HCI) are involved in treatment and care for the sick and injured and, as a result of their occupation, are exposed to various diseases and potential injury. Hospital epidemiology or epidemiology of health-care workers (HCWs) involves the same principles associated with general epidemiology except it focuses on a specific industry. There are some hazards that are somewhat unique for HCWs, such as ethylene oxide, needlesticks, and exposure to blood-borne pathogens. The concept of HCWs was traditionally related to the hospital setting, but today it has expanded into the community. This chapter discusses the general concepts of epidemiology and presents some of the more unique hazards that those in this group may encounter. One of the biggest concerns for a hospital epidemiologist is a nosocomial disease, sometimes called a hospital-acquired infection (HAI). Infectious diseases were at one time considered a problem of the past. However, microbes have adapted to the onslaught of antimicrobials and are developing resistance faster than ever. Historically, these problems were associated with hospitals but have begun to spread into the community and environment and even to patients that are at home. These diseases are becoming of global importance and are now having a major impact on health-care costs.

INTRODUCTION

Epidemiology is often categorized as a basic science of health care and focuses on the occurrence of disease (Timmreck 1998; Lilienfeld and Strolley 1994). An understanding of this subject is necessary for HCWs. Through the study of epidemiology trends, the occurrence and events of disease can be evaluated, along with identification of disease events. Epidemiology is not an investigation of individuals but of a population. Here the population of concern is HCWs; however, this can also be extended to others such as patients and visitors to hospitals and health-care clinics. This environment is HCI and is classified here as hospital epidemiology (HE). Some have also called this subject "health-care epidemiology." Epidemiology provides information in rates so that comparisons can be made with other studies and populations. Often these rates are identified as incidence or prevalence. Incidence is the number of new cases arising over a given period of time, for example a year. Prevalence is the total number of cases in a given time, again, for example, a year.

In clarifying these rates, they can be represented as a relative risk (RR) or in clinical trials as a hazard ratio (HR) (Spruance et al. 2004; Lilienfeld and Strolley 1994).

Historically, HE was related to infectious disease, but today it is shifting and including other areas of health care and related activities of medicine and allied health (Rihn et al. 2005). This has even expanded into the community setting and home environment with the growth of home health care (Gultekin and Huffman 2008), especially with the rise of antibiotic-resistant microbes such as the bacterium *Staphylococcus aureus*. Today, this organism is commonly seen in a resistant form called methicillin-resistant *S. aureus* (MRSA) (Alp et al. 2009). Occurrences of this nature have changed the face of HE (Liang et al. 2011).

There are four "types" of epidemiological studies that can be conducted. These are ecological, cross-sectional, case control, and cohort. In addition, there can be clinical trials. From these studies, information may be in the form of RR or HR. Epidemiology looks at person, place, and time when examining a study. Studies can also be categorized as observational (either analytical or descriptive) or interventional (experimental). Here, for example, descriptive studies can be either of a cross-sectional or ecological design and can be used to assess the occurrence of disease (Hernberg 1992). The simplest form of study is ecological (Checkoway, Pearce, and Crawford-Brown 1989). However, these investigations cannot establish a close causal relationship and may suffer from ecological fallacies (Lange 1991). Cross-sectional studies also cannot provide a close causal relationship; they measure the population at one time (point prevalence) but do not provide an incidence rate. Studies of this nature, along with ecological studies, are useful in generating a hypothesis (Kirkwood and Sterne 2003). Analytical epidemiology can be either case control or cohort, which can be prospective or retrospective in form. The easiest of these is case control providing an odds ratio (OR), while cohort can result in either an OR or an RR in providing the estimate of risk. These studies do have to consider confounders, which influence the outcome and can include activities like smoking, age, race, and sex (Kirkwood and Sterne 2003). Studies control for these common confounders but depending on the study, others may exist (e.g., air pollution). Experimental studies could be represented through clinical trials. Although generally not a major part of HE, they provide much of the basis for medical therapy and some aspects of evidence-based medicine.

Commonly, epidemiology is evaluated through the "epidemiological triangle" (Figure 6.1). This provides a relationship of interaction between the host (here man),

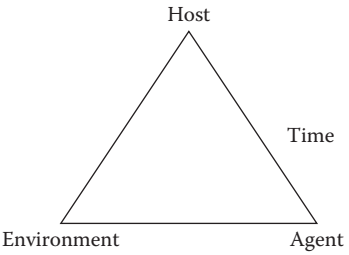

FIGURE 6.1 Epidemiological triangle.

the agent (e.g., disease), and the environment. With this association, there is also time for infectious diseases, called an incubation period. This can be short in time or very lengthy as associated with chronic diseases such as tuberculosis (TB) and hepatitis C (HCV). With the discussion of incubation time, there must also be an understanding of communicability. These concepts become critical in preventing disease and breaking the chain of transmission. This chain consists of the infectious agent, reservoir, portal of entry, means of transmission, portal of exit, and susceptible host. There are some people carrying infections agents that apparently do not result in harm to the host, and these are commonly called carriers. Overall, these ideas are crucial in understanding infectious disease occurrence.

In some cases, the disease may present itself as an outbreak. This can exist in different forms, ranging from worldwide (pandemic), as seen with influenza, to regional events (epidemic), to a local occurrence (endemic). One of the best preventative measures against some commonly occurring outbreaks (e.g., influenza) is vaccination. In most cases, the trend of some diseases can be predicted but can periodically vary, making them in some ways not completely predictable. This was seen with swine flu (H_1N_1) in 2009 where the peak occurred in October (*Mortality Morbidity Weekly Report* [MMWR] 2010). However, for most diseases, as the number of susceptible hosts declines, so will the disease (Hawker et al. 2005). The rate of a disease is dependent on the number of secondary cases from an originally infected person. This reproduction number (R_0) can greatly vary; for example, in the swine flu, it was estimated to be 1.4–1.6 (Liang et al. 2009).

To fully understand epidemiology, it is important to know its history. For epidemiology, there is no actual starting point; however, it can be categorized into different eras (Saracci 2007). Traditionally, this classification consisted of early epidemiology (fifth century BC to 1830), classical (1830 to 1940), and new epidemiology (1940 to present day). However, there may be a fourth category, molecular epidemiology, which may have started in or around 1990 with the advent of molecular applications to this field. In part, this may have occurred concurrently with biological monitoring (Schulte and Perera 1993). The era of molecular biology is commonly said to have started with the work (publications) of Avery, McLeod, and McCarty on bacterial transformation (Avery, MacLeod, and McCarty 1944; Trun and Tempy 2004). Although epidemiological investigations were reported throughout history, a common starting place is with John Snow. He is often considered the father of epidemiology, and his study of cholera is considered a classic investigation. Snow, in 1831–1832, was the first to use rate in evaluating disease occurrence and identified water as one source of cholera. He also provided a solution in ending an outbreak in London by removing the pump handle from a water well that had its source from the Thames River.

Possibly the next major contributor, at least related to HE, was Ignac Phillip Semmelweis around 1847, who is often considered the father of hand washing (Centers for Disease Control and Prevention [CDC] 2002; Bencho and Schejbalova 2006; Bolon 2011). In many ways, this epidemiological investigation established the most basic form of preventive medicine that exists today (i.e., hand washing). These concepts were followed by Louis Pasteur and Robert Koch. This subject continues to evolve even with the changing concept of infectious disease. Today, it is even

suggested that tumors may be an infectious agent; an example of this is the facial tumor outbreak infecting the Tasmanian devil (McCallum 2008). Thus, the landscape of HE is ever changing.

HOSPITAL-ACQUIRED DISEASES

Hospital-acquired diseases (HADs) or HAIs, which are also called nosocomial diseases or infections, have become a common problem in medical settings (Weinstein 1998). These are infections that originate at or within health-care facilities. Traditionally, these infections arose in hospitals and were considered to be primarily a result of overuse and misuse of antibiotics. It has been estimated that nosocomial infections (NIs) were responsible for 88,000 deaths in the United States in 1995 (Weinstein 1998). The most recent report indicates this number has risen to at least 99,000 deaths per year (McFee and Abdelsayed 2009). It has been estimated that about 10% of all hospital patients in the United States contract an NI during their stay. The rate of these infections appears to be increasing, with some suggesting that this is due to shorter hospitalizations and more severe illnesses in patient populations. In 1975, the rate for NIs was 7.2 per 1000 patient days, and this rate rose to 9.8 per 1000 patient days in 1995. In 1995, the cost of these infections was estimated at $4.5 billion (Weinstein 1998). Today, HADs are not limited to hospitals but exist in various types of HCIs.

There are various ways of classifying pathogens, for example, listing them as conventional (classical), conditional, or opportunistic pathogenic organisms. Certainly some microbes fit in more than one of these categories. Classic or traditional pathogens are those that can cause disease in normal healthy people (e.g., *S. aureus*). Conditional pathogens are those that cause disease in patients with reduced resistance or that have given special opportunity to the microbe (e.g., *Clostridium tetani*). Opportunistic organisms are those that take advantage of damaged or diminished resistance or immunity (e.g., *Pneumocystis carinii*). In some ways, these organisms that were not traditional pathogens are now emerging as concerns for patients and HCWs. For example, recently, *Serratia marcescens* was isolated from the hands of HCWs in a neonatal unit and is suspected to have originated from contaminated breast milk (Bayramoglu et al. 2011).

There are a number of reasons why this problem is occurring, with the most important factors being an increased number of compromised patients, a higher prevalence of pathogenic organisms, and an increased effectiveness of pathogen transfer among patients (Weinstein 1998). Nosocomial diseases are generally caused by opportunistic organisms (microbes) and have been mostly related to bacteria. The bacteria that have historically been associated with these infections (i.e., NIs) are *Enterococcus* species (spp.), *Escherichia coli*, *Pseudomonas* spp., and *S. aureus*; however, the diversity of species and strains is dramatically increasing. Today, bacteria are not the only organisms of concern related to nosocomial diseases. For example, fungi have emerged as an important organism in these infections (e.g., *Candida krusei*, which is resistant to azole antifungal agents). At a Brazilian university hospital, it was reported that non-*Candida albicans* infections that were hospital related occurred at a rate of 0.39–0.83 events per 1000

TABLE 6.1
Some Nosocomial Infectious Disease Agents

Organism	Reference
Acinetobacter baumannii (B)	Slama (2008)
Burkholderia cepacia (B)	Lopes, Goulart, and Starling (2007)
Clostridium difficile (B)	Chaudhry et al. (2008)
Group A streptococci (B)	Weinstein (1998)
S. aureus (B)	Weinstein (1998)
Pseudomonas aeruginosa (B)	Weinstein (1998)
Escherichia coli (B)	Weinstein (1998)
Enterobacter spp. (B)	Weinstein (1998)
Enterococcus faecalis (B)	Arias and Murry (2008)
Klebsiella pneumonia (B)	Weinstein (1998)
Candida krusei (F)	Weinstein (1998)
Candida lusitaniae (F)	Weinstein (1998)
Aspergillus spp. (F)	Haiduven (2008)
Fusarium spp. (F)	Peman et al. (2006)
Scedosporium apiospermum (F)	Peman et al. (2006)
Herpes (V)	Weinstein (1998)

B = bacteria; F = fungi; V = virus.

patient days (Girao et al. 2008). Thus, the rate of infections by *C. albicans* would be dramatically higher since studies have reported that this fungus is the most common isolate and the reported rate is only for non-*C. albicans* species (e.g., *C. glabrata*, *C. tropicalis*, *C. parapsilosis*). In an Icelandic study, it was reported that *C. albicans* represents 61.6% of all the fungal infections related to the bloodstream (Asmundsdottir et al. 2008). This study also noted that the highest rates were observed in intensive care units (ICUs). Viruses have also been identified as emerging organisms that can be nosocomial and carry resistance. Herpes virus has been shown to have resistance to acyclovir (Weinstein 1998). Table 6.1 lists some of the organisms that have been identified in the literature as being nosocomial agents.

EXAMPLE MICROBES: REPRESENTATIVES

There are a number of microbes that have emerged as multidrug-resistant organisms (MDROs) and are discussed in the literature and media. These include *S. aureus*, *Acinetobacter*, TB, and enterococci. As mentioned, these are important HAD/HAI agents as well as community or environmentally acquired (Gultekin and Huffman 2008). Certainly, these are not the only organisms of concern, but they provide a basis for discussing some of the problems associated with resistance and NIs. The rise of antibiotic resistance can be identified as an emerging disease.

S. AUREUS

There are more than 20 different species of described in *Bergey's Manual of Systematic Bacteriology*. However, *S. aureus* and to some extent *Staphylococcus epidermidis* are the common pathogens. *S. epidermidis* is a common inhabitant of the normal flora of the skin, gastrointestinal (GI) tract, and oral cavity, while *S. aureus* is found in the nasal passages. It can also be transient at other body locations. Microbiologically, *S. aureus* forms yellow colonies and *S. epidermidis* are commonly white in color. These bacteria are catalase positive and oxidase negative, and *S. aureus* can grow in salt (sodium chloride) concentrations as high as 15%.

S. aureus can cause a number of suppurative (pus-forming) infections and toxinoses. This organism is commonly associated with various infections (Table 6.2). In hospitals, 95% or more of these organisms are resistant to penicillin (MRSA), including the semisynthetic penicillins (e.g., methicillin) (Heymann 2004). *S. aureus* has a number of potential virulence factors. These include surface proteins that allow the organism to colonize the skin and help in the invasion of tissue. When in tissue, other factors allow spread, such as hyaluronidase, an interstitial barrier. *S. aureus* can also make protein A, which prevents phagocytosis and can disrupt immunological "reactions."

Resistance to penicillin in *S. aureus* was first observed in 1947. Later, in 1961, resistance was reported for methicillin in Great Britain. The first case of MRSA in the United States was observed in 1968. This organism is actually resistant to the entire class of penicillin-related antibiotics, which are called beta-lactams. Today, greater than 90% of nosocomial *S. aureus* isolates are resistant to methicillin. This "class" of drugs includes penicillin, methicillin, and oxacillin. In one study (Ali, Abbasi, and Mirza 2007), 42% of *S. aureus* isolates were found to be resistant

TABLE 6.2
Diseases Caused by *S. aureus*

Impetigo
Staphylococcal scalded skin syndrome or Ritter disease
Toxic shock syndrome
Cellulitis
Abscesses
Carbuncle
Bedsores
Septic phlebitis
Sepsis
Endocarditis
Osteomyelitis
Pneumonia
Urinary tract infection
Food poisoning disease
Septic arthritis
Conjunctivitis

to methicillin. Vancomycin-intermediate-resistant *S. aureus* was first observed in 1996 in Japan and later in Great Britain, France, Asia, and Brazil, in patients treated with vancomycin for extended periods. Vancomycin-resistant *S. aureus* emerged in a Michigan patient that had a foot ulcer in 2002. Although this form of resistance is presently unusual, additional cases are beginning to emerge (CDC 2004). Vancomycin-resistance can be transferred from *E. faecalis*, and this resistance is plasmid-borne. Resistance can also be chromosomal. *S. aureus* has been reported to exhibit resistance to antiseptics and disinfectants, including quaternary ammonia (Ioannou, Hanlon, and Denyer 2007). The emergence of such resistance raises many important questions and issues for the HCI and community.

The survival of this organism in the community has been shown to be variable. Outdoors *S. aureus* (on crumb rubber) has a survival time of 3 hours or less, with detergent being highly effective in removal (McNitt and Petrunak 2009). Although some bacteria may remain, natural conditions do not favor survival. During summer conditions, this organism has been shown to survive less than 2 hours in an outdoor environment. There was better survival in the indoor environment, with bacteria detectable after 12 days, however, the concentration was low and may be of little practical importance. Survival was dramatically reduced when treated with antibacterial agents (e.g., detergents). Locations other than health-care facilities are becoming of greater importance, and in some ways, there is limited information concerning these settings (Begier et al. 2004). Transmission of *S. aureus* occurs through contact with a person who has a purulent skin lesion or is an asymptomatic nasal carrier of a pathogenic strain. Hands are reportedly the most important way of transmitting the infection. It has been suggested that 20%–30% of the general population are nasal carriers of coagulase-positive staphylococci (Heymann 2004).

Tuberculosis

What has become of great concern is the spread of multidrug resistance (MDR) and extensively drug-resistant (XDR) TB. MDR TB is identified when the organism is resistant to both isoniazid and rifampicin, which are considered the first-line drugs in the treatment of this disease. XDR TB occurs when the organism is resistant to both the first-line and second-line drugs, which are any of the fluoroquinolones and at least one of the three injectable drugs (Comment 2006). The common injectable drugs used are amikacin, kanamycin, and capreomycin. Streptomycin is also used as an injectable drug in therapy of this disease (Granich et al. 2005). A variety of *Mycobacterium* species can cause TB (Table 6.3). In 2007, there were 13,293 cases of TB in the United States, with a rate of 4.2 cases per 100,000 people. The highest rates are seen in foreign-born and racial minorities. However, the rate, per 100,000, dramatically varies geographically, with a rate of 0.4 in Wyoming and 10.2 in the District of Columbia. The duration of therapy is dramatically different for non-MDR TB as compared with MDR TB. For non-MDR and MDR, the time of therapy is 8.5 and 19.3 months, respectively (Granich et al. 2005). The case fatality rate for MDR TB greatly varies from 12% for those without human immunodeficiency virus (HIV) to about 90% with HIV. The cost of treating an individual with MDR TB ranges from $28,217 to $1,278,066 (Granich et al. 2005). In California, pre-XDR TB has

TABLE 6.3
Some *Mycobacterium* Species That Have Been Reported to Cause Tuberculosis

Species	Reference
Mycobacterium tuberculosis	Addo et al. (2007)
Mycobacterium bovis	Addo et al. (2007)
Mycobacterium africanum	Addo et al. (2007)
Mycobacterium avium	Dhungana et al. (2008)
Mycobacterium kansasii	Dhungana et al. (2008)
Mycobacterium xenopi	Thaunat et al. (2004)
Mycobacterium chelonae	Hsieh et al. (2008)

dramatically increased from 7% in 1993 to 32% in 2005. For XDR TB, in California, 83% of those with this strain were foreign-born patients, and 43% had arrived in the United States within a 6-month time period. As far as country of origin, Mexico was the most common, although 29% of the cases emerged during non-XDR therapy (Banerjee et al. 2008). Cases also commonly arise from the Philippines and Vietnam (Granich et al. 2005). Worldwide, the World Health Organization (WHO) reported that in 2006 there were 489,139 cases of MDR TB and 45 countries reporting cases of XDR TB (CDC 2008b). It is likely that this is an underestimate. Those with HIV have a high coinfectivity with TB, suggesting that members of this population are at greater risk. Although there are no clear data on the number of HCWs infected, these numbers alone demonstrate the risk, especially when information on the patient is unknown. However, it is known that even where the general incidence is low, HCWs are at increased risk of this disease as a result of patient contact (Hirama, Hagiwara, and Kanazawa 2011). In Portugal, it was reported that 1.7% of physicians and 1.0% of nurses have TB (Torres-Costa et al. 2010). In locations where TB is endemic, the rates are much higher. For India, one study found that 50.2% of nursing students were positive for 10 mm or greater with the tuberculin skin test (Christopher et al. 2010). If one bacterium is considered sufficient to cause an infection, it has been estimated that the risk of disease from *Mycobacterium tuberculosis* from 1 hour of exposure is 0.79% (Weber and Stilanakis 2008). It has been reported that the infective dose for this organism is around one to five bacilli (Balasubramanian et al. 1994).

The primary route of exposure to TB is through airborne droplets. Since it is common to treat patients whose status is unknown, HCWs are often at increased risk for this disease. What makes this even a greater risk is the prolonged and repeated exposure. As long as the sputum contains the microbe, a person is theoretically able to communicate the organism. The incubation period is 2–10 weeks. However, effective chemotherapy can greatly reduce communicability after about 2–4 weeks. Those with chronic diseases are more susceptible to these agents. Evaluation for exposure is commonly conducted through a skin test called the purified protein derivative (PPD) (also called Mantoux tuberculin sensitivity test). Test results are measured in intermediate units of 5, 10, and 15 mm of redness (erythema). There is

a vaccine for TB, the Bacillus Calmette-Guerin (BCG), which has been reported to be somewhat effective; although, those that have had this vaccine will often be positive for the PPD test. There is a test currently available for those that had the BCG vaccine, the QuantiFERON®-TB Gold test (QFT-G). The disadvantage of this test (QFT-G) is that it has to be performed within 12 hours of the blood draw.

The TB test (PPD) is a skin reaction that examines the amount of induration. Most infected people will react to an intermediate strength (5 international units [IU]) of PPD. However, about 5%–10% of those with an active case will be negative. For those that are immunocompromised or have HIV, a 5-mm induration or greater is considered positive. A 10-mm or larger reaction is considered positive for people infected less than 2 years as well as those at high risk (e.g., diabetes, end-stage kidney disease). For those that are low risk, a reaction of 15 mm or greater is considered positive (Heymann 2004).

Enterococci

The genera *Enterococcus* consists of bacteria that are gram-positive, facultative anaerobic cocci that normally inhabit the bowels of people and many animals, along with the female genital tract. It has been estimated that human feces contain up to 10^8 colony-forming units per gram of *Enterococcus* (Huycke, Sahm, and Gilmore 1998). Vancomycin-resistant enterococci (VRE) were first reported in 1986, approximately 30 years after vancomycin was used for the treatment of bacterial infectious diseases. Vancomycin has been used since the 1950s, and its use dramatically increased in the 1970s and 1980s. For resistance to exist in this group of organisms, multiple genes must be involved, and this is the suggested reason for the lack of occurrence of VRE infections for such a long period of time (Murray 1998). However, the primary reason for the emergence of VRE as a nosocomial agent was as a result of treating antibiotic-associated diarrhea in hospital settings through oral therapeutic routes (Rice 2001). VRE are now a common cause of NI in HCI and can triple hospital costs and length of stay for an infected patient (Nguyen, Leung, and Weizman 2011).

It is thought that the initial resistant strain(s) arose as a result of using a related antibiotic, glycopeptide, in animals as a growth promoter in Europe (Manson et al. 2003). This is based on the genetic similarity of VRE strains isolated from animals and people, most notably in Europe (Bates, Jordens, and Griffiths 1994). Apparently, resistance continues to remain in animals even after the antibiotic is discontinued, which occurred in the European Union in 1997. In New Zealand, vancomycin-resistant *E. faecalis* and *Enterococcus faecium* were isolated in chickens approximately 5 years after its discontinued use as a prophylactic measure (Manson, Smith, and Cook 2004). Similar cases have been observed in other countries and in other animals, including finding VRE in milk and food products (Biavasco et al. 2007).

VRE are now considered a common worldwide nosocomial pathogen (Tacconelli and Cataldo 2008). This agent is commonly spread by HCWs through cross contamination of their hands (Jehl et al. 2011). Nosocomial strains have been identified in the United States and Europe to be part of a "distinct genetic lineage" to *E. faecalis* (Tacconelli and Cataldo 2008). This strain is characterized as having ampicillin resistance and has been identified as one reason why VRE emerged in

the United States without having a community reservoir (Leavis et al. 2003). In addition, vancomycin has also been more widely used in the United States as a treatment agent, which has been suggested to be a contributing factor for its increased prevalence in the United States as compared with Europe (Tacconelli and Cataldo 2008). For hospital patients, colonization and infection rates are high and have been increasing over time, while there is little colonization in the community population and animals in the United States. However, in Europe, there exists colonization in healthy people and animals, but the infection rates in hospitals have remained relatively low (Leavis et al. 2003). This difference between the United States and Europe appears to be related to existence of *esp* gene and the genetic make-up confirming ampicillin resistance (*purK*1 gene) (Leavis et al. 2003).

This group is identified as group D streptococci and consists of more than 17 different species. The most common species encountered clinically are *E. faecalis* and *E. faecium* (Chou et al. 2008; Linden 2002). Of enterococci infections, *E. faecalis* and *E. faecium* account for 90% and 5%–10% of all infections within this genus, respectively (Simonsen et al. 2003). Six phenotypes of resistance to vancomycin have been reported and are identified as vanA, vanB, vanC, vanD, vanE, and vanG. The most common is vanA; however, vanB and vanD have been observed in both the United States and Europe (Patel 2003; Rice 2001). It has been suggested that genetic information for VRE resistance was obtained (i.e., transferred, including conjugation, transduction, and transformation) from other bacteria and then selected for in the agricultural industry because of the use of avoparcin, a glycopeptide. When VRE become a resident of the intestine or urinary tract and do not result in disease, this is referred to as colonization (CDC 2008a). It has been well established that resistance is commonly transferred among bacteria (Weigel et al. 2007). These reports suggest that similar genetic information exists in *S. aureus* that is vancomycin-resistant and this genetic information is being exchanged among the bacteria through conjugation (Zhu et al. 2008).

Avoparcin is a vancomycin-related glycopeptide (antibiotic) that was commonly used in Europe and in other areas (e.g., New Zealand) as a growth promoter for pigs, calves, beef cattle, and turkeys, and for preventing necrotic enteritis in chickens (Tacconelli and Cataldo 2008; Novais et al. 2005; van den Bogaard and Stobberingh 2000). In the Netherlands, it has been estimated that 80,000 kg of this drug was used annually until 1997. In April 1997, the European Commission banned the use of avoparcin along with other antibiotics, and there was then a reduction in glycopeptide-resistant microbes (Maschmeyer 2005). Denmark and Germany banned its use in 1995 and 1996, respectively. As a result of using this antibiotic, commensal flora in animals commonly contained VRE. In countries where avoparcin was not used in agriculture, no VRE were detected in animals or from healthy members of the general population (van den Bogaard and Stobberingh 2000). However, after discontinuance of avoparcin, there has been a decline in VRE resistance in the agricultural industry. Presently, about 5%–15% of the healthy people in the Netherlands are colonized with VRE, which is a large community reservoir. Throughout the rest of Europe where use of avoparcin was low, the reservoir population is about 3%.

Avoparcin was never used in the United States as a growth promoter, and this may be one of the primary reasons for a lack of community-acquired colonization (Ridwan et al. 2002). However, studies have shown that even after discontinued use,

VRE can remain high in livestock and poultry for years and thus may be an important "background" reservoir (Novais et al. 2005; Manson, Smith, and Cook 2004). In many cases after discontinuance of avoparcin, glycopeptide-resistant enterococci (GRE) were dramatically reduced. For example, in Danish poultry farms, the GRE changed from 72.7% in 1995 to 5.8% in 2000 (Johnsen et al. 2005). However, in other locations, this resistance has not changed. In Norway, it was at 18% for farms that used avoparcin 3 years after its discontinuation. Danish farms approximately 5 years after the ban saw similar results (Johnson et al. 2005). It has been suggested that this persistence is maintained through plasmid transfer (Johnson et al. 2005) and that continued use of other antibiotics maintains selection of GRE and VRE resistance (Novais et al. 2005). Thus, resistance for VRE is related to plasmids that contain resistance to other antibiotics (e.g., erythromycin), and their selection adds in maintaining a multitude of resistances. A study by del Campo et al. (2003) reported that this persistence can be transferred from animals to healthy people, who then may become colonized. This suggests that those working in animal facilities and on farms may be colonized by VRE through occupational exposure and as a result become a community reservoir. These people may then spread colonization to the general population, allowing the maintenance of VRE in the community. As different antibiotics are used in agriculture, there may be a continued selection for multidrug resistance, including VRE, which permits continued input of resistance to the local community.

The most common scenario involving the colonization of enterococci is that of the intestinal tract. However, colonizing can also occur at other sites (e.g., the urinary tract). Generally, this does not result in symptoms or infection for the patient but serves as a future reservoir for the bacteria and can result in transmission. When this genus does cause disease, it is commonly associated with bacteremia, endocarditis, meningitis, and wounds, and urinary, catheter-related, intra-abdominal, and pelvic infections (Simonsen et al. 2003). This group of bacteria is also commonly found on the skin, mouth, and female genital tract. Those at greatest risk for infection are the critically ill and those who have cancer, have received a transplant, or have been receiving long-term antibiotic therapy. HCWs are also at risk because of protracted exposure to these organisms. Overall, this group has a somewhat low virulence; however, since most of the people infected are already debilitated, mortality and morbidity are often increased. It is common that those who develop an NI from this group will have an increased hospital stay, which has been reported to average about 2 weeks. For patients that are critically ill, mortality rates from these infections may exceed 50%. When the infection occurs in the abdominal cavity or urinary tract, the resulting attributable mortality may be as high as 30% (Ridwan et al. 2002). For the time period 1995 through 2002, 9% of nosocomial bloodstream infections in the United States were caused by enterococci, and of this group, 2% and 60% were due to vancomycin-resistant *E. faecalis* and *E. faecium*, respectively (Tacconelli and Cataldo 2008). Patients that have been receiving antibiotic therapy, particularly antibiotics for anaerobes, for at least a week are at increased risk of infection and exhibit a higher stool density of VRE (Tacconelli and Cataldo 2008; Donskey et al. 2000, 2002). These higher densities of VRE also appear to enhance shedding of the bacteria, resulting in a high contamination of the environment. This could result in an increased number of

infected cases and colonization and further spread resistance in an institution. Even those that have had three negative cultures for VRE resumption of antibiotic therapy have been reported to result in a positive stool culture for VRE (Donskey et al. 2002). This suggests that a residual nature of infection and colonization may exist. Thus, even when patients have negative cultures after colonization or infection, they may still carry a small, undetectable population of VRE in the gut or elsewhere.

VRE colonization often lasts for a long time. One study (Henning et al. 1996) reported that infected patients can remain carriers for 19–331 days; however, it has been reported that some may shed the bacteria for at least 5 years (Baden et al. 2001). This makes these people primary vectors in transmission (Baden et al. 2001). Antibiotic therapies that are effective against anaerobic bacteria appear to enhance a carrier state and can result in a longer persistence of VRE in the gastrointestinal tract (Rice 2001; Donskey et al. 2000).

Enterococci have been shown to survive for long periods of time on environmental surfaces. This is one important factor in their transmission. These bacteria can survive for months even on dry surfaces. One investigation reported that detectable VRE were found 4 months after inoculation on a dry surface (Wendt et al. 1998). For fabrics, survival has been reported to be greater than 90 days (Neely and Maley 2000). However, this study suggests that the amount of inoculum is related to survival, and low concentrations (e.g., 10^2 bacteria) had a shorter survival time, although they were detectable for days. Neely and Maley (2000) suggest that survival is not influenced by the organisms' antibiotic resistance, indicating that both VRE and wild type are similar in survival characteristics. This would indicate that VRE have a similar survival time as those which are not resistant. Since most laboratory coats and items used to decorate hospital rooms are made from various fabrics, these items are suggested to be good reservoirs for microbes and may also act as a possible vector (e.g., lab coat). This is consistent with other survival studies that indicate these organisms can also reside on countertops, stethoscopes, and glass (Neely and Maley 2000). Hayden et al. (2006) reported that 41% of HCWs had VRE on their hands, before washing, after caring for patients that were infected or suggested to be colonized.

When comparing the enterococci with other microbes, one study that examined bacteria in ICUs found that overall they have the longest survival times (Gastmeier et al. 2006). Most bacteria have been reported to exhibit a median survival time of 10 days, while for enterococci (*E. faecalis* and *E. faecium*), this value is around 50 days (Gastmeier et al. 2006). These investigations are supported by environmental microbiology studies. Sinton et al. (2007) reported that the enterococci have a high survival rate in bovine feces and outdoor environments. This study suggests that this group of bacteria is very resistant to environmental pressure and that pastures may be a reservoir of these organisms. Even in warm environments, in summer time, there was good survival (months to years).

Overall, these studies suggest that enterococci, including those that are identified as VRE, have a long survival time and could be classified as organisms resistant to environmental factors. This indicates how important it is to properly clean and disinfect all surfaces and items, including patients that have been identified as colonized. This disinfection should not be limited to patient rooms but equipment as well.

In the United States, since VRE were first reported in New York City, NIs have spread rapidly. Resistance has increased in ICUs from 0.3% in 1989 to 7.7% in 1993. According to one Canadian study, enterococci are the sixth most common organisms isolated from ICUs and third and second most common for blood and urine specimens, respectively (Zhanel et al. 2008). Today, the rate of resistance has been reported to be about 60%. In Louisiana, the number of VRE cases dropped from a high of about 400/100,000 in 2000 to around 100/100,000 in 2006 (Louisiana Office of Public Health 2007). The age group most greatly affected was 65 and older, suggesting that this is a highly susceptible segment of the population. However, the percent of enterococci that are vancomycin-resistant steadily increased from about 40% in 2000 to about 60% in 2006 in some locations. This appears to be related to the rate of hospital-infected cases of VRE, which rose from about 7/100,000 admissions in 2000 to about 15/100,000 admissions in 2006. However, in some geographic areas (e.g., Brazil), there have been few cases of VRE infections (Ribas et al. 2007). There also appears to be a difference in the infection rates between Europe and the United States. This appears to be due to the spread of vanA phenotype (transposon). This transposon appears to be more common and easily transferred in environments where glycopeptides and/or cephalosporins are or were heavily used (Ribas et al. 2007). However, the most recent report for 2006–2007 indicated that enterococci caused approximately one in eight hospital infections (Tacconelli and Cataldo 2008; Louisiana Office of Public Health 2007).

For NIs, the potential of acquisition is related to the length of the hospital stay (Montecalvo et al. 1995). Thus, the longer a person is exposed to VRE, the greater the likelihood that an infection will result, especially in susceptible patients. When compared with controls with similar diseases, patients that develop VRE infections had a much longer hospital stay. On average, this stay was 11 days longer (Yang et al. 2007). In addition, patients that occupy rooms where the previous patient had VRE colonization are at increased risk of becoming infected or colonized themselves even if the room was well cleaned and disinfected (Drees et al. 2008a, 2008b; Huang, Datta, and Platt 2006). These findings suggest that enterococci are highly resistant to cleaning and patient's rooms that have been previously occupied by a VRE-colonized or infected patient, for approximately 2 weeks, can act as reservoirs for these agents (Drees et al. 2008b). It is also suggested that HCWs treating patients in these rooms, after the VRE patient has been removed, may pick up the organisms and transfer bacteria (VRE) to other patients or locations. Overall, this suggests that rooms themselves that had VRE-colonized patients, for approximately 2 weeks, may serve as a potential vector. Here, a physical structure (room) is acting as a vector for disease. For ICU rooms, it has been suggested that there is a 40% increase in the odds of transfer from a VRE-colonized patient to the next patient occupying that bed (Tacconelli and Cataldo 2008).

Enterococci have been shown to survive and be transmitted on the hands (Perencevich et al. 2004). Hand washing appears to be one of the most important and effective methods for preventing transfer of and subsequent infection by these organisms and others (Duckro et al. 2005; Weber and Stilianakis 2008). Duckro et al. (2005) reported that touching inanimate objects with the hands can also result in contamination with VRE. This supports the importance of cleaning

and disinfection practices and shows that almost any location can be a potential reservoir (Drees et al. 2008b). Blood pressure cuffs, patient rooms, suction equipment, soap dispensers, bed rails, and the like can act as a source. For example, Duckro et al. (2005) reported that blood pressure cuffs associated with VRE-colonized patients had 100% transfer of these microbes. It has even been reported that VRE can colonize clinical microbiology laboratories (Tacconelli and Cataldo 2008). When a patient has fecal incontinence, there is a high rate of environmental contamination as compared with those that are not increasing the risk of transfer (Tacconelli and Cataldo 2008). Even with gloves, there can be contamination when hand washing is not effective. However, effective hand washing for 30 seconds with soap and water has been shown to completely eliminate the organism, while only 5 seconds of washing had no effect in changing the concentration (Tacconelli and Cataldo 2008). This supports the original concept established by Semmelweis and Holmes.

Adequate disinfection is critical in the control of enterococci (Eckstein et al. 2007). Even with routine cleaning by housekeeping staff, Eckstein et al. (2007) reported that approximately 30% of the locations tested remained positive for VRE. However, after thorough cleaning using a disinfecting agent (e.g., 10% bleach), no enterococci were detected. This cleaning/disinfection requires that all surfaces be treated and those conducting this activity have appropriate training. It was also suggested that there should be a requirement for continual education regarding the cleaning and disinfecting process. This is supported by other studies (Hayden et al. 2006) that observed a reduction of VRE hospital-borne infections when improved environmental cleaning was instituted. However, Hayden et al. (2006) also noted that environmental cleaning has limited effectiveness if strict hand washing requirements do not exist. Employment of gloves has also been suggested to be effective, but such effectiveness is reduced when there is inadequate hand washing (Tacconelli and Cataldo 2008). Thus, it appears that hand washing is the key to any program, followed by effective cleaning.

Acinetobacter Baumannii

Acinetobacter baumannii is not a new pathogen but has recently become of concern as an opportunistic infectious agent and is currently responsible for 2%–10% of all gram-positive infections (Richet and Fournier 2006). An increased rate of infection due to this organism, or its general group (genus), is most likely a result of an increase in the susceptible population. In addition, there has been an increase in the rate of antibiotic resistance of this bacterium, making it a superbug (Liang et al. 2011). Multidrug resistant *A. baumannii* (MDRAB) appears to have inherent resistance to many antibiotics and has emerged as an important opportunistic nosocomial pathogen. Its pathogenicity appears to be more related to antibiotic resistance rather than virulence. Morgan et al. (2010) reported 38.7% of HCWs treating patients colonized with *A. baumannii* became contaminated in some form. This shows how easily such an organism can be spread and transferred to other patients or locations.

Sources of this organism include soil, food, hospital settings, almost any surface, and equipment. Its natural reservoir has yet to be identified but is likely the

"general natural" environment (e.g., soil). These bacteria can colonize healthy people, usually on the skin but also the throat, nose, and intestinal tract. Studies have suggested this organism is a very effective colonizer (Perez et al. 2007). Those who are most sensitive to infection include critically ill patients, burn patients, and the immune-suppressed along with those having chronic diseases and the elderly. Infections usually involve pneumonia, urinary tract and skin problems, and meningitis, with those having had previous antibiotic therapy, dialysis, and drainage tubes being at greater risk. Outbreaks in American soldiers returning from Iraq were observed starting in April 2003 and were suggested to be a result of exposure to Iraq soil. In Europe, *Acinetobacter* spp. is the seventh most common organism isolated from critically ill patients (Beggs et al. 2006). Numerous hospital outbreaks have been reported as a result of MDRAB (Jawad et al. 1996). Jawad et al. (1996) reported that *A. baumannii* has very good survival on fingertips and dry surfaces as compared with other gram-positive bacteria. The organism also appears able to be spread by an airborne route as well as through medical equipment. These modes of transmission make this organism an important and potentially dangerous nosocomial pathogen. It appears that some patients and HCWs serve as an important transmission mechanism. Jawad et al. (1996) reported that there are considerable survival differences between strains. It is suggested that strains isolated from dry conditions have better survival capability than those from a moist environment (Beggs et al. 2006).

Clostridium Difficile

Clostridium difficile is a gram-positive, spore-forming bacteria that has become associated with antibiotic therapeutic diarrhea. Since it is a spore former, it has also become a common problem as a nosocomial infectious agent and is known as Cdiff (McFee and Abdelsayed 2009). NIs from *C. difficile* have been steadily increasing over the past decade and now account for about 15%–25% of all antibiotic-associated diarrheas. Having a *C. difficile* infection has been suggested to increase mortality by 10%–30% (Rohda, Bartolini, and Jones 2009). In 2005, in Quebec, *C. difficile* accounted for a nosocomial infectious disease rate of 15 per 10,000 patient days (Pepin, Valiquette, and Cossette 2005). Both infection and colonization occur for all age groups although it has become a common infectious agent in long-term facilities (Pituch 2009). This organism has also become well established as an agent responsible for NIs (Ajao et al. 2001).

This organism exists in both vegetative and spore forms. The vegetative form is highly susceptible to disinfectants, while the spore form is very resistant. Sources of this organism can be almost any item that becomes contaminated. Commonly, this organism is transmitted through an oral-fecal route. Fomite transmission can also occur. Generally, long-term antibiotic therapy will result in the patient's elimination of his or her normal gut flora. Because of this elimination, *C. difficile* has an opportunity to occupy this niche. *C. difficile* can easily overgrow and outcompete any remaining normal bacteria in the bowel after or during antibiotic therapy. Toxins produced by *C. difficile* can result in diarrhea and related manifestations. Symptoms of *C. difficile* can emerge after a few days of therapy but are most prevalent for those

with long-term therapy. Antibiotics most commonly associated with this organism are those that are broad-spectrum, especially clindamycin and broad-spectrum penicillins (McFee and Abdelsayed 2009).

Incorporation of probiotics has been suggested to have benefits in preventing and controlling *C. difficile* (McFarland 2011). This finding has been supported by an experimental study (Kaur et al. 2011). Probiotics are microbes that are intentionally taken for purposes of colonizing the GI tract, especially in adhering to the mucosal surfaces (Isakow, Morrow, and Kollef 2007). There is no one microbe that serves all beneficial aspects, but a variety that confers positive characteristics. The purpose of these organisms is to outcomplete pathogens and prevent occurrence of infections and colonization. Beneficial microbes not only help maintain microbial ecology in the gut but also provide vitamins (vitamin K), protection against allergies and ulcerative colitis, and the breakdown of nutrients (Isakow, Morrow, and Kollef 2007).

Due to this organism being a spore former, effective cleaning is much more difficult than for other microbes. This organism is also developing antibiotic resistance and is become of greater importance as an antibiotic-resistant opportunistic pathogen (Huang et al. 2009). Antibiotic-resistance forms of *C. difficile* make treatment even more difficult and expensive.

SURVIVAL TIME

The survival time of microbes is important and, in many ways, is at the heart of their spread. There have been numerous reports of outbreaks that were associated with surfaces or objects (Neely and Maley 2000). The time that an organism can survive outside its host greatly varies. Some published survival times of microbes associated with various materials and surfaces are shown in Table 6.4. As seen, most organisms can survive for at least days, with some able to survive much longer extended periods of time. Those that are spore formers, such as *C. difficile,* will likely have the longest persistence. Spore-forming bacteria can be considered a special problem since they are difficult to destroy. Some agents, such as Chlorox, are effective against spores, but others, such as alcohol, are not. For this reason, alcohol-based hand agents are not considered effective against bacteria that produce spores (e.g., *Clostridium* and *Bacillus*). When these types of microbes are not in a spore state, the cells are considered to be vegetative and are more sensitive to environmental conditions (Jump, Pultz, and Donskey 2007).

INFLUENZA

Influenza (an RNA virus) and related types of viruses (e.g., coronavirus, or SARS [severe acute respiratory syndrome]) have become a major concern for the HCI and general public (Coker 2009). For HCWs in Spain (at a major hospital), the seasonal vaccination rate for 2009–2010 influenza was 26.7% and 14.8% for the pandemic form (H_1N_1) (Del Campo et al. 2011). In an Italian hospital, the rate for vaccination of HCWs for the pandemic flu was 18% (Amodio et al. 2011; Miyakis et al. 2011). The flu can potentially kill millions of people a year and has caused pandemics since

TABLE 6.4
Survival Times of Microbes on Surfaces

Organism	Time Period	Reference
S. aureus	11 days, on plastic patient chart	Huang, Datta, and Platt (2006)
	9 days, table top	
	9 days, cloth curtain	
	18 days, glass coverslip	Jawad et al. (1996)
	21 days, cotton fabric	
	56 days, dry mop in hospital	Oie and Kamiya (1996)
Acinetobacter	>4 months[a], on dry surfaces	Wendt et al. (1997)
	6 days, dry filter paper	Allen and Green (1987)
	13 days on formica	Musa, Desai, and Casewell (1990)
	18 days, glass coverslip	Jawad et al. (1996)
C. difficile	3 hours, moist surfaces (vegetative)	Jump, Pultz, and Donskey (2007)
	Months, spores	Jump, Pultz, and Donskey (2007)
E. faecium	>4 months[b]	Wendt et al. (1998)
	>90 days, cotton fabric	Neely and Maley (2000)
E. faecalis	33 days, cotton fabric	Neely and Maley (2000)
E. coli[c]	>28 days, stains steel surface	Wilks, Michels, and Keevil (2005)
S. marcescens	10 days, glass coverslip	Jawad et al. (1996)
M. avium	90 days in deionized water	Archuleta, Mullens, and Primm (2002)
Yersinia pestis	2–4 hours, dry stainless steel	Rose et al. (2003)

[a] Survival is highly variable depending on strain tested.
[b] Under dry conditions.
[c] *E. coli* O157:H7.

the beginning of man. With the emergence of the swine flu in Mexico during the spring of 2009, there appears to be even a greater concern than usual (novel swine-origin influenza A [H_1N_1]) (Virus Investigation Team et al. 2009). There are three types of human influenza viruses, A, B, and C. Type A can infect humans as well as birds, horses, pigs, seals, whales, and other animals. This is the type that most commonly causes worldwide pandemics. Influenza B can cause disease but is generally restricted to children. However, it can become epidemic. Type C is generally a mild form of this disease. Historically, the bird flu was of the greatest concern and is still a major risk for causing a pandemic. Most recently, the biggest concern has been associated with the swine flu. Influenza A virus is highly pleiotropic with shapes varying from spherical to filamentous. There is a lipid envelope that contains the two primary receptors, neuraminidase (NA) and hemagglutinin (HA). The antiviral agents that have been developed are directed toward NA, while HA is important for host and cellular specificity (Weber and Stilanakis 2008). Generally, enveloped viruses are less stable in the environment than non-enveloped; however, this generalization has many variations and exceptions. For example, the SARS virus is enveloped and is considered stable in the environment.

Influenza can be transmitted in one or a combination of three ways: droplet, contact, and airborne (aerosol) (Tellier 2006; Weber and Stilanakis 2008). Classification of each of these three transmission forms is by aerodynamic diameter (d_a). Airborne, droplet, and contact transmission are defined as having a $d_a < 10$ μm, $10 < d_a < 100$ μm, and $d_a > 100$ μm, respectively. When a person coughs and sneezes, they eject particles having a d_a ranging from 1 to 2000 μm. Those that are larger than 10 μm will likely settle quickly and have a contact effect. The smaller ones can be airborne and may be inhaled, with deposition in the lower respiratory tract being at the lower particle size range (e.g., 1 μm). Factors that are important for virus survival are temperature, relative humidity (RH), and ultraviolet (UV) light. Generally, it has been considered that the virus survives well at low RH; however, this evidence has some restrictions. This is one of the reasons given for seasonality of flu in higher latitudes. In the tropical regions, there can be more than one season of the flu, with many having two. Lower temperatures have also been suggested to increase survival with the best at a low RH. However, as mentioned, there is considerable variation related to these factors.

The reason for variation in flu seasons is that there may be a more predominate mode of transmission through contact in the tropics, while aerosol is more important in the temperate regions. The theory here is that in a tropical environment the higher RH causes larger droplets to form, which are removed from the atmosphere (Weber and Stilanakis 2008). However, experimental evidence is not well established in supporting these ideas. Fomite transmission (hand-to-mucus membranes) is considered the most important route for transmission and hand washing is a major deterrent in the spread of the virus.

The UV radiation in sunlight is effective against influenza A. The poorest inactivation rates are associated with the winter time period. When combined with temperature and RH, UV light can be effective in preventing the spread of this virus. Other viruses, such as coronavirus, are also greatly influenced by UV radiation. This has been suggested to be another reason the flu season occurs in the winter in temperature regions; however, this did not appear to influence the swine flu in the spring of 2009 (Coker 2009). As of April 29, 2009, Coker (2009) reported that 21 countries had reported cases of this influenza (H1N1). As of September 2009, there had been approximately 3500 deaths worldwide as a result of this virus, showing how rapidly an infectious agent can spread even in the summer months.

In the indoor environment, airborne transmission does not appear to be an important route for spread of this disease. Droplet transmission can result in spread but is also of low probability. Deposition through droplets is the most likely and efficient route for this disease. This is a contact mechanism and involves transfer through the mucus membranes and conjunctiva. These viruses do not survive well on the hands, with a likely survival time of about 15 minutes based on the transfer of the virus from tissues to hands (Weber and Stilanakis 2008). However, the frequent contact with fomites and the rubbing of the eyes and similar membranes enhances this transmission route. Survival on surfaces is highly variable, with many studies suggesting a first-order inactivation constant, which appears to be around 1.32 $days^{-1}$ (Weber and Stilanakis 2008). The infective dose (tissue culture infective $dose_{50}$ [$TCID_{50}$]) for influenza A is around 0.67 for the respiratory epithelium

(Weber and Stilanakis 2008). The number of virions in this dose is not known, but certainly this value is contained in one droplet.

The incubation period for influenza varies among the types. Lessler et al. (2009) estimated that median incubation time periods for influenzas A and B are 1.4 and 0.6 days, respectively. For influenza A, the 95% confidence interval was 1.3–1.5 days. The rhinovirus, probably the most frequent agent in causing the common cold, has a median incubation time of 1.9 days. Attempts to detect the disease in travelers are likely problematic as a result of these short incubation time periods, especially when considering that travel time from Mexico to the United States can be less than a few hours.

Control measures in preventing infection of HCWs have been evaluated in a number of reports relating to SARS and would have applicability to influenza (Lange 2003; Jefferson et al. 2008). As with almost all infectious diseases, the most effective method is frequent hand washing. During outbreaks, use of personal protective equipment (PPE) is often looked to as a frontline measure of protection (Nicas 2006; Lange and Mastrangelo 2006). Jefferson et al. (2008) conducting a quantitative approach and reported that the OR is lowered through employment of masks (N95 respirators), gloves, and gowns. This study also supports the concept of hand washing, which also reduced the OR. Lange (2003), using a qualitative approach, reported that nonfiltering respirators (e.g., surgical masks) were not effective in preventing SARS. These results show the importance of proper PPE and that its use can be effective in preventing disease in HCWs.

HAND WASHING

Hand washing is considered the cornerstone of infectious disease control and is commonly related to hand hygiene (Bencho and Schejbalova 2006). This practice emerged around 1822 and was introduced by the French pharmacist A.G. Labbarrague, who employed chlorides of lime on soda for removing foul odors from corpses. This was extended to physicians as a mechanism of disinfection and preventing transfer of disease. Semmelweis is given the greatest amount of credit for the concept of hand washing; however, Oliver Wendell Holmes Sr. (1809–1894), a Harvard physician, is thought to be the first to initially implement this practice. This concept was brought into practice by Semmelweis in 1846, who observed a higher rate of puerperal fever in women who had babies at the General Hospital of Vienna. Semmelweis required that all physicians wash their hands, and as a result, this disease dramatically decreased. What made Semmelweis aware of that "contamination" was comparing disease occurrences in obstetric wards operated by physicians and midwives. The midwives did not perform autopsies, and as such were not exposed to many of the infectious diseases. However, as with Holmes, Semmelweis was heavily criticized for requiring and instituting hand washing.

During the early part of the nineteenth century, up to 25% of woman that had babies in a hospital died from puerperal fever (childbirth fever). The organism that causes this infection is *Streptococcus pyogenes*. In 1843, Holmes, before Semmelweis's findings, suggested that childbirth fever was an infectious agent and was contracted from attending physicians. It is interesting to note that Holmes

studied medicine in France and may have gained some insight into the problem from this experience. Holmes emphasized the importance of hand washing and hygiene, which at the time was rejected. His forethought escaped the practice of medicine during this time period and was even criticized by distinguished obstetric professors Hugh L. Hodge and Charles D. Meigs, who jointly dismissed the theory of contagions. Even today, the concept established by Semmelweis and Holmes is frequently forgotten and requires continuous relearning (Hoskins 2008). Hand washing is probably the most important preventative practice in mitigating NIs and requires continual relearning. This discussion shows the resistance that exists in regard to hand washing. Although its importance is well known today, there remains a great reluctance of HCWs to consistently wash their hands.

Hand washing can be accomplished with soap and water or alcohol-based sanitizers. When using soap and water, the hands should be washed with ample lather along with scrubbing all surfaces. Washing should last for 20–30 seconds and then the hands should be rinsed. Hands can be dried with paper towels, and if possible, the towel can be used to turn off the water. Alcohol-based agents should be applied to the palm of the hands and then hands should be rubbed over all surfaces until dry. Hand washing with products that are alcohol-based will not be effective against spore-forming bacteria (e.g., *C. difficile*); thus, there are disadvantages to this form of sanitizer.

NONINFECTIOUS HAZARDS

Traditionally, there was little discussion of noninfectious issues in HE. However, events that were commonly associated with industrial and commercial environments have caught up with health care. Today, there is a greater interest in physical and chemical events than in the past. Much of this emerges from a better understanding of risk and hazards encountered by HCWs (Boiano et al. 2009). These issues have also been driven by rising workmen's compensation (WC) rates. In many ways, industrial hygiene is forming a subdiscipline for HCWs as it has in other industries (e.g., chemical processing). As pressure increases on the HCI, there will be greater concern for noninfectious events in this occupational population (HCWs). One of the major emerging concerns on the horizon are the hazards associated with shift work (Schernhammer and Thompson 2011). The International Agency for Research on Cancer (IARC) has suggested that shift work be classified as a group 2A carcinogen (possibly carcinogenic to humans). In addition, considerable evidence is mounting that this activity raises the risk of cardiovascular diseases (CVDs) (Fritschi 2009; Frost, Kolstad, and Bonde 2009).

Latex Gloves

Reaction to natural rubber latex (NRL) gloves by HCWs has become of greater concern. Hypersensitivity to latex was first reported in 1979 and is generally associated with prolonged exposure to latex. With the establishment of "universal precautions" in 1985 that dictate increased barrier requirements, there has been a dramatic

increase in glove use. Latex is obtained from rubber trees, *Hevea brasiliensis*, which is extracted through a chemical and heating process. The cause of these allergies appears to be related to low-molecular proteins that result in IgE-mediated reactions. There are some fruits that show cross reactivity, such as bananas, chestnuts, kiwi, tomatoes, and avocados (Reddy 1998). Reported sensitivity for HCWs has been identified to be in the range of 2.9%–22%. WC claims per 100,000 have ranged from 0.71 in Minnesota to 2.66 in Washington state. In a long-term study in Oregon, the rate per 10,000 was 0.58 cases (Horwitz, Kammeyer-Mueller, and McCall 2002). Although they observed a small increase over time, this rate is not statistically significant. This slight increase may be due to more HCWs using gloves. The majority of problems with NRL gloves have been associated with dermatitis. However, there are a few reports of asthma (Horwitz, Kammeyer-Mueller, and McCall 2002). The most common body part affected is the hands, followed by areas of the upper body. Although NRL gloves (products) are not a major hazard to HCWs, it is becoming a bigger issue, especially when looking at costs associated with WC. However, it should be noted that one fatality was reported in the Oregon study.

Anesthetic Gases

Anesthetic gases are commonly used in medical settings. It has been estimated that in the United States, 250,000 HCWs are exposed to these agents. Most of these gases are used for sterilization and in the sedation of patients. Agents that are commonly used today include nitrous oxide (N_2O), enflurane, isoflurane, desflurane, sevoflurane, and halothane. The number of HCWs exposed to these agents is in the hundreds of thousands. Locations where these agents are employed included a wide variety of medical settings beyond the hospital, such as dental offices. As a result, exposure to these agents is common and can result from leakage or accidental release into the atmosphere.

Exposure to these gases, at least under short-term conditions, can result in the worker becoming partially anesthetized (Nayebzadeh 2007). From this, a variety of conditions can result including headaches, drowsiness, poor concentration, hypotension, irritability, depression, dissociation, and confusion. These effects can result in poor judgment and place other staff and patients at risk. There can also be increased costs for health care (i.e., for HCWs) along with a higher absentee rate. Such effects are commonly associated with high exposure levels.

Chronic studies of anesthetic agents, which are used to evaluate long-term exposures at low concentrations, have not provided conclusive results as seen with those that are shorter in duration. However, some investigators have reported increased rates of spontaneous abortion, congenital problems, and liver and kidney cancer (Ahlborg and Hemminki 1995; Szymanska 2001). It has been suggested that patients treated with chloral hydrate are at increased risk for various forms of cancer (lung, stomach, prostate, skin, and mouth) even after short-term exposure (Haselkorn et al. 2006). This is based on HCWs' exposure using an extrapolation for these cancer sites extended to the patient population, with consideration that their exposures will likely be more of a chronic nature. These suggestions are consistent with studies that evaluated HCWs who administer anesthetic agents (gases), some of which are

suggested to be carcinogenic as well as represent a reproductive hazard (Shortridge-McCauley 1994; Szymanska 2001). Presently, most of the anesthetic gases have not been assigned permissible exposure limit (PEL) values (as establish by the U.S. Occupational Safety and Health Administration [OSHA]); however, one substance nitrous oxide (N_2O) does have a threshold-limit value (TLV) value of 50 ppm (as published by the American Conference of Governmental and Industrial Hygienists [ACGIH]). N_2O has been reported to also be a reproductive hazard, with epidemiological and animal studies suggesting that it can cause spontaneous abortions, congenital abnormalities, and teratogenic effects (Hathaway et al. 1991). The mechanism for these effects has been suggested to be N_2O's ability to oxidize vitamin B_{12} to an inactive state. This vitamin is important in DNA activity, especially as related to methionine synthase. Inhibition of this system may result in a disruption of cell division; however, it has been reported that male anesthesiologists do not have a change in their sperm count or morphology.

Probably the most important agents are those that are halogenated. Thus, they should be carefully considered when looking at exposures. Herr et al. (2008) suggested that evaluation of halogenated agents at an upper limit of 2 ppm should be considered. However, when halogens are in combination with N_2O, this value should be lowered to 0.5 ppm and the limit for N_2O sets at 25 ppm. This is based on the concept that halogenated agents when included with other anesthetics may cause synergistic effects and as such would warrant a lower value for each.

Disinfectants

There are a large number of disinfectants used in the HCI. Table 6.5 provides a list of common agents employed and a summary statement of their mechanism or activity. Most of the agents are discussed in this chapter. It should be noted that not all of these agents listed are true disinfectants, but some are considered sanitizers. Disinfection is generally referred to when a majority of the microbes are destroyed, with some making an exception for spores (Russell 2003). Here, the definition will be more comprehensive and include spores and vegetative structures and will consider this method as a mechanism of eliminating the organisms. Sanitation on the other hand, is a reduction of microbes to an acceptable level and is commonly associated with cooking and washing clothes. It is also commonly applied in the food industry. Some agents that have been used for disinfection and sanitation (e.g., mercury compounds) will not be mentioned because of the uncommon use in the HCI. There are multiple factors that influence the effectiveness of these agents and these include pH, amount of organic material, temperature, concentration, type of organism, and amount of exposure time. Table 6.6 provides the relative effectiveness of various agents against commonly encountered groups of microbes.

Generally, the ideal sterilization is autoclaving, although dry heat sterilization can be employed as well for some items or materials. This involves steam heat and is used in the cooking industry (e.g., canning, pressure cookers). This form of disinfection is defined as 121°C, at 15 psi for at least 15 minutes. Ideally, autoclaving will kill all microbes, but a larger the volume of material will require a longer time period. Thus, time is a critical factor when evaluating effectiveness of disinfectants. There is

TABLE 6.5
Agents Used for Disinfection[a]

Substance	Effect
Chlorine	Halogen; highly electronegative, and can strip electrons and denature enzymes, and oxidizes sulfhydryl groups; effective against bacteria, spores, fungi, and viruses; commonly used because of its low toxicity and effectiveness; related to iodine
Phenolics	Carbolic acid; degrades and denatures proteins and cell walls/membranes; effective against vegetative cells, fungi, and most viruses, not effective against spores and hepatitis B
Alcohols	Hydrocarbons with one or more hydroxyl groups (−OH); ethyl and isopropyl are applicable as antimicrobials, methyl is not effective, isopropyl is generally most effective; denatures (coagulation) proteins, dissolves lipids, and damages membranes; needs some water for effectiveness; most solutions are 70% alcohol; effective (but low level) against vegetative cells, fungi, and some viruses; most effective against enveloped rather than nonenveloped viruses; not effective against bacterial spores
Hydrogen peroxide	Inhibited by organic matter; effect is direct and indirect action with oxygen (electronegative effect); effective against bacteria (vegetative), viruses, fungi, and, at high concentration, spores
Detergents	Soaps are detergents, and this is a polar molecule that acts like a surfactant; anionic detergents have limited effectiveness; cationic detergents are most effective; disrupts cell membrane; vigorous rubbing increases effectiveness
Formaldehyde	Formaldehyde (CH_2O) inactivates nucleic acids and proteins and dehydrates the cell; effective disinfectant but toxic; effective against bacteria, fungi, viruses, and spores; alkylating agent, disrupts DNA with a mechanism of donating an alkyl group to another compound; disrupts proteins
Glutaraldehyde	Effective against bacteria, fungi, viruses, and spores; disrupts proteins and enzymes (cross linking); alkylating agent
Ethylene oxide (ETO)	Disrupts proteins and nucleic acid; alkylating agent; effective against bacteria, fungi, viruses, and spores; ETO sterilizer is a chemoclave; exposure can be toxic
Chlorhexidine	Organic with chlorine and two phenol rings; effective against cell membranes and denaturation of proteins; effective against vegetative cells (bacteria) and some fungi and viruses; not effective against spores; exhibits low toxicity
Quaternary ammonia (QA)	QA contains NH_4^+ and is generally a good disinfectant although hard water may make this less effective; G– bacteria can grow in the preparation, and these agents are not effective against nonenveloped viruses and fungal and bacterial spores; effective against enveloped viruses and G– and G+ bacteria; is a cationic biocide; mechanism of action is disruption of membranes; limited effectiveness against mycobacteria; commonly used in the food industry; can cause irritation to mucus membranes and respiratory tract

[a] The terms "disinfection" and "sterilization" are often misunderstood. Disinfection is the reduction of viable microbes, while sterilization is the elimination of all microbes. In some cases, a disinfectant will act as a sterilization agent when a sufficient amount of time is allowed. Sanitizers are used to kill microbes that are important in disease causation and are commonly used in the food industry.

TABLE 6.6
Effectiveness of Agents against Different Types of Microbes

Agent/Effectiveness	Bacteria	Nonenveloped Virus	Enveloped Virus	Bacterial Spore	Fungi
Chlorine (I–H)	X	X	X	X	X
Phenolics (L)	X		X		
Alcohols (I)	X		X		X
Hydrogen peroxide (H)	X	X	X	X	X
Dtg (L)	X				
CH_2O (I–H)	X	X	X	X	X
Glut (H)	X	X	X	X	X
ETO (H)	X	X	X	X	X
Chl (L)	X				
QA (L)	X		X		

Note: CH_2O = formaldehyde; Dtg = detergents; ETO = ethylene oxide; Glu = glutaraldehyde; Chl = chlorhexidine; QA = quaternary ammonia. H = highest; I = intermediate; and L = low are levels that indicate how extensively this agent is used against a wide variety of microbes. The highest level (H) is most effective against all organisms, while the lowest level (L) is the least effective. Prions are not discussed and constitute a unique requirement for disinfection. Concentration of agent and time of exposure must always be considered when evaluating disinfection and sanitation.

relative resistance of microbes to various agents. The most resistant are prions, followed by protozoan spores and parasitic eggs, coccidian, bacterial spores (spores); nonenveloped viruses (e.g., rhinovirus), *Mycobacterium*, fungi, gram-negative (G−) bacteria, gram-positive (G+) bacteria (vegetative), cocci, and enveloped viruses (e.g., influenza) are the most susceptible (Russell 2003).

CHLORINE/IODINE

Chlorine is a halogen and is located in group VII of the periodic table. It is highly electronegative and requires one electron to fill its orbital (octet). Iodine is less electronegative. Oxygen is also electronegative. Chlorine can be used as a gas (Cl_2) or in a liquid form (hypochlorite [OCl]). The most active form is hypochlorous acid (HOCl). This agent is relatively unstable but is very effective in denaturing proteins and oxidation (common sites for oxidation are sulfhydryl groups [S–H]). One of the advantages of this substance is its low cost and that it is fast acting. However, it has some limitations in that some mold spores (e.g., *Cyptosporidium*) are resistant to it in comparison with vegetative bacterial cells (Russell 2003). As with VRE, chlorine is frequently used for disinfection. It can be used on most surfaces; however, because of its strong electronegativity, staining can result. It is easy to prepare and is effective. The biggest disadvantage is its toxicity, particularly as a gas. Chlorine can cause irritation to the eyes, mucus membranes, and pulmonary system.

Thus, care has to be exercised in using this agent, especially in larger quantities and in a closed environment (Hathaway et al. 1991). Chlorine (an oxidizing agent) can be reactive, so it must be used with caution when combined with other chemicals (e.g., ammonia).

Iodine is usually in an aqueous form or combined with alcohol. As with chlorine, it is effective against all types of microbes. Iodine's action appears related to a reaction with thiol groups (R–SH) on proteins. For viruses (capsid), this agent causes morphological changes rather than disrupting their genetic information. One of the problems with iodine is that it can stain materials and is therefore limited in general application.

PHENOL

Phenol was the agent used by Lister in 1867 as an antimicrobial to "disinfect" a patient's skin before surgery. This agent is effective against most microbes. However, at high concentrations, it has limited effectiveness against bacterial spores (Russell 2003) and hepatitis B (Cowan and Talaro 2006). Another limitation of this agent is its toxicity. This agent is most effective against G+ bacteria and enveloped viruses, but not nonenveloped viruses. In general, it should not be used in critical or semicritical areas as a disinfectant or on porous surfaces. Residual phenol can have toxic effects. Its mechanism of action appears to be related to membrane disruption and damage. The agent is found in household cleaners (e.g., Lysol) as well as triclosan. Triclosan is commonly added as an antimicrobial (bacterial) agent to various products (e.g., soap).

ALCOHOL

Alcohol is a commonly used agent. It is sometimes used in combination with iodine. The mechanism associated with this agent is dependent on its concentration. Since it causes proteins to coagulate, water is necessary for this process. In general, the ideal concentration is 70% alcohol and 30% water. At 100%, the agent will dehydrate the cell and inhibit growth, but not disrupt proteins (Cowan and Talaro 2006). This agent is not effective against bacterial spores and to some extent against coccidia (e.g., *Toxoplasma gondii*). For this reason, alcohol-based sanitizers are not recommended for spore-forming bacteria. Ethyl and isopropyl are the most effective alcohols, with isopropyl being best overall. Methyl should not be employed because of its low effectiveness.

HYDROGEN PEROXIDE

Hydrogen peroxide (H_2O_2) has been shown to be an effective agent against a broad range of microbes. Peroxides are effective as a result of being an oxidizing agent that acts through formation of hydroxyl free radicals. This oxidization causes denaturation of proteins and enzymes, particularly related to thiol groups. In one study (Barbut et al. 2009), H_2O_2 was reported to be more effective against *C. difficile*

spores when compared to 0.5% sodium hypochlorite (Barbut et al. 2009). However, the presence of protein-related material (serum) appears to reduce effectiveness (Piskin et al. 2011). If not properly stored, peroxides can lose activity. Exposure to high concentrations can cause irritation and inflammation to the upper respiratory tract.

FORMALDEHYDE

Formaldehyde (CH_2O) is an aldehyde (COHR) that acts by agglutination and cross-linking proteins. Here, the oxygen would exhibit electronegativity. This chemical is soluble in water and is a colorless gas. It is frequently used in pathology and hemodialysis and for sterilization of nonautoclavable instruments (Oie and Kamiva 2002). When in the gaseous form, irritation to the eyes and mucus membranes can occur. Exposure to this agent occurs through inhalation, ingestion, and dermal routes. The current PEL is 0.75 ppm-time-weighted average (TWA) with an action level of 0.5 ppm-TWA. A ceiling limit has been established by ACGIH, which is 0.3 ppm. Pulmonary edema and death have been reported at levels around 50–100 ppm.

Exposure to this chemical on multiple occasions can result in sensitization and loss of olfactory detection (tolerance). Nasopharyngeal sensitization can occur along with respiratory irritation and immunological stimulation. Warshaw et al. (2007) reported that about 13% of the U.S. population will respond immunological upon patch testing.

This chemical was historically considered to be a carcinogen, most notably as related to the nasopharyngeal region. Its carcinogenicity has been identified through animal testing. Recent epidemiological studies have not confirmed the animal studies, especially for the respiratory system (Bosetti et al. 2008). Marsh and Youk (2005) suggested that this difference in observed carcinogenicity among animals and humans is a result of variation in the mouth and nose structures. However, many standard texts do not mention or discuss the differences in reported carcinogenicity and do not usually include this most recent information. There does appear to be some relationship between formaldehyde and the occurrence of cancer in the hematopoietic system (Bosetti et al. 2008).

GLUTARALDEHYDE

Glutaraldehyde (Glut), an aldehyde, is considered a cold sterilant and is used for items that cannot be autoclaved, such as suction bottles and dialysis equipment. This agent is commonly used to disinfect endoscopes (Bordas et al. 2005). For endoscopes, disinfection with agents that are glutaraldehyde free has been suggested to be less effective, especially against bacterial spores (Miner et al. 2007). Endoscopes represent a classic example of an item that is difficult to disinfect and exists as a major source of contamination and cross contamination (Bisset et al. 2006). These items are heat sensitive and require another form of sterilization beside autoclaving. Glut is also used in pathology for preparation of histology slides and in the development of x-rays. Elevated exposure can result in a number of health

concerns including lung irritation, skin sensitization, nosebleeds, mucus membrane irritation, asthma, dermatitis, hives, nausea, and headaches. Concentrations of this substance are employed in a range from 1% to 50%. Ventilation is generally required for this substance. If exposure occurs, it should be washed off as soon as possible. The TLV is 0.2 ppm-TWA. Presently, there is no PEL, although the National Institute of Occupational Safety and Health has made the recommendation that OSHA adopt the ACGIH exposure value.

ETHYLENE OXIDE

Ethylene oxide (ETO) is used to sterilize instruments and materials that cannot be autoclaved (e.g., endoscopes) (Frăţilă and Tanţău 2006). These agents are generally sensitive to heat and moisture. ETO is highly flammable and will mix with water and solvents. It is a colorless gas at room temperature but can be in a liquid form at high pressure or low temperatures. The PEL limit is 1 ppm-TWA and has an excursion limit of 5 ppm. OSHA has a standard for ETO and requires monitoring of this agent in the workplace (29 CFR 1910.1047).

Studies have identified this agent as a carcinogen, and it has been associated with increased rates of leukemia (Landeigran et al. 1984). ETO can cause chromosomal aberrations and sister chromatid exchange in leukocytes. There are also noncarcinogenic effects from this agent, including spontaneous abortions, cytotoxic effects, nausea, dizziness, and cardiovascular and renal damage. Those exposed to this agent can also experience skin and tissue irritation.

SHIFT WORK

Shift work is common with HCWs. Reports have indicated that those working in rotating shifts have an increased risk of various diseases (van Mark et al. 2006). IARC has suggested that shift work can be considered carcinogenic. Cancer sites that have been suggested to be associated with shift work are breast, prostate, thyroid, and colon (Davis and Mirick 2006; van Mark et al. 2006). The biological basis of these diseases is disruption to the circadian rhythm. It is suggested that these changes are related to the sleep cycle, especially in regard to melatonin. For breast cancer, Megdal et al. (2005) found a consistent elevated breast cancer rate when evaluating various studies. This association existed even after adjusting for confounders. These findings are supported in a Seattle investigation that examined changes in various circadian-related hormones (Davis and Mirick 2006; van Mark et al. 2006).

There have also been reports of higher rates of CVD associated with shift work (Fritschi 2009). This increased risk has been suggested to be due to job stress and strain (van Mark et al. 2006). It is well established that there is a higher rate of cardiovascular events in the early morning as opposed to other times (Mosendane, Mosendane, and Raal 2008). This increased risk has been also associated with circadian rhythms. Abrupt changes in the sleep cycle cause the resynchronization of rhythms and as such can have an effect on the heart. There has also been a reported association of increased hemoglobin A1c, suggesting this activity

impacts metabolism (Suwazono et al. 2010). These changes can also result in an increased risk of elevated blood pressure, dyslipidemia, insulin resistance, and obesity.

There have also been suggestions that shift work increases the risk of infection (van Mark et al. 2006). This may be a result of oxidative stress on the system. It appears that antioxidant capacity is greatly influenced by shift work changes and that there is a decrease in its capacity after a night shift.

Although IARC has identified it as a cancer agent, there remains considerable controversy regarding shift work (Yadegarfar and McNamee 2008; Frost, Kolstad, and Bonde 2009) with not all investigators agreeing on the risks (Fritschi 2009). This issue will likely become of greater concern since it is now exists as a potential claim under WC (Ross v. Michelin North America (Canada) Inc., [2002] N.S.J. No. 538 (N.S.C.A.), Nova Scotia Court of Appeals). The Danish government has recognized breast cancer for those performing shift work as a compensable injury, creating a new precedent (Wise 2009). However, this concept has not been fully adopted by the U.S. courts. (U.S. Supreme Court, 99-460 Scheffler, William V. v. Dow Jones & Co.)

ANTINEOPLASTIC AGENTS

Antineoplastic agents are cytotoxic drugs used in the treatment of cancer because of their ability to inhibit cell division. There are five classes of cytotoxic agents: alkylating, antibiotics, antimetabolites, mitotic inhibitors, and miscellaneous compounds. Many patients treated with these drugs experience numerous side effects, including hair loss, other cancers, and malformation of children born to women that had been treated. Studies have suggested that administration and preparation of these drugs by HCWs can result in similar effects as seen in treated patients.

One of the greatest risks to HCWs from these substances is reproductive risks. Fetal loss as a result of exposure has occurred in the first trimester of pregnancy. These agents in general can be considered mutagens, teratogens, and genotoxic materials when classified based on their mode of action. In a study by Harris et al. (1992), a significant association was observed in nurses exposed to low concentrations of antineoplastic agents and chromosomal damage (breaks and micronuclei frequency). These low-level exposures suggest that HCWs are at an increased risk of disease (e.g., cancer) from these agents even at low levels and when attempts are made to employ personal protective measures. Chronic exposure can also result in nonreproductive and noncancer effects. These include headaches, nausea, diarrhea, vomiting, and dizziness. However, the greatest risk is associated with cancer. Even those that are filling prescriptions for these agents have been reported to be affected (Testa et al. 2007).

MERCURY

Mercury (Hg) is commonly used in clinical facilities, such as in thermometers. Most events involved with this heavy metal are associated with accidents, although it is used in pathology (e.g., histology slides). When this metal is released (e.g., spilled), droplets often occur and can be trapped under and in materials and over time become

volatilized. In many ways, this constitutes one of the major hazards associated with this metal. Hg is absorbed through the skin and lungs. Generally, the greatest concern is chronic health effects. Routine monitoring should be conducted after the occurrence of a mercury spill. High-exposure concentrations can cause coughing, chest pain, salivation, kidney damage, and reproductive effects. One of the biggest concerns for this metal is unknown spill events. This may represent an unknown hazard to HCWs.

RADIATION AND RADIONUCLEOTIDES

The two types of radiation are ionizing and nonionizing. In most cases, there are strict controls on ionizing radiation. There are three forms of this type of radiation: gamma, beta, and alpha. Devices like x-ray machines produce gamma and beta radiation, while treatment using radionucleotides more commonly involves alpha. The nonionizing radiation most commonly encountered is UV light. UV light ranges in frequency from about 100 to 400 nm. This radiation is most effective against microbes in the range of 240–260 nm. Germicidal lamps are usually at 254 nm. This agent can cause damage to an organisms DNA through the formation of pyrimidine dimmers as well as the formation of free radicals. UV is commonly used in the HCI as a general disinfectant (sterilization agent). The spectrum of UV is often classified as UVA (long wave [320–400 nm]), UVB (medium wave [280–320 nm]), and UVC (short wave or germicidal [100–280 nm]). UVB is the cause of sunburns, and UVA is sometimes called Wood lamp or black light. All UV radiation can cause damage, including cataracts.

HCWs can be exposed to both ionizing and nonionizing radiation. Most radiation sources (ionizing) are used for therapeutic and diagnostic activities, although some are used in the laboratory setting. Hazards of radiation have been well established, and it has been well recognized that there is a need for control. Nonionizing radiation is also used in health care and consists of mostly UV radiation. However, other wavelengths can be used as well. UV light is frequently used as a disinfecting agent and for preventing the spread of microbes in a number of settings.

BLOOD-BORNE PATHOGENS

Blood-borne pathogens (BBPs) are any organism that can be transmitted through body fluids, including blood. The most common agents transmitted are hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV. HBV is the most common chronic blood-borne infection (BBI). OSHA has established a standard for BBPs (29 CFR 1910.1030). Body fluids include a wide variety of materials, for example, unfixed tissue, HIV-containing cell cultures, saliva, semen, vaginal secretions, and pericardial fluids. This standard indicated that almost anyone can be exposed. Each job task must be evaluated without regard to use of PPE. This can be accomplished through the use of universal precautions. Such precautions include the use of various types of PPE and measures to prevent such events as needlesticks. There are a number of reported requirements under the standard, and they include, for example, various exposure incidents. It is estimated that worldwide, 9% of HCWs experience exposure

each year (Al-Benna 2010). Any employee that may be exposed to blood or potential infectious material (BBI), regardless of any specific exposure incident, must be offered the full hepatitis B vaccine. This must be offered no later than 24 hours after an event. If the event falls within the criteria of the standard, then postexposure procedures are also required.

The OSHA standard includes employees that clean up contaminated surfaces or surfaces that would result in occupational exposure. This can also include those that are assigned duties in regard to first aid (Department of Consumer and Business Services 2009). Employers are required by the standard to establish a written plan. All exposed personnel must also be given training at the time of initial employment and annually. Some of these agents are both an acute and chronic hazard. For example, HBV and HCV can both cause liver cancer.

SHARPS

Needlestick injuries are commonly reported by HCWs (Perry, Gomaa, and Jagger 2009). Clarke, Schubert, and Korner (2007) reported a needlestick rate of 488 per 1000 full-time employees. Needlesticks can result in transmission of a large number of infectious agents, especially BBPs. The same is true from other types of sharps (e.g., scalpels). In the United States, about 380,000 percutaneous injuries occur each year (Jayanth et al. 2009). According to Jayanth et al. (2009), at least in India, 8.5% of these injuries occur during recapping of needles and about 19% result during disposal of sharps.

INJURIES

Injuries, such as those associated with the musculoskeletal system, are becoming a more common problem for HCWs. Much of the driving force related to injuries is WC. One study suggests that the largest number of musculoskeletal injuries occur in nurses, nurse's aides, and radiological technicians (Pompeil et al. 2009). Forty percent of these injuries resulted from lifting, while 23% related to repositioning the patient. The study by Pompeil et al. (2009) suggested that use of mechanical lifting systems could reduce these injuries. Another study (Karahan et al. 2009) found that about 66% of those in a large hospital reported having back pain. The highest percentage of back pain was reported by nurses (77%). Approximately 78% of the respondents reported that their back pain began after starting work. Of this population, 33% reported seeking medical attention for the back pain. These studies indicate the magnitude of the problem. A better understanding of ergonomic issues may also assist in reducing these events.

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7 Staffing and Medical Errors

Beth Piknick

The Stories are Gruesome

A Washington State man finds that a surgeon left a 13-inch instrument in his body only when he sets off metal detectors at the airport. Two women die in a Connecticut hospital after being given nitrous oxide (laughing gas) instead of oxygen. A doctor in New York operates on the wrong knees of two separate patients.

If you are a patient or a family member of a patient entering a hospital today, the single most important factor determining the outcome of your care is the number of patients assigned to the nurse responsible for that care. Understaffing of registered nurses (RNs) and excessive patient assignments have been directly linked through dozens of scientific studies to a dramatic increase in the risk of medical errors, patient injuries, hospital-acquired infections (HAIs), and thousands of patient deaths each and every year.

You can have the greatest surgeon in the most modern hospital in America, yet if after that surgery, you are placed on an inpatient unit where your nurse has too many patients, say six patients instead of four on a general surgical floor, then you are at a 14% increased risk of dying from a complication from that surgery. This is according to a study by Linda Aiken, who states, "For each additional patient over-assigned to an RN, the risk of death increases by 7% for all patients. Patients in hospitals with a 1:8 nurse-to-patient ratio have a 31% greater risk of dying than patients in hospitals with a 1:4 nurse-to-patient ratios."[1] These are staggering statistics that you'll find, as you read on, are ignored.

Nurses are the surveillance system in a hospital. Think of it: in today's health-care environment, if you are in the hospital, you are very, very sick. The only reason you are in the hospital is because your condition is severe enough to require around-the-clock monitoring and observation by an RN. At any moment, your condition could and will change. Nurses are the ones who are trained to administer and monitor any number of medications and to monitor procedures to measure and evaluate the progress of your recovery. One of my colleagues in the intensive care unit compared her job caring for a complex patient, with all the tubes, devices, and machinery, to that of an airplane pilot flying in bad weather. Steering the patient to a safe discharge requires constant vigilance and careful attention to the subtle changes indicated by all the data and information presented to the nurse. If a nurse has too many patients, there is a likelihood he or she will not be in the room to spot that subtle change in

oxygen levels; to see that change in heart rhythm or urine output; to just put his or her eyes on the patient; or to see that the change in skin color that can signal the onset of problem. If the nurse not there or do not have the time to process this information, he or she can miss a cue and the patient can crash. In the simplest of terms, RN staffing matters; it is a matter of life and death!

When I was approached to write this chapter, I was initially hesitant. I am an RN and writing does not come that easily to me. As an RN, I am a patient advocate. This has led me to my role as a nurse activist. Nurses as a whole are very comfortable taking care of the needs of our patients. We, as a rule, are not comfortable talking about what we do in the course of our daily practice.

I was comfortable in my role as a nurse taking care of patients and being their advocate. Working in the intensive care unit and taking care of critically ill patients and their families is rewarding and stimulating. At that time, I was not a person who was politically active by any means, was not into public relations, and certainly was not into conflict. But I found myself in that arena almost by accident. After returning from maternity leave after my second child, I was told that I was unable to return to the intensive care unit. The reason did not make much sense, and every time I questioned the decision, I was given a different reason. None of the reasons seemed appropriate. My facility was represented by the Massachusetts Nurses Association (MNA), so I went to the officers in my facility to seek assistance. They were unable to offer me any. I recalled that shortly before I left for maternity leave, I had an incident involving my shift supervisor and the chief of the intensive care unit. Ironically, the incident involved unsafe staffing. I had told the chief that we did not have enough staff for that shift. The chief was a neurosurgeon whose patients were always on every 15 minute vital signs and we had three of his patients is the unit at that time. He supported my opinion and lashed out at the shift supervisor, who in turn reported the incident to the chief nursing officer, and I was told the incident would not be forgotten. Little did I know this would be the beginning of more than two decades of patient advocacy. So I did my apparent punishment, which was a year on a medical-surgical floor. After working exactly a year there, a position in the intensive care unit became available.

After making my presence known to the MNA local union leadership, who are always looking for new, interested nurses, they asked me to be a part-time representative on the MNA-negotiating committee at my hospital. I already knew that my profession was dismissed and devalued, and our opinions ignored. This provided an opportunity to change that. Now I had truly become a nurse advocate as well as a patient advocate. My ability and willingness to be an activist continued, and 30 years later, I became the president of the MNA, a position I held for 4 years. During those 4 years, I became the face and voice of an organization representing 23,000 RNs and health-care professionals at a time when the debate over the issue of RN staffing and its impact on patient safety was at its height in our state.

As I mentioned earlier, as an RN, you are dedicated to your patients not just as their primary caregiver, but as their advocate. Under my nursing license, my ultimate responsibility is not to my place of work but to the patients under my care. In fact, every nurse is personally accountable for the safety of his or her patients, legally and ethically, no matter what conditions under which he or she practices the profession. While it may not always be comfortable to some, it is the duty of each and every RN

to advocate for his or her patients, whether by advocating for a patient to a physician, a nurse manager, a family member, or even lobbying elected officials.

My stint as president was an amazing learning experience, and one of the most important takeaways from those years was that as a patient advocate, no opportunity to speak out for your patients can be squandered. Patients need to know how important the issue is and how to keep safe. Younger nurses need to know that it was not always this dangerous. It does not have to stay this way, and there is hope that the patient care environment will improve.

Thirty years ago, hospitals had a very different environment. I say this not to be nostalgic about the good old days but to give context to how critical the situation has become in today's acute-care hospitals. When I first began nursing, patients were not as sick as they are today. Nurses were able to spend adequate time with each patient, assessing changes in their condition, educating them and their families about their diagnoses and medications, and perhaps even taking a few minutes to have a conversation with them, get to know them a little, and ease their fears and concerns. But changes in reimbursement, the onset of managed care, and the rapid consolidation that followed hospital deregulation altered this equation. "Cost cutting and ballooning workloads are creating more problems for patients, too. Falls, bedsores, and failures to rescue patients are up."[2] As hospitals looked to wring cost savings out of their operating budgets, they took a number of different approaches. One tactic was to cycle patients throughout their systems more quickly and to only keep those in hospital beds whose condition was very serious. This meant more patients could come through the hospital on a given day with significantly fewer hospital beds available for only the sickest patients. This increase in volume and traffic, if you will, was good for the bottom line, but it meant that on a given shift, a nurse could take care of as many as 10 patients who are acutely ill. A nurse could have as many as perhaps six patients at one time, but two or three could be discharged or transferred and then two or three more admitted to his or her care. So now a nurse could have been responsible for up to 12 patients during his/her shift.

A nurse of 5 years recently shared with me that she was looking for another position. Nursing was her second career. She was looking for something that would encompass all her skills. She was frustrated with the "McDonald's care." To give an example, during one 12-hour shift in an emergency center, one nurse started out taking care of seven patients (already too much), which included three psychiatric patients. The seven patients were very sick. One was unstable and required close monitoring. Two were discharged home, which requires a multitude of paperwork plus the discharge instructions given to the patient. Plus, these patients and the families had lots of questions. So, in the meantime, what is happening to the unstable patient? Especially since after the two discharges, another three patients were admitted to the emergency center. The nurse was unable to give medication in the required amount of time. At one time, during the 8-hour shift, two nurses had taken care of 19 patients. What do you suppose may have happened to the unstable patient?

Years ago, before the hospitals were more concerned about the bottom line and reimbursements, a nurse could take care of perhaps six to eight patients on a medical-surgical floor at one time, but they were not as sick as they are today. You might take care of a couple of new postoperative patients and perhaps some patients who

had their surgery several days before and were ambulating the hallways. They could care for themselves a bit and were just about ready to go home. You may also have a healthy patient that had been admitted just for a couple of days for tests/procedures. If any of them were to be discharged, they would usually be discharged during the day shift, not all hours of the day or night, as is the case now. Now those patients who are staying in the hospital are far sicker than the generation of patients preceding them. Today, if you are assigned six or eight patients, because none of them are walking around and all of them are very, very sick, you are required to give constant monitoring and attention. This puts added strain on the bedside nurse, requiring nurses to work at a faster pace.

Nursing practice today is tougher than ever. Patients on the floor are on intravenous drugs with medications that cause complications very quickly. Almost all patients are on cardiac monitors to detect irregularities before they turn into problems. Some floors even have respiratory ventilators unheard of years ago outside a critical care unit. The amount of technology with patients grows every year, with the media recently publishing stories about a new phenomenon, known as alarm fatigue, which is where nurses become deaf or numb to all the various alarms, bells, and whistles attached to their patients.[3] Add to the new requirements electronic record keeping, more extensive paperwork for each patient, and strict rules for hand washing and infection control, and you get a picture of a chaotic and unmanageable work environment, with less time spent with each patient. In fact, according to the prominent study published in the *Journal of the American Medical Association* (JAMA), each of those eight patients assigned to that nurse is at a 31% increased risk of injury or death.

If the increase in patient acuity was met with an appropriate increase in staffing, such changes might have been manageable. But instead of taking this logical step, not only was staffing not maintained, it was decreased. We saw nurses replaced with unlicensed assisted personnel. We saw nurses laid off for the first time in nursing history. We saw nursing vacancies disappear and not be replaced; therefore, nurses actually saw their patient loads increase. For the first time, we heard the term mandatory overtime. This is a method of staffing that is now commonplace, where nurses are supposed to go home at the end of their shift at a certain time but then told that they cannot leave. It does not matter if they have been up for almost 24 hours, they stay. They stay or run the risk of termination. They stay but run the risk of making errors that could harm their patients and potentially lose their license to practice.

For example, one nurse I worked with started her shift at her regular time at 3 PM. She was supposed to go home at 11:30 PM. For many weeks, the manager who made out the schedule knew that during this particular shift, the floor was down one nurse. There were no attempts to fix that. According to some managers, you do not fill an empty slot gambling that the floor's census will be low. This particular nurse had been up since 6 AM; she was working on 4½ hours sleep. Instead of going home at 11:30 PM, she was going home at 7 AM. The following was taken from an unsafe staffing form, "Objection and Documentation of Unsafe Staffing/Unsatisfactory Patient Care," a form that is used in many union facilities all over the country. This nurse was working the 3-11:30 shift. "I have been up since 6 AM. I have small children at home with no childcare for this morning. I feel unsafe to take care of my patients and also unsafe to take care of my children tomorrow."

In one acute care hospital, there were two nurses taking care of seven patients with high acuity. There were no nursing assistants and not even a secretary on the floor. Some of the patients were so ill that one nurse was not able to take care of some of the patients properly and safely. These patients were postoperative cardiac surgical patients. Several of the patients were on continuous cardiac intravenous medications. These types of medications must be closely monitored. They can cause sudden life-threatening complications and changes in condition that require quick intervention by the nurse. A patient went unbathed, and the nurse was unable to change the sheets and unable to turn him or her. The inability to bathe and change position leads to patient complications such as decubitus/bedsores, life-threatening blood clots, and/or pneumonia.

There was a patient on a surgical floor who was several days post-surgery. This patient should have been discharged after a couple of days. He had developed complications. Due to those complications, he was in the hospital for much longer than anticipated. Now he was developing more complications due to the lack of staff. There was not enough staff to ambulate this patient on a regular basis; therefore, he developed a problem in the base of his lungs. This was causing him to have decreased blood oxygen levels, which led him to have trouble breathing. This can easily turn into pneumonia. There was also concern that the patient was developing blood clots in his legs, which could move to his lungs or heart causing life-threatening complications-failure-to-rescue, leading to death. All this can be directly related to lack of exercise, lack of movement, and lack of anyone able to get him out of bed and walking.

In 2003, the Institute of Medicine concluded that "the environment in which nurses work is a breeding ground for medical errors which will continue to threaten patient safety until substantially reformed. The study finds increased infections, bleeding and cardiac and respiratory failure associated with inadequate nurses staffing."[4] In 2006, another study found that "patient safety outcomes are related to the quality of the nursing practice environment. Strong correlations exist between low staffing levels and increased emotional exhaustion which leads to more patient complaints, nonsocial infections (infections from hospital care such as staph and urinary tract infections) and medication errors."[5]

Do you think the two previously mentioned nurses need these studies to inform them of this scientific information? I think not! These are the things we have been saying for years that have been dismissed. Nurses went into the nursing profession not to harm patients. If we feel that we are harming them or that we might, we leave. We do not necessarily leave the profession, but rather leave bedside nursing. This is the vicious cycle, and the only way to make it stop is to let nurses do our jobs. Let us take care of the patients the way we were educated to do, and let us take care of the patients the way we want to do. After all, that is why most of us became nurses—to take care of patients. The cycle is not going to change unless something happens and unless we as patient advocates make it change.

After over a decade of doing the "best we can" and after much debate and more agonizing debate, nurses began to speak out. We continued to be quiet and "do our best" by our patients, but we were no longer quiet elsewhere. We began to call attention to unsafe conditions. Patients were not only no longer receiving quality care, they were not even getting safe care. We started to speak publicly, not to scare people

but to try and enlist support in remedying the situation. I believe some people are listening. The public overwhelmingly supports nurses. The public trusts nurses. It is the number one trusted profession, by 81%, according to an annual Gallop Poll of the most trusted professions.

The past decade has been a turbulent time for U.S. hospitals and practicing nurses. News media have trumpeted urgent concerns about hospital understaffing and a growing hospital nurse shortage. Nurses nationwide consistently say that hospital nurse staffing levels are inadequate to provide effective care. The Joint Commission of Accreditation of Healthcare Organizations (JACHO) is an organization that accredits and licenses various health-care facilities including acute care hospitals. To be successful, hospitals must adhere to strict guidelines and follow strict practice and safety standards. Technically, this is a voluntary accreditation, but it is treated as mandatory and hospitals take it quite seriously. That is why it is very ironic when, in 2002, a report by JACHO stated "that the lack of nurses contributed to nearly a quarter of the unanticipated problems that result in death or injury to hospital."[6] In all the seriousness of JACHO, it never ceases to amaze me how this statement plus all the other supporting data is ignored.

Nurses looked for solutions through their collective bargaining agreements. Few were successful. The results were and are too slow, and the care was not getting any better, so we tried legislation. In 2004, California became the first state to implement minimum nurse-to-patient staffing requirements in acute care hospitals.[7] The ratio was according to a particular type of unit. With one state's passage, many thought others would follow. Massachusetts filed legislation this year for the fourteenth time.

To me, as a nurse working at the bedside, passage of this should have been simple and immediate, a no-brainer. It should be common sense to the legislators. It is all about safety. Other industries are regulated for the public's safety. In Massachusetts, we regulate the number of children assigned to teachers in daycare, but if that child is hurt and goes to the hospital, there is no legal limit on the number of sick children that nurses must be forced to care for; it makes no sense. The opposition to this legislation from the hospital industry has been overwhelming. The hostility was palpable, and the pressure was too much for many legislators to bear. The Massachusetts Hospital Association strongly opposed this bill and the entire concept of being regulated. As it spread to other states, the American Hospital Association opposed those as well.

The alternative solution proposed by the industry to solve this problem was to form committees that had no authority. I have sat on such a committee. It is a waste of time and energy because it goes nowhere. Another solution was to be more transparent through the Hospital Association's *Patient First* website. This website stated how many patients a nurse was taking care of on a particular floor in a particular facility. This solution had a number of flaws. First of all, the numbers posted were often bogus, and did not reflect what was actually happening. Secondly, no patients really knew about the website, and few, if any, ever used it. And most important of all, few patients have a real choice of where they receive care. If your hospital is near other hospitals and you are in an emergency situation, an ambulance is going to head to the nearest hospital, and no patient is going to pull out a laptop and compare the staffing levels in that facility and tell the ambulance driver to go left instead of right.

None of these approaches worked, and they demonstrate that voluntary compliance is not substitute for mandatory adherence.

So what can we do? What can you do? Ultimately, we need to pass federal or state legislation that sets a safe limit on nurses' patient assignments. A recent study about the success of the California safe staffing law found that patients in California with mandated RN-to-patient ratios are safer than patients in states without the regulations. In the complete research findings by Aikens et al. published in JAMA, they determined the following: "Our results suggest that the California hospital nurse staffing legislation represents a credible approach to reducing mortality and increasing nurse retention in hospital practice, if it can be successfully implemented.[8] Our major point is that there are detectable differences in risk-adjusted mortality and failure-to-rescue rates across hospitals with different RN staffing ratios."[9] *Every* patient in *every* hospital deserves this level of protection in *every* state. As I said at the beginning of this chapter, RN staffing matters; it is a matter of life and death.

ENDNOTES

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8 Working Conditions and Patient Safety
Impacts on Medical Errors

Steven Hecker

CONTENTS

INTRODUCTION

On September 19, 2010, Kaia Zautner, a 9-month-old critically ill infant, died in part as a result of a miscalculated medication dose at Seattle Children's Hospital. On April 3, 2011, Kimberly Hiatt, the critical care nurse who administered that medication, committed suicide. Hiatt had been fired by the hospital and had been struggling with the Washington Board of Nursing to retain her license. This tragic sequence of events and the commentary it has generated is just one case among many to illustrate that 12 years after the Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System*, medical errors and their prevention remain enormous issues in the U.S. health-care system (Kohn, Corrigan, and Donaldson 2000). While the intervening years have seen a great deal of attention paid to patient safety, both within the health-care system and from the public, the impact of that attention remains limited. Some experts see this increased interest and research in patient safety reflecting a strong will to change; others, including some involved in the IOM report itself, are struck more by the failure of many parts of the system to make those necessary changes (James 2005).

At the extremes in addressing lapses in patient safety are temptations to "blame the last person to touch the patient" (Rivera and Karsh 2008) or to throw up one's hands at the complexity of the factors involved. The factors contributing to medical errors

and patient harm are legion, and complexity in health-care systems and institutions is one such factor. Complexity also poses a challenge to parsing the major variables and identifying interventions to address deficiencies. The research enterprise underway to tackle these questions, in the United States largely under the auspices of the Agency for Healthcare Research and Quality (AHRQ), is laudable. Evidence-based interventions are necessary to improve a variety of systems and processes in health-care delivery. However, the slow pace of improvement seen thus far, and indeed the indication that rates of medical errors have hardly changed in the past 10 years (Blum et al. 2011), does raise questions about how long we can wait for the needed evidence to be developed on a multitude of specific elements of the health-care system, and whether we know enough to recommend some fundamental measures that can be taken now in the area of cultural and systems changes. The risk of paralysis by analysis always exists in a landscape as vast as the U.S. health-care system.

One direction taken in the quest to reduce medical errors and improve patient safety is the application of lessons learned from high-reliability organizations in which the consequences of failure are unacceptable, like aviation and nuclear power (Nance 2008; Hughes 2008). Most participants in the health-care system, as consumers or employees, would undoubtedly agree that health care should be a high-reliability sector. Unfortunately, that is not yet the case, and the slow pace of change even since the groundbreaking IOM report reflects this. However, a potential benefit of looking at health care this way is the growing acceptance of the application of systems and human factors engineering to health care and patient safety, processes that have the potential for a more productive approach to understanding and modifying components that contribute to medical error. Both the Systems Engineering Initiative for Patient Safety and the input-transformation-output model of health-care professional performance offer promising models for diagnosis and intervention with a focus on human performance in the context of health-care systems (Carayon et al. 2006; Karsh et al. 2006).

Whether our health-care institutions and government policy makers have the will to devote the resources to bring continuous improvement to patient safety remains to be seen. One broad area in which more must be done soon is that of health-care provider working conditions.

SCOPE AND DEFINITION OF WORKING CONDITIONS

This chapter addresses the influence of health-care working conditions on patient safety. This four-word phrase encompasses an enormous range of factors and combinations, so it is important to circumscribe the scope to attempt a practical analysis. Working conditions itself is a broad category, and we must ask as well *whose* working conditions.

We will use as a starting point in defining working conditions the seminal evidence report on this topic funded by AHRQ. This review evaluated five categories of working conditions: staffing, workflow design, personal/social issues, physical environment, and organizational factors. This classification scheme was derived from existing literature at the time and the advice of an expert panel. There are limitations to this arrangement in that it is not specific to any one category of health-care

provider, and one could argue that some of the definitions it provides, including specific subcategories, include misclassifications. However, this study is often cited in subsequent research and is therefore as useful as any for the sake of this analysis.

Classification Scheme for Working Conditions

The following listing uses the original review scheme as its basic outline. Some of the specific elements in each category are provided in the original review (Hickham et al. 2003), while others have been added based on subsequent investigations as cited below. Where questions of misclassification are found, they are pointed out.

Staffing includes (Clarke and Donaldson 2008)

- Number of personnel relative to service volume
- Staff qualifications, including education, experience, skills, and so on
- Model of care delivery, that is, mix of credentials, RN, LPN, and CAN
- Work schedules

Workflow design focuses on job activities, including

- Nature and scope of tasks
- Task design including redundancy, complexity, and distractions
- Interactions among workers in completing tasks including transfer of information and responsibilities to others ("hand-offs")
- Workplace design, including ergonomics of technology and equipment; while included in this category, this factor is in reality an interaction of physical work environment with human factors and task design

Personal/social issues might also be called *psychosocial factors* and would include

- Social support
- Empowerment of direct care staff in decision making
- Control over pace of work
- Stress
- Job satisfaction
- Professionalism

Were the original review being done today, workplace violence and bullying, whether patient–employee, supervisor–employee, or employee–employee, would likely be a subcategory of its own (Lipscomb et al. 2010).

Physical environment is given a quite limited scope in the original review but includes a multitude of factors, some of them overlapping with other categories, including

- Layout of patient care rooms
- Distance between storage areas for needed patient-care items and patient beds

- Design of beds
- Patient handling equipment availability, appropriateness, location, and condition
- Noise, lighting, and other environmental conditions

Organizational factors or organizational culture include

- Evaluation and reward system
- Accountability systems
- Team structures
- Managerial style

The latter category overlaps and interacts with several of the personal/social issues in that management style and systems can to a large extent determine employee empowerment, job satisfaction, and other so-called personal/social issues.

The Evidence Base for Working Conditions and Patient Safety

The 115 studies ultimately included in the 2003 review provided evidence that these working conditions affect patient outcomes related to patient safety, the rate of medical errors, and the rate of recognition of such errors after they occur (Hickham et al. 2003). The weight of the evidence varies for different specific conditions, but the overall picture strongly suggests that progress in patient safety can be made by focusing on working conditions.

It is impossible to do justice to the broad range of working conditions issues in this single chapter, so it will primarily focus on the area of staffing, scheduling, and workload, targeting nursing personnel as the largest category of frontline health-care workers and one for whom working conditions have been critical topics of debate. Discussion of these topics will necessarily bring in other related working condition factors and other health-care professions. In particular, the long-running debate over the scheduling and work hours of interns and residents, though addressing physicians rather than nurses, provides important additional data and experience to this discussion (Blum et al. 2011).

STAFFING, WORKLOAD, AND SCHEDULING

Staffing, particularly for nursing occupations, has received the most attention as a factor in patient safety outcomes. In the face of an aging population, increasing patient acuity, rapidly inflating costs of hospitalization, and a shortage of skilled nursing personnel (Carayon and Gurses 2008), nursing labor organizations and consumer advocates have campaigned for staffing ratios as a way of improving the quality and safety of patient care while reducing the physical and psychological stress of nursing jobs.

Recent examination of the nurse staffing literature leads to mixed findings that are no doubt frustrating to frontline caregivers and nurse advocates (Clarke and

Donaldson 2008). While optimal staffing ratios for particular settings are not fully known, the relationship between adequate staffing and important patient outcomes has been clearly demonstrated (Hughes and Clancy 2005). Even skeptical investigators acknowledge the following:

> A critical mass of data suggests that staffing at the lower end of the continuum may place patients and nurses at heightened risk of poor outcomes. Therefore, it appears hazardous to patients and staff to staff at the lowest levels relative to peer units and health care organizations.
>
> **Clarke and Donaldson**
> *2008*

However, the search for more specific correlations and recommendations for staffing practice has been slow going. Investigators complain of inconsistent outcome and staffing measures, uncertain temporal relationships, inappropriate units of analysis, and other limitations. In the advocacy for evidence-based practice, they demonstrate that for many suppositions, the evidence is just not yet available.

> While many feel experience and specialty training have logical associations with quality of care and patient safety, empirical data regarding their impact are very limited at present.
>
> **Clarke and Donaldson**
> *2008*

To be fair, these authors go back and forth between the lack of experimental or quasi-experimental data in support of staffing ratios and like measures and the need to take into account clinical experience and cumulative anecdotal evidence, illustrating the frustration that many feel.

It is worth quoting at length a prominent U.S. quality expert, Donald Berwick, on the trap we have fallen into in the exercise of evidence-based medicine:

> But, we now have a problem: we have overshot the mark. We have transformed the commitment to ''evidence-based medicine'' of a particular sort into an intellectual hegemony that can cost us dearly if we do not take stock and modify it. And because peer reviewed publication is the sine qua non of scientific discovery, it is arguably true that hegemony is exercised by the filter imposed by the publication process. The failure of the publication filter to accommodate the kind of discovery that drives most improvement in health care—and the failure of those working in healthcare improvement to reconfigure the filter appropriately—is the message of the paper … by Davidoff and Batalden [that] addresses the narrower issue of publication standards … [and] … an epistemology of a new and broadened understanding of the evidence needed for the improvement of care. The argument for that epistemology is not a simple one, but its intuitive force is somewhat easier to uncover with a simple question: ''How much of the knowledge that you use in your successful negotiation of daily life did you acquire from formal scientific investigation—yours or someone else's?''

> Did you learn Spanish by conducting experiments? Did you master your bicycle or your skis using randomized trials? Are you a better parent because you did a laboratory study of parenting? Of course not. And yet, do you doubt what you have learned?
>
> Broadly framed, much of human learning relies wisely on effective approaches to problem solving, learning, growth, and development that are different from the types of formal science so well explicated and defended by the scions of evidence-based medicine. Although they are far from [randomized controlled trials] in design, some of those approaches offer good defences against misinterpretation, bias, and confounding. In the world of clinical care, especially in the quest for improvement of clinical processes, is it plausible that those approaches—the ones we use in everyday life—might have value too, used well and consciously, to help us learn?
>
> The answer is ''yes.'' And yet, the very success of the movement toward formal scientific methods that has matured into the modern commitment to evidence-based medicine now creates a wall that excludes too much of the knowledge and practice that can be harvested from experience, itself, reflected upon. The iconoclasts of the past now have power, and they can define who will be seen as iconoclasts of the present.
>
> **Berwick**
> *2005*

Evidence from Resident Physician Research on Work Hours

Berwick's point is illustrated by the ongoing policy making regarding resident physician work hours. In 2003, the Accreditation Council for Graduate Medical Education (ACGME) introduced working hours limitations for medical residents, including a weekly limit of 80 hours and up to two "extended" (more than 24 hour) shifts per week. These rules were prompted by research indicating elevated rates of medical errors, work-related injuries, and motor vehicle crashes on the way home from work among residents working extended shifts (Blum et al. 2011). Subsequent research found continuing adverse consequences under the 2003 rules, prompting an IOM comprehensive review of resident working hours and safety that was completed and published in 2009 (Institute of Medicine 2009). As a result, ACGME issued new rules effective July 1, 2011, including a limit of 16-hour shifts, but applying only to first-year residents (Blum et al. 2011).

The debate over resident work hours and the resistance of ACGME to full implementation of the IOM recommendations provides yet another example of the failure to act on evidence to control medical errors as well as the issue of who should monitor and control application of such evidence-based guidelines. Practitioners and medical educators contending that the IOM recommendations have gone too far argue that physicians in training must learn to work and make decisions when fatigued, and that this is an essential skill for physicians. They also point out that restricting shift length increases the number of handoffs, another potential risk factor for errors and adverse patient outcomes (Gold 2011). The Harvard Work Hours Health and Safety Group, however, presents extensive evidence from research on medical residents and numerous other working populations that decrements in performance after 16 hours of consecutive work are unavoidable in humans (Blum et al. 2011).

Here we are presented with a case in which human factors experts have established beyond reasonable doubt that the current practice is harmful to both doctor and patient, but the guardians of medical training seem to be arguing that somehow doctors are different from any other workers in terms of performance and that they must be trained to overcome these human limitations. Clearly, economic and cultural factors are also motivating opponents of further work hour restrictions, as such restrictions would significantly increase training costs as well as require changes in practice by attending physicians. The extensive recommendations of a Harvard stakeholder group convened to address these challenges in the larger context of work redesign for resident training are an excellent model of what is needed throughout the health-care system in regard to modifying working conditions to improve patient safety (Blum et al. 2011).

Related Aspects of Time and Workload

It is not only the direct effects of understaffing and excessive workload on medical errors that should concern us, but also the extreme time pressure under which direct care staff commonly work, which is a barrier to improvement efforts in patient safety. For example, the state of Washington's safe patient handling (SPH) legislation passed in 2006 mandates a number of program requirements for acute care hospitals (Revised Code of Washington 2006). Among them is the establishment of a safe patient handling committee in which at least 50% of the members are direct care staff. The law is well intentioned, in that the evidence is clear that direct care staff involvement in the identification of patient handling risks and especially in the selection of patient handling equipment is critical to the adoption and use of such equipment by employees to reduce risks to both workers and patients. The law also requires that employees who use the equipment receive training on its use.

In monitoring the implementation of SPH programs under the law, we hear again and again about the difficulty that committee members have in spending even minimal time on SPH committee activities. A provision intended to empower direct care staff cannot succeed if those very staff need to make choices between patient care and participation in the committee or if exercising one's committee role creates an added burden on staff left on the floor. Similar tensions exist in designating sufficient training time for workers when staffing is tight.

In the same vein, Kellie and colleagues (2008) report on a patient safety improvement prototype focusing on medical event reporting, sense-making from near misses and actual events, and implementing organizational changes identified from errors and failures. In two study hospitals, the investigators found that few near misses were recorded during the normal reporting process.

> … factor leading to the low numbers of identified near misses was that team members acknowledged their difficulty in taking time away from patient care to complete their near-miss reports. This became evident when staff were asked for examples of near misses, and they readily recalled recent near misses.
>
> **Kellie et al.**
> *2008*

The authors conclude that

> This tension among frontline workers between taking care of patients' needs and taking steps to learn from near misses and events is not likely to go away….[W]e will need to find a way to address this issue if we are going to improve patient safety on the front lines of health care.
>
> **Kellie et al.**
> *2008*

Much of the literature accepts as a given the resource constraints that limit the flexibility for employee participation in safety and quality improvements. It is doubtful that much progress can be made unless such participation and empowerment is granted primacy and staffing is adjusted to accommodate it.

A HUMAN FACTORS APPROACH TO PATIENT SAFETY

The application of human factors and systems engineering to the related problems of work design, task flow, workflow, and medical error prevention is a promising development. An interesting example is provided by Carayon and Gurses (2008) with regard to nursing workload and patient safety. The authors argue that while there is clear evidence of high nursing workloads negatively impacting patient outcomes and nurses' stress and job satisfaction, simply increasing nurse to patient ratios may neither be possible due to costs and a shortage of skilled nurses, nor a simple answer to the problem. A better understanding of workload at the microsystem level through human factors analysis can better diagnose the problem and lead to a more targeted solution. The key measure here is the *situation-level* workload, which can widely vary between nurses with the same job title. Components of this workload may include physical distance the nurse must travel between patient rooms and to retrieve supplies, the relative calm or chaos of the environment, and the availability of equipment and information needed to deliver safe patient care.

High workload can affect nurses, and therefore patient safety, in multiple ways. Insufficient time can cause the nurse to not perform tasks necessary to good patient care. It may also limit the communication and collaboration between nurses and between physicians and nurses. High workload can lead to high levels of stress and ultimately to burnout. Excessive workload can lead to "violations," that is, deliberate deviations from practices put in place to maintain safe and secure operations (Carayon and Gurses 2008). A distinct but related aspect of time pressure and workload is interruptions, very common in nursing practice, with potentially serious implications for patient safety (Patient Safety and Quality Healthcare 2010).

Once the causes of situational workload are identified, and they may be quite varied, the human factors approach designs interventions to reduce or mitigate excessive workload. Ideally this would involve work system redesign, but for those elements that cannot be redesigned, balancing interventions may be needed (Carayon and Gurses 2008). These might include additional social or cognitive support. An important caveat is that changes to one element of a work system may affect other

elements, in either positive or negative ways. It is necessary to identify such effects ahead of time and account for or mitigate them.

While the human factors engineering approach offers promise in addressing improved working conditions and patient safety, it is clear from the process described in this chapter that considerable time and resources are required. Interventions themselves may not be expensive (Grout 2007), but the time to assess needs and design solutions can be. The embrace of lean principles and practices by an increasing number of hospitals provides an opening for attention to work redesign for patient safety, but as in manufacturing, it is critical that such processes improve working conditions and not simply make hospitals more efficient (Graban 2008).

CONCLUSION

We must ask some pointed questions to advance the discussion on working conditions and patient safety. On the topic of nurse staffing and workload, for example, we can concede that research may have not yet determined the optimum staffing ratios for various kinds of units. And, perhaps many nurses can and do perform heroically to care for their patients in the face of long shifts with rare breaks. But is this any way to run our health-care institutions, pushing dedicated employees to their limits? Most reasonable people would say no, it is not. Nurses have voted with their feet out of the hospital and out of the profession to let us know that something is not right. AHRQ and other research have shown that fundamental interventions to improve working conditions are in the interest of patient safety.

> A large part of patient safety centers on the right working conditions for nurses within a climate of patient safety—a climate that recognizes when errors occur, provider negligence is the factor we should consider last. Several AHRQ-funded studies found that effective systems-level approaches to foster a patient safety culture include a blame-free environment emphasizing continual learning based on voluntary reporting of errors, which inform an evidence-based approach to amend current practices and to focus on patient-centered [care]. When this approach is not taken, adverse working conditions can result, which affect patient safety and can also indirectly impact nurses' stress level, health, and job satisfaction.
>
> **Hughes and Clancy**
> *2005*

But this approach cannot be effectively taken without management leadership and support at all levels, not just in the launching phase but consistently over time. To the argument that our hospitals do not have the resources to increase staffing and control workload, we must examine the assumptions in this position. How are resources currently allocated in our health-care system? How could those resources be better allocated if, for example, we did not spend such vast sums on care and treatment with little apparent benefit in the last months of life (Gawande 2010)? Or if we were not paying for the immense marketing budgets of pharmaceutical companies? Granted these are not things that an individual institution can necessarily control, but we are in the midst of a debate about the nature of our health-care system, so we must engage them.

The quest for more detailed data and validation of the specific impact of patient safety interventions will go on, but we cannot afford to sacrifice the health and lives of more patients and health-care workers in the meantime. We have seen that even where the evidence is strong, as in resident working hours, resistance based on professional culture and financial interests is not easily overcome. This struggle is partly scientific and evidence-based, but it is most definitely political as well. The effectiveness of the deep involvement of direct care workers in the protection of their own and patient safety and health and the application of human factors methods to health-care improvement are supported by science. Some employers have recognized this and implemented continuous improvement programs that genuinely empower employees and systematically analyze health-care processes and structures. This remains far from the norm, however, and if we allow resource constraints, real or contrived, to dampen these efforts, the cause of patient safety and improved health-care working conditions will continue to advance slowly, if at all.

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9 Shift Work and Its Impact on Medical Error

Christine Pontus and Susan Farist Butler

CONTENTS

Wide-Awake Surgery Led to His Suicide

A West Virginia man's family claims inadequate anesthetic during surgery allowed him to feel every slice of the surgeon's scalpel—a trauma they believe led him to take his own life 2 weeks later. Sherman Sizemore was admitted to Raleigh General Hospital in Beckley, West Virginia, on Jan. 19, 2006 for exploratory surgery to determine the cause of his abdominal pain. But during the operation, he reportedly experienced a phenomenon known as anesthetic awareness—a state in which a surgical patient is able to feel pain, pressure, or discomfort during an operation, but is unable to move or communicate with doctors.

According to the complaint, anesthesiologists administered the drugs to numb the patient, but they failed to give him the general anesthetic that would render him unconscious until 16 minutes after surgeons first cut into his abdomen. Family members say the 73-year-old Baptist minister was driven to kill himself by the traumatic experience of being awake during surgery but unable to move or cry out in pain.

SHIFT WORK AND ITS IMPACT ON MEDICAL ERROR

The need to keep operations going 24 hours a day and 7 days a week in such industries as health care requires that many work around the clock. The 2004 Bureau of Labor Statistics states that nearly 15 million people work full time on evening, night, and rotating shifts or other employer-arranged, irregular schedules.[1] More than 20% of the U.S. workforce is involved in shift work, and nearly 30% of full-time employed nurses participate in shift work.[2] Approximately 40% of the American workforce experience fatigue on the job, and almost 70% of the general public does not get enough adequate sleep during the week.[3]

CIRCADIAN RHYTHMS

In spite of our modern world, the human body still operates with circadian rhythms that rise and fall as they did since the dawn of time. Individuals who work rotating or irregular shifts experience a different set of problems than those who have a consistent day time work schedule. Chronic fatigue and its associated problems are compounded by many variables. Fatigue affects our cognitive functions, and the ability to process an assortment of information is reduced. Evening and night shift workers are often susceptible to fatigue and are at risk for injury. Fatigue has been associated with reduced performance, increased medical errors, and workplace accidents.[4]

Shift work can also interfere with quality of sleep. Nurses who worked night shifts experienced frequent as well as severe disruptions in their sleep.[5] Fatigue is a common issue in relation to shift work and extended duration of shifts.[6] Due to our genetic and functional abilities, people are naturally active during the day with a tendency to rest at night. Our slower reflexes, poor sense of smell, and lack of night vision left us prey to larger and faster nighttime hunters. In the primitive world, rest and shelter were our means of survival in the dark of the night. We became accustomed to operating on a daily basis when the sun was up. Human beings are designed to perform at peak levels during the day as opposed to night. Our bodies' design and daily biological functions are what scientists call "circadian rhythms."[7]

We need to actually slow down at night to restore and rejuvenate ourselves. There are both physical and mental consequences bestowed upon the worker who is not able to restore or receive enough rest between shifts.[8] There are approximately 3 million registered nurses (RNs) who support our health-care system in America by providing direct care to patients in the hospital setting.[9]

Have you ever worked a night shift or been up for an extended period of time, as when traveling? Did you notice it was hard to focus and found eating something to keep awake caused difficulty with indigestion? When you finally did get to sleep, as tired as you were, did you find it became a struggle to do just that? Rather than sleep, did you toss and turn and finally get up because sleep was impossible?[10] For those who work double or rotating shifts, this is all too common. This is often the powerful effect of an individual's circadian rhythms. "Circadian" comes from the Latin phrase meaning "about a day." There are many circadian rhythms, which are physical functions that follow a daily pattern. A few of these important rhythms are sleeping, waking, blood pressure, body temperature, production of hormones, digestion, and secretions of adrenaline.[11] Our biological clock regulates our daily cycles and functions, which control our bodies' energy levels. To work against this normal biorhythm is an extra physiological demand, a stress, on the person working these hours. It risks degradation in clinical judgment and work performance, as well as ill health and diminished quality of life for the nurse (employee).

The term "extended work shift" generally indicates extending the length of hours in a work shift to more than 8 hours. This often contributes toward a shorter workweek in the number of days one actually comes in to work.[12] The term "shift work" speaks to a work-hour system in which a group of workers extends the period of production past the conventional day to include coverage on a 24-hour basis.[13]

Stress, poor performance, clinical errors, and ill health are often observed among nurses who work evenings, nights, or shifts longer than 8 hours. These problems have been measured and discussed in many observational studies. Two important and distinct causative factors are length of work time and working against a person's normal circadian rhythm. Working beyond 8 or 9 hours causes a measurable decline in performance, and schedules that do not respect circadian rhythms are taxing and stressful, and they also diminish performance. It is important to consider both factors in efforts to provide high-quality clinical care and for the health and quality of life for the nurses working off shifts. More and more evidence supports the reality that nurses are at greater risk for making errors when working longer shifts.[14] Shift work and extended work hours have a great impact on both the individual and organizations that utilize this type of staffing pattern. Not all workers are capable of performing on an irregular or extended hourly basis. The 12-hour shift has the potential to contribute to human error and accidents in the work place.[15]

In a recent review, Simone Keller[16] discusses the human and performance costs of both shift rotation and extended work periods. She reports that 13 million healthcare errors occur every year, and between 48,999 and 98,000 of those errors cause deaths. This serious statistic demonstrates how shift work and extended work hours contribute to the poor performance. Keller finds that nurses working more than 8 hours report decreased productivity and vigilance with higher rate of errors and near errors. In other industry studies fatigue and error, post-hoc analyses of Three Mile Island, Chernobyl, and Exxon Valdez found fatigue to be a major factor in the errors leading to each of these catastrophes. The consequences of over-scheduling nurses are unambiguous and serious. This serious situation requires an urgent response. Nurses working more than 12.5 hours per shift have an error rate nearly double those working 8-hour shifts. Those with extended work hours experience diminished capacity for critical thinking, as well as poorer physical health, in the form of fatigue, sleep deprivation, failures of resilience, increased rates of cancer, and other illness. For both good performance and healthy nurses, scheduling and working hours must respect his/her physical capacities and physical needs for rest and recuperation.

The Institute of Medicine (IOM) report *Keeping Patients Safe* explicitly recommends that voluntary overtime be restricted. Currently, there is no state or federal regulation restricting the number of hours a nurse may voluntarily work within 24 hours or a 7-day period.[17] The documentation of hazards associated with sleep deprivation among resident physicians has brought about changes in house staff rotation polices. Relief from having to work mandatory overtime is not in sight for all nurses. In 2001, the American Nurses Association (ANA) conducted a survey in which nearly half the respondents reported that mandatory overtime was being used to cover staffing shortages. Many facilities still use mandatory overtime to staff their organizations. The use of mandatory overtime is not the answer to nurse staffing shortages. This practice is extensive and pushes nurses beyond their ability to work safely and to provide appropriate, quality care to patients.[18]

The ANA states that mandatory overtime may be a contributing factor toward nurses leaving the profession. Overtime is defined as the hours worked in excess of an agreed upon, predetermined, regularly established work schedule, as identified

by contract, usual scheduling practices, and policies or procedures. Professional licensure assumes nurses are autonomous in that they are responsible and accountable for their decisions and activities. With the industry imposing mandatory overtime and removing the ability of the nurses to determine their own fitness for duty, patient safety and the nurses' ability to fulfill their legal obligations of licensure are endangered.

Sixteen states have restrictions on the use of mandatory overtime for nurses. Fourteen identified restrictions in law: Alaska, Connecticut, Illinois, Maryland, Minnesota, New Jersey, New Hampshire, New York, Oregon, Pennsylvania, Rhode Island, Texas, Washington, and West Virginia. Two other states have provisions in regulations: California and Missouri. In 2009, North Carolina legislated the study of mandatory overtime as a staffing tool.[19]

FATIGUE ALERTNESS AND SAFETY

Approximately 20% of Americans claim to have fatigue powerful enough to interfere with activities of daily living. A physical cause has been estimated to be responsible 20%–60% of the time. Emotional or mental causes cover the other 40%–80% of cases of fatigue. Unfortunately, fatigue can also occur in individuals who experience intense physical or mental activity (or both).[20]

Dr. Matthew B. Weinger describes fatigue as a global term encompassing the effects of both acute and chronic sleep loss, as well as physical and mental exhaustion. Obviously, these factors interact. In addition, fatigue is exacerbated by personal factors like emotional stresses, as well as other negative work factors, such as high work volume and cumbersome processes.[21] Those with extended work hours experience diminished capacity for critical thinking, as well as poorer physical health, in the form of fatigue, sleep deprivation, failures of resilience, increased rates of cancer, and other illness. For both good performance and healthy nurses, scheduling and working hours must respect nurses' physical capacities and physical needs for rest and recuperation.[22]

Once a nurse is sleep deprived, it is difficult to recover. "Acute fatigue can be classified as mental fatigue due to mental overload or underload or physical fatigue."[23] While this may be recovered from, Rogers[24] reports that long-term fatigue "is irreversible and no longer responds to worker compensation mechanisms." Similarly, Jeanie Geiger-Brown and Alison Trinkoff write, "recovery studies … also demonstrate that it took much more than a full night's sleep for the participants to return to full neurobehavioral functioning."[25]

According to Weinger's studies of recurrent partial sleep deprivation, sleeping 5–6 hours a night can lead to impairment. A decrease in performance accumulates with continued partial sleep deprivation as observed in individuals with chronic insomnia (defined as difficulty sleeping on a frequent basis) or in physicians working regularly recurring call or night shifts. It has been noted that in the early morning hours, after nearly 24 hours without sleep (e.g., at the end of a difficult night on call), psychomotor performance can be impaired to an extent equivalent to or greater than what is currently acceptable for alcohol intoxication.[26]

Does the term being on "autopilot" sound familiar? People who are extremely fatigued often experience what is called "automatic behavior syndrome" (ABS). Dr. Martin Moore-Ede, MD, PhD, an expert in the field of sleep disorders, refers to ABS as a low level of alertness that precedes nodding off. It is characterized by the inability to react effectively to change. People are present with eyes wide open set in a blank stare; brain wave activity is similar to that of being asleep. During this lower mental state, individuals can perform routine tasks for 20–30 minutes or more without active awareness. It is precisely this failure to stay connected to the environment that creates the inability to maintain situational awareness. This lack of awareness is generated from a loss of memory and perception, as well as an inability to respond to changing conditions signals and communication.[27]

SHIFT WORK

Health-care providers working rotating shifts or nights who experience this unthinking stage of reduced alertness may not react effectively to change in their duties. Diana McMillian conducted a Canadian web-based survey of 536 critical care nurses who worked primarily 12-hour shifts on a day–night rotation, with 15% working only nights. Between two consecutive night shifts, 72% got 6 hours or less daytime sleep, 20% got 4 hours or less, and 32% reported that they "always felt tired."

Twenty-five percent reported personal injury or near injury directly related to their fatigue, with 16% reporting incidents or errors affecting patients that were directly related to their fatigue. On their drive home, 43% reported having fallen asleep while stopped at a traffic light, 31% reported having fallen asleep while driving, and 20% reported having a motor vehicle crash or near miss.[28] Often nurses who work nights or rotating shifts are heard to say, "I do not know how I got home," "I do not remember driving home," or "I cannot tell you how many times my neighbor or husband woke me up in the car in my driveway or garage."

"Some of the qualitative data about these accidents or near accidents are chilling," says Dr. McMillan. "They talked about being totally disoriented. They talked about looking up at the road and wondering where they were. They talked about frequently getting home and wondering how they got there. … Nightshift work is fraught with both homeostatic and circadian challenge. It's a perfect storm."[29]

A report of the National Commission on Sleep Disorders Research by the U.S. Department of Health and Human Services reveals that sleep deprivation increases health risks such as heartburn, high blood pressure, heart attack, premature aging, and increased appetite. The report also revealed that sleep deprivation increases the incidence of having microsleep (short unintended episodes in loss of attention) induced accidents. The direct cost of accidents resulting from lack of sleep is $56 billion per year, with 25,000 deaths and 250,000 disabling injuries.[30]

Shift work and its related problems are conditions that affect quality of life. The consequences of being sleep deprived begin only a few days after sleep reduction. The body produces proinflammatory cytokines and increases sympathetic output and insulin resistance. There is evidence that induced fatigue from lack of

sleep contributes to hypertension, diabetes and impaired glucose tolerance, obesity, heart attack, and stroke. Unhealthy behaviors, depression, and immune system challenges occur by reduced natural antibody production.[31] (This is an occupational health issue as shift work and sleep deprivation lead to personal health issues for workers. In turn, this becomes an obvious patient safety issue too.)[32]

To maintain functional health-care organizations, schedules involving shift work and workers must be managed in an effective and consistent manner. Health-care workers need be supported within a functional environment to properly use the skills they have acquired to provide safe patient care. The question is: Why, in the world of patient care, among well-intended health-care providers, have extended work hours been allowed to continue for so long?

HEALTH CARE AND THE MEDICAL MODEL

The traditional medical model educates physicians to believe that if they study and work hard enough they will not make any mistakes. This way of thinking has saturated our health-care system for years. Individuals working within health care have been held hostage to this way of thinking; consequently, if a mistake did occur, it had to be theirs' or another's fault. Unfortunately, this view does not take into account the individual's role as one of various components within a larger system. Together, the system can create risky situations that may result in error and potential harm.[33] When error or potential harm is no longer seen as something dangerous, it becomes what Diane Vaughn called the "normalization of deviance." This specifically refers to the accumulated effect of continuously cutting corners over time, eventually leading to an ineffective or inappropriate response.[34]

The Swiss cheese risk model of defense, demonstrated by Professor James Reason, predicts that potential accidents will occur by a failure of at least one and up to four layers of control (called defensive layers). They are organizational influences, management system failures, preconditions for unsafe acts, and the unsafe act itself. His assertion is that many defenses have certain conditions upon which they will fail. When failures of defensive layers coincide, an accident will then happen.[35] Contributing to the possibility of mistakes are errors of commission, for example, administering the wrong medication to a patient because it looks or sounds like another. This type of error happens 1 out of 300 times. Another type of error, called omission, is the unintentional act of forgetting to do something correctly and is likely to occur 1 out of 100 times.[36] The following are contributing factors that can negatively affect human performance and lead to error:

- Limited short-term memory—being late or in a hurry
- Limited ability to multitask—interruptions and stress
- Lack of sleep—fatigue and injuries

As simple as this list appears, these factors can contribute toward the profound effect shift work takes on the body.[37]

Reason[38] writes,

> Two approaches to the problem of human fallibility exist: the person and the system approaches. The person approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness. The system approach concentrates on the conditions under which individuals work and tries to avert errors or mitigate their effects. High-reliability organizations—which have less than their fair share of accidents—recognize that human variability is a force to harness in averting errors, but they work hard to focus that variability and are constantly preoccupied with the possibility of failure. Organizing schedules of employees to their human capacities will help prevent failure.

In the executive summary of the IOM report *Keeping Patients Safe*, four sources of threats to patient safety in the work environment are listed as (1) management, (2) workforce, (3) work process, and (4) organizational culture. The corresponding safety defenses listed are (1) adopting evidence based on management and leadership practices, (2) maximizing the capability of the workforce, (3) design work and workplace to reduce error, and (4) creating and sustaining a culture of safety.[39]

Physicians in training who are scheduled to work the traditional 24-hour shifts incur a greater risk of injury to their patients and others. These individuals make 36% more serious medical errors with five times as many serious diagnostic errors, and they experience twice as many on-the-job attention failures at night. They also suffer 61% more needlestick and other sharp injuries after 20 hours of work.[40]

Barger et al.[41] conducted a web-based survey, across the United States, in which 2737 residents in their first postgraduate year (interns) completed 17,003 monthly reports. The association between the number of extended-duration shifts worked in the month and the reporting of significant medical errors, preventable adverse events, and attentional failures was assessed. The study viewed first-year interns and compared their performance when they worked appropriate hours to when they worked extended shifts, up to 30 hours. When they worked no extended-duration shifts compared with between one and more than five extended-duration shifts, they were three to seven times more likely to report at least one fatigue-related error.

Barger et al.[41] states,

> "Similarly, fatigue-related adverse events increased by around seven and eight times, respectively, compared with months in which no extended-duration shifts were worked. Fatigue-related preventable adverse events associated with the death of the patient increased by ~300% in interns working more than five extended-duration shifts per month; they were also more likely to fall asleep during lectures, rounds, and clinical activities, including surgery." This increase in errors is a serious risk to patients, meriting a revision in administrative practice.

The survey concluded that extended-duration work shifts are associated with increased risk of significant medical errors, adverse events, and attentional failures in interns across the United States. These results have important public policy implications for postgraduate medical education.[42] The significance of this study was that it showed that graduate medical education in the United States still allowed up to nine marathon shifts (30 hours at a stretch) per month, even though the total number of hours worked is capped. The study shows that the long shifts worked by

interns are bad for patient safety, as they are more likely to cause harm that would not otherwise happen:[43] "Interns working five or more extended-duration shifts per month reported more attentional failures during lectures, rounds, and clinical activities, including surgery and reported 300% more fatigue-related preventable adverse events resulting in a fatality."[44]

Barger and colleagues found that fatigue-related medical errors increased 3.5-fold and 7.5-fold, respectively, with one to four and with five or more extended shifts in a month. The respective odds ratios for fatigue-related adverse events were 8.7 (95% CI, 3.4–22) and 7.0 (95% CI, 4.3–11), respectively.[45] This study clearly reveals the association between adverse events and extended work shifts. It is of noted significance that individuals reported to be negatively impacted by as little as one to four extended shifts work per month. As Coxe points out, this reveals that "latent errors" are contributing toward increase risk and decrease safety in our health-care environment.[46]

Sleep-related motor vehicle accidents are reported to be higher with individuals who work more than 60 hours per week, work irregular hours, work at night, and are sleep deprived. Studies show that remaining awake for 19 consecutive hours slows cognitive function and reaction time.[47]

OTHER STUDIES

In a study conducted by Spear and Tucker, nurses performed an average of 100 tasks in an 8-hour shift with each task taking an average of 3 minutes. The study showed that nurses are interrupted at least once an hour and do not have sufficient time to prioritize as they are jumping from task to task. It was concluded that as a result of this environment, the nurse is so busy multitasking that one would not notice a patient care issue until it reached a critical level.[48]

Underreporting was noted in a short 1-month study of medication errors at a large military hospital. During this time frame, nurses used daily anonymous receipts, revealing 6% of the medication errors and 15% of the near misses were formally reported. Another study found that physicians are more likely to report potential injuries to patients on a confidential basis, using an e-mail system with daily prompts rather than an established protocol for reporting.[49]

Data and analysis from Rogers showed that work duration, overtime, and hours worked per week affect error rate. The odds of making an error were three times greater when nurses worked 12.5 hours or more. Working overtime increases the chance of making at least one error regardless of how long the original shift was scheduled for. As this study points out, significant errors do not appear until work hours exceed 12.5 hours per day. An actual increase in risks begins to occur when shift durations exceed 8.5 hours. The study clearly concludes that more errors are made as a result of longer work hours. The results of this study are consistent with other studies linking increased accidents and neuropsychological deficits among hospital staff, which contributed to two known facility-wide epidemics of *Staphylococcus aurous*. Upon investigation, it was found that the hospital was understaffed and nurses were fatigued and stressed by high patient caseloads.[50]

ACTION FOR HEALTH AND SAFETY PROFESSIONALS

Prevention is one of the primary functions of occupational health and safety. Implications of extended-duration work shifts for occupational health and safety professionals are many.[51] Creating a comprehensive plan of action for organizations with individuals who work rotating and/or night shifts is a daunting challenge. Some of the considerations for the worker include continuous monitoring of different lengths of work shift, workloads, overtime, and rest breaks between working shifts.[52]

By supporting the health-care worker, we ensure more positive patient outcomes. Alertness and clear thinking are essential for the nurse to be fully able to use his/her clinical skills. The dual goals of maintaining optimal cognition and performance in clinical care and simultaneously protecting the employee from the deleterious effects of stress and sleep deprivation are synchronous, working together in the interests of both the nurse and the patient. These are but a few of the details that need to be considered when contemplating this issue and must be thoughtfully applied.

Stress in one person echoes throughout the system. By attending to each employee's fundamental biological needs, the administration creates a context of capability and trust that will improve the performance of both the individual and the overall institution. These practices and values are essential to good care of staff and patient.

ENDNOTES

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10 Bullying and Medical Errors

Kathleen Bartholomew

CONTENTS

An Open-Heart Invasive Procedure…On The Wrong Patient

Joan Morris (a pseudonym) was a 67-year-old woman admitted to a teaching hospital for cerebral angiography. The day after that procedure, she mistakenly underwent an invasive cardiac electrophysiology study. After angiography, the patient was transferred to another floor rather than returning to her original bed. Discharge was planned for the following day. The next morning, however, the patient was taken for an open-heart procedure. The patient had been on the operating table for an hour. Doctors had made an incision in her groin, punctured an artery, threaded in a tube and snaked it up into her heart (a procedure with risks of bleeding, infection, heart attack, and stroke). That was when the phone rang and a doctor from another department asked, "What are you doing with my patient?" There was nothing wrong with her heart. The cardiologist working on the woman checked her chart, and saw that he was making an awful mistake. The study was aborted, and she was returned to her room in stable condition.

Only 6 months into my tenure as nurse manager, a sentinel event occurred, which directly linked bullying behaviors to medical errors. On morning rounds, I was informed that a patient had been found with an oxygen saturation of 52% and taken to the intensive care unit (ICU). An MRI (magnetic resonance imaging) showed anoxic changes of the brain that were so significant, the physician was concerned his patient would not return to baseline. Even on a full rebreather mask, the patient could not converse normally. I took the patient-controlled analgesic

(PCA) machine into my office and opened it up to find that the machine had been mistakenly programmed for morphine instead of dilaudid—the patient's decreased saturation was a direct result of receiving more than 10 times the normal dose of narcotics.

Just then, the door opened and the nurse who was responsible for the patient came into my office. Before bursting into tears, she mumbled something under her breath. After reviewing the narcotic administration policy and debriefing her shift, I finally asked, "What did you say when you first came into my office?" It sounded like "I shouldn't have let them get to me." Immediately the young nurse's eyes shot downward to the floor as she told her story …

> I was about 7 or 8 minutes late for my shift last night. When I came around the corner of the nurses' station, a group of nurses who had been talking suddenly stopped when they saw me. I don't mean to be paranoid, but the conversation never picked up again. I went into the ladies room—you can hear from there you know. Ellie said, "She'll never make a good nurse, will she?" Then someone else whose voice I didn't recognize said, "She just doesn't have what it takes. Does she?" I let those words destroy me. This is all my fault.

No amount of consoling or counseling could remove her pain. Six weeks later she transferred off the unit to the very first position in the hospital. Was this an isolated event, or a trend? As a manager, I realized that if I did not change the conditions under which this event happened, there was a high possibility it could happen again. I understood clearly that my patients would never be safe until the nurses themselves were safe and that my role as a nurse leader must expand to accept the responsibility for creating and monitoring the atmosphere in which my nurses worked as well as their clinical competence. What were those systemic conditions?

CULTURE OF HORIZONTAL HOSTILITY: TERMINOLOGY AND DEFINITION

Numerous terms have been used to describe rude and uncivil behaviors in the literature, and this lack of coherent terminology has been an impediment to the research: lateral violence, verbal aggression, incivility, bullying, and horizontal hostility, to name only a few. In general, bullying in the United States is a term used to describe uncivil behavior from someone who has power over you, or vertical aggression. Rude behaviors from peers are referred to as horizontal or lateral hostility. Horizontal hostility is defined as a consistent pattern of behavior designed to control, diminish, or devalue a peer (or group), which creates a risk to health or safety (Farrell 2005). Some specific examples are

- *Overt*: Name calling, bickering, fault finding, criticism, intimidation, gossip, shouting, blaming, put-downs, raised eyebrows
- *Covert*: Unfair assignments, refusing to help someone, ignoring, making faces behind someone's back, refusing to work with certain people or not work with others, whining, sabotage, exclusion, fabrication

The covert forms of hostility are acknowledged to be more damaging because ambiguity increases stress. They are also more prevalent because 93% of all communication is nonverbal. Eye-rolling and raised eyebrows are cited as the most frequent form of hostility in the nursing profession, unless you work in the emergency room, where staff perceived "withholding information" as the most common form of hostility. Because nurses are known to have a passive-aggressive style of communication and to be conflict-avoidant, the nonverbal behaviors are rarely called out, and the behaviors are then embedded in the culture as "normal." Self-doubt increases, self-esteem decreases, and a cycle of oppression is established. Keeping workers oppressed serves the dominant group (administration) whose primary goal is to control resources to ensure profit in order to be financially viable, because health care in the United States follows a business model.

Direct Relationships to Medical Errors

The current system is perfectly designed to hide the relationship between bullying and medical errors because both bullying and horizontal hostility create feelings of shame in all humans, regardless of level of education. Neither physicians nor nurses report bullying because the common perception is that "there must be something wrong with me." The deep-seated emotion of shame keeps the very behaviors we need to address traveling just under our cultural radar, like an undertow, invisible and strong, taking our profession way off course.

The case study that opened this chapter was a rare gift and an anomaly, because admitting that you are upset about a hostile behavior in the current culture is the same thing as admitting that you are weak and vulnerable. In addition, clinical competence often excuses these behaviors. For example, I have never seen a hospital draw the line on abusive physician–nurse behaviors, until after the sentinel event that claimed a patient's life. An ICU nurse who was intimidated by the physician delayed calling him at night, which resulted in the patient's death. But until someone dies or is harmed, reluctance to call is overlooked by hospital leaders, despite an Institute of Healthcare Improvement (IHI) study in 2006 which found that out of the 84% of sentinel events involving communication errors, 67% involved physicians, and the three main reasons were delay in care, reluctance to call, and incomplete or unclear communication.

In one study where verbal abuse from physicians was noted by over 90% of participants, 76% also witnessed negative nurse-to-nurse behaviors. (This is called "submissive aggressive syndrome." When overpowered, primates will consistently walk away and overpower an innocent bystander.) Nurses reported that 71% of those behaviors resulted in medical error, of which 29% resulted in death (Rosenstein and O'Daniel 2008). In another study by the American College of Physician Executives (ACPE), 21% of physicians could directly attribute an adverse clinical event to a disruptive physician.

The majority of studies, however, link bullying behaviors to cognition. The vast majority of tasks performed by physicians, nurses, and pharmacists are cognitive and require a significant amount of concentration, such as drawing up, administering, or ordering medicine; assessing medical status, patient progress, or plan of care; selecting the right surgical instrument; deciding if the patient is

responding appropriately; taking vital signs; and so on. The delivery of health care is predominantly a cognitive task.

Fieldwork by Pearson and Porath (2009) found that more than half of those people who experienced incivility at work reported that they lost time worrying about the uncivil incident and its future consequences. Researchers found that simply *witnessing* rude behavior in the workplace "significantly impairs our ability to perform cognitive tasks" (Porath and Erez 2007). After three studies investigating the objective consequences of both direct and indirect rude experiences, researchers found that both were harmful to task performance. Furthermore, they found that even a one-time event can affect objective cognitive functioning and creativity (Porath and Erez 2007). In fact, human beings are so affected by rude behavior that simply *imagining* a rude event or one-time exposure to rudeness may have serious consequences for objective performance on cognitive tasks (Porath and Erez 2007). Researchers have found interference to the working memory and noted that people perseverate about the event, perhaps in an attempt to make sense of the behavior (Porath and Erez 2007).

Even if staff are not aware that rudeness affects them, they may still exhibit cognitive losses (Porath and Erez 2007). As human beings, we are simply not capable of utilizing our optimal cognitive skills when emotionally upset. Feelings of anxiety, anger, or sadness tend to distract and demotivate (George and Brief 1996). Studies in organizational development have found that when a person who has previously been disruptive (a deviant) enters our workplace, our attention is taken away from cognitive tasks as we unconsciously monitor the deviant's behavior (Felps et al. 2006). Furthermore, rudeness from only a few offenders affects everyone because it undermines trust, which is the basic building block of all teams.

Isolated Event or Trend? Prevalence

Bullying behaviors can be found throughout the caregiver spectrum from nurses and residents to pharmacists, with physician intimidation being the most common. An Institute of Safe Medication Practices (ISMP) survey of over 2095 health-care workers found that physician-prescribers were cited twice as often as other health-care professionals as exhibiting intimidating behaviors. Another 1997 study examining the effects of intimidation on 35 pediatric nurses over a 3-month period found that 71.4% of them reported being yelled at or loudly admonished, 45.7% had been victims of insults, and 85.7% were spoken to in a condescending manner. Unfortunately, one-third of nurses believed that such behavior was "part of the job."

Estimates of lateral violence in the nursing workplace range from 46% to 100% (McCall 1996; Stanley et al. 2007). Another one-third of nurses perceived emotional abuse during their last five shifts worked (Roche et al. 2009). In another recent survey, 30% of respondents ($n = 2100$) said disruptive behavior happened weekly, and 25% said monthly (http://www.advisory.com/International). A study of emergency room nurses found that 27.3% had experienced workplace bullying in the last 6 months, with many staff bullied by their managers, charge nurses, or directors, as well as by physicians and peers (Johnson and Rea 2009).

Bullying behaviors are common in medical schools as well—in fact, they are an integral part of the medical education culture (ISMP Survey: The Hospitalist

2007). In a study of 2884 students from the class of 2003 at 16 U.S. medical schools, 63% reported having been belittled by faculty and 71% by house staff. Not reporting medical errors is also common. Despite having completed patient-safety training, only about half of the 76% of medical students who observed a medical error reported that error.

Clearly, hostile behaviors happen throughout the caregiver spectrum. Yet both formal research and informal observation reveal that these behaviors come from a small group of people—less than 5%. The problem is that the effect is grossly exaggerated (Felps et al. 2006), long lasting (Farrell 2005), and affects future behaviors long past the actual event (Porath and Erez 2007). But, while hostile behaviors are common, it is very uncommon for them to be addressed. The majority of hospitals have policies, but very few are actually enforced by leadership.

Impact on the Individual

The impact of rude behaviors on the individual has been well documented. These behaviors have a profound impact on the individual physically, psychologically, socially, and emotionally (Farrell 2005). Even 5–10 years after the event, the victim still demonstrated symptoms of PTSD. One study of 30 nurses who experienced hostility found that they displayed the same characteristics common to battered wife syndrome (Bartholomew 2006, 2010): keeping silent, maintaining anonymity, PTSD, and low self-esteem.

However, from the staff nurse or manager perspective, the impact is consistently minimized by all parties involved, leadership as well as staff. Hostile behaviors are the cultural "norm" and not acknowledged by the vast majority of nurses—*why would I notice something that everybody does*? The on-boarding process of assimilation ensures that we pick up the behaviors of those around us in order to belong to the group. The most common strategy employed by nurses to deal with hostility is denial, which is "a primitive and desperate method of coping with otherwise intolerable conflict, anxiety, and emotional distress of pain" (Laughlin 1970, p. 57). Nurses rarely report workplace violence; only one in six incidents were formally reported (*Journal of Clinical Nursing*, February). Furthermore, hostile behaviors are intermittent and not a consistent part of the hospital society. Unfortunately, however, intermittent reinforcement is the strongest.

Impact on the Team

High-reliability organizations such as aviation and nuclear power know that collegial interactive teams prevent errors by providing a safety net in which people can catch other's human errors (Nance 2009). Humans cannot accurately assess how stressed or tired they are; that information can only come from an objective assessment by a team member that knows them well. Since being tired, upset, or stressed affects our cognitive abilities, we must form a team to prevent errors and keep our patients safe. However, the trust required for collegial teams is consistently undermined by a culture that allows less than 5% of health-care workers to not play by the rules. For example, if a surgeon brings in $22 million a year, his behavior is overlooked. Or if a

nurse has strong clinical skills, her behavior is tolerated. Disruptive nurses and physicians have one thing in common: they are all clinically competent and the behavior has been tolerated for a long period of time.

> She was like gangrene. I told the director that she was infecting all of us but still, she (the director) did nothing. I told her again and again. Finally, people just started leaving.

> The charge nurse has a cow that says "moo" when you squeeze it. And every time a certain nurse walks by, that's just what the charge nurse does. I work in an ER. The "mooing" is a sign to everyone that you are "milking" your patients—not moving fast enough. I told the director—but she said she would have to put it in next year's budget requests.

The majority of hospitals have one thing in common as well: they permit a few health-care workers get away with rude behaviors. "You get what you accept, and what you accept sets the norm" (Bujak 2010). What is clear about the current culture is that for many nurses, it is not psychologically safe and that the danger to our cognition is almost never noted, until after the event. The current lack of collegial interactive teams in health care is primarily due to an established core value of physician autonomy and poor leadership (Nance 2009). For these reasons, hostility prevails, trust is undermined, teams do not form, and medical errors happen. Because these behaviors reflect the "norm," events are rarely captured.

ABSENT AND INEFFECTIVE LEADERSHIP

Despite the data, leadership in health care (from frontline to executive level) has failed to create the team environment proven to create a safe environment and has not heeded the critical call for leveling the power dynamics. A recent study directly linked teamwork and mortality: for every quarter of team training, mortality dropped 0.05 per thousand cases (Neily, Mills, and Young-Xu 2010).

A recent meta-analysis of all articles published on patient safety showed that a patient-safety culture possesses seven distinct subcultures. The first is "leadership." This is where we fail. Leaders do not perceive their own cultural norms because they themselves are a part of that everyday drama. Therefore, they do not dedicate the necessary funds and resources to change the culture and allow a few disruptive health-care workers to continue destroying trust. Despite the Joint Commission standard set in 2009 for hospitals to address disruptive behavior, little has changed, except in those institutions where someone has already died because of disruptive behavior. Leaders perceive relationship issues as "soft stuff" and therefore not worthy of budget allocation, so education in this area is slim to none. Ironically, nothing could be further from the truth.

To complicate matters, the role of the nurse manager has changed dramatically over the past decade. No one is on the unit to monitor or address hostile behaviors by either physicians or nurses because managers are in meetings or in their offices trying to deal with the implementation of electronic records, IT, and new protocols

and mandates from regulatory bodies. Ours is a failure of perception. From sociology, we know that a major cause of failure to perceive a problem is "distant managers" (Diamond 2005). No one is on the units monitoring the behaviors as interior and exterior stressors increase, so the behavioral issues proliferate. From a systems perspective, this is a common and critical failure.

> When rounding on a PICU unit in a 1000-bed hospital I discovered that all the nurses with under two year's experience were working on the first pod. On the second pod were nurses with 3–5 years experience. And on the last pod (closest to the break room) were all the nurses with more than 20 years experience. Where was management?

MISTRUST SQUARED: LACK OF TRANSPARENCY

Making harm visible would increase trust, which is the fundamental characteristic of a team. But the damage from medical errors is driven underground in the current culture because of shame and a litigious society. There is a long-standing cultural "meme" that says, "A good nurse/doctor does not make mistakes." Yet our solutions to eliminating errors do not even begin to address these powerful long-standing cultural norms. Both nursing and medical school curricula have failed change to abolish this established myth. For example, I was speaking on creating a "just culture" to a group of third-year medical students and asked, "When was the last time you did something wrong?" A voice from the back of the room called out, "When was the last time I did something right?" We immediately stopped the presentation and discovered that the entire class felt the exact same way. As long as we continue to beat up residents and nurses and deliver their education in silos and as long as nurses and physicians continue to feel ashamed of imperfection and hide their last medical mistake, nothing will change.

Because of a culture of blame and shame, medical errors are underreported and hidden within the system. There is no universal system for reporting errors or a way that hospitals are immediately notified of an error to ensure that it does not happen again. For example, in Seattle, a woman died from injecting soap instead of dye into the bloodstream. Sadly, after the death, leaders heard that other hospitals had precisely the same conditions that were the genesis of the fatal error: unlabeled clear solutions in stainless steel bowls. Other industries such as aviation have a mandatory central reporting system, and so should health care (http://www.facebook.com/truthbeforetrust).

This is no longer an esoteric desire for some future date, but in fact an ethical mandate to learn immediately from mistakes and prevent repeats system wide. Organizations try every "flavor of the month" they can to reduce errors, but their energy is misdirected at the symptom and not the underlying cause: the culture. For example, one hospital rolled out a huge initiative backed by adequate funding from the board to create a "just culture." They will never succeed because abusive behavior was still occurring throughout the organization. It is impossible to create such a culture without trust; trust can never be attained in a culture of secrecy where rude and intimidating behaviors are tolerated. The biggest problem is that healthcare leaders have failed to perceive their own culture.

POOR COMMUNICATION SKILLS AND INABILITY TO CONFRONT = FEAR-BASED CULTURE

It is also well known that miscommunication is the number one cause of all sentinel events. In a study of over 2400 sentinel events, communication was the number one cause, so serious that over 75% of the patients died. A recent study of over 4000 health-care workers revealed that nurses were afraid to speak up because of fear of retaliation, fear of making the situation worse, or fear of isolation from the group (Bartholomew 2006, 2010). Health care is a fear-based culture and strong leadership over a long period of time is needed to change a culture. However, due to a focus on financial survival in a time of great change, health-care leaders' attention is constantly diverted to the bottom line and the consistency needed to change the current culture has been insidiously sidetracked.

A tremendous amount of emotional energy is required to maintain and fuel a fear-based culture. This energy, if redirected, could prevent mediation errors and keep our patients safe. Patients will never be safe until caregivers are psychologically, emotionally, socially, and physically safely communicating in collegial teams. This is not "soft stuff' but a hard-core reality of the current culture. How do you lead a fear-based culture? Focus on language and behavior (tribal leadership), and hold all staff accountable for the same rules.

Solution: Systemic Cultural Change

It is well known that *structure* dictates *process*, which produces *outcomes* (Donabedian 2005). If we work backward from the outcomes (medical errors), we can identify the processes (culture of hostility and bullying maintained by ineffective leadership and poor communication skills) to address the structure that creates medication errors (business hierarchy).

Hostility thrives in a typical hospital hierarchy. It is all about power. How do you prevent medical errors? By disseminating power and forming a team with the core value of safe patient-centric care. Leaders must accept the challenge and personal responsibility for shifting power from a hierarchy to a tribe. What difference does the best surgeon in the world make if post-op you place the patient into an MRSA-infected room? What difference does the best nurse make if she does not question a medication order for fear of bothering the physician? All members of the team must know and experience their roles and the value that their specific position brings to the patient.

Health care still functions as a hierarchy, with its focus on command and control rather than the relationships between the different parts. This power gradient will always produce oppression, which is the major theory behind horizontal hostility and vertical aggression (Freire 1970). In human groups of unequal power, the dominant group exerts so much pressure downward, that the oppressed group cannot direct its power upward, so they unconsciously attack each other. Nurses are responsible for the outcomes (quality and safety) yet have no access to the resources needed to accomplish that goal (staffing ratios).

Question: If you walk into a group of people anywhere in the world and want to know if they function as a hierarchy or a tribe, what one question would you ask them?
Answer: Do you lock up your food? (Quinn 1999)

In health care, the resources that both physicians and nurses need are locked up by the hierarchy. For example, much debate has ensued over staff ratios when the real question should be: "Why isn't the only person who has all the information necessary to make a sound decision, the charge nurse, not allowed in the current system to ask for the number of nurses needed?"

But advances in quantum physics dictate that instead of addressing medical errors as a problem to be fixed in the system, we should look at the entire system and the relationship of those parts to each other. Looking at the system demands that we pay attention to the culture, and primarily, to the relationships of the caregivers to each other. Complexity science teaches us that health care is a complex adaptive system and that "no person, no matter how wise or powerful, can control outcomes in complex adaptive systems" (Lindberg, Nash, and Lindberg 2008). Yet, we still manage and direct health care based on Newtonian physics, dictating solutions in silos from above and wondering why nothing significantly changes.

Business schools have taught for years the mantra "Culture eats strategy for breakfast." Yet the current hospital administrative culture consistently behaves as if its edicts on strategies and tactics can decrease medical errors while ignoring the culture in which mistakes are embedded.

A night nurse was complaining about bar coding so I asked her, "What's your work-around?" Slowly she raised the sleeve on her lab coat to reveal eight patient ID bands.

CONCLUSION

The statistics as put forth in this book are alarming—and inaccurate. Medical errors are severely underreported in a fear-based culture. The problem is further entrenched in the general societal culture where the huge number of harm and deaths due to preventable error never makes the evening news. (If it did, we would have more support from the general public and therefore government funding.) In the broader societal context, patients continue to place unwarranted and unearned trust in their caregivers and hospitals because of a long-standing belief that when we proclaimed "do no harm" a century ago, we actually meant it.

How can a system succeed at addressing its inadequacies if it does not have a realistic picture or tally of the impact and harm? Or if that harm is so deeply embedded in the culture that it does not even register to its own leaders, let alone consumers? When preparing for a board retreat I asked the chief risk manager about her medication errors and she replied, "Medication errors are by far the major cause of our sentinel events—over 70%. But, only one person died and one is a paraplegic."

"Only one?" The words echoed in my head long after the phone call had ended, poignantly reflecting the norms of the current culture where one death is tolerated, as long as it is not your own child or parent.

Leaders must understand the culture that they are leading and use this knowledge to frame decision making, especially budget allotments. The current fear-based culture is characterized by bullying behaviors and self-silencing (Bartholomew 2006, 2010). A health-care worker must know beyond a doubt that he or she will be respected and appreciated for speaking up and owning patient safety. Only education and leadership can debunk the current myths that keep the information we desperately need to decrease medical errors suppressed in the culture. To reduce medical errors from a social science systems perspective, leaders must focus on language and behavior and accept their pivotal role as stewards of a brand new safe, team-based culture that

- Chases "zero," that is, holds the vision that it is possible for there to be *no* medical errors if the system is designed to catch them. The first characteristic of this system would be that it is psychologically safe for the workers
- Holds all staff accountable to the same rules. This is called "institutional integrity," which breeds trust
- Collegial interactive teams where caregivers feel free and safe to ask questions and objectively comment knowing that omnipotence and infallibility are myths. These teams can only occur:
  - If power is disseminated and physician autonomy is replaced by the core value of "patient-centric care"
  - If the team has been educated and trained in assertive communication to engage rather than avoid conflict

We will *never* be able to realistically assess the number of medical errors caused by bullying and hostile behaviors until we create a safe culture, which cannot happen without visionary leaders that poignantly understand that human factors are the trump card in the poker game we play every day with our patient's lives.

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11 The Relationship between Lateral and Horizontal Violence and Bullying
Nurses and Patient Safety

Christine Pontus and Pamela M. Ortner

CONTENTS

A 13-inch Souvenir

Donald Church, 49, had a tumor in his abdomen when he arrived at the University of Washington Medical Center in Seattle in June 2000. When he left, the tumor was gone—but a metal retractor had taken its place. Doctors admitted to leaving the 13-inch-long retractor in Church's abdomen by mistake. It was not the first such incident at the medical center; four other such occurrences had been documented at the hospital between 1997 and 2000. Fortunately, surgeons were able to remove the retractor shortly after it was discovered, and Church experienced no long-term health consequences from the mistake. The hospital agreed to pay Church $97,000.

Nurse Ortner remembers

> Even though it was over 30 years ago, I remember it as though it happened yesterday. While working in a small Detroit community hospital as a licensed practical nurse (LPN) on a med-surg unit, I had given a patient scheduled AM medications when I was called to the room. The patient's mouth, tongue, and airway had begun to swell, to the point at which her tongue was protruding from her mouth. Several calls to the resident were not responded to; when the resident finally arrived on the floor, he was clearly irritated. When he saw the patient, the swelling had, for the most part, subsided. The resident did a medication review, only discontinuing the anticoagulant despite my concerns that the antibiotic may have been the causal factor. At the next medication round at 2 PM, when the antibiotic was again given, the swelling occurred as it had previously, but was enhanced. When the resident did not respond to multiple calls, I called the resident "Stat" to the unit. When the resident arrived, he was clearly upset and began yelling at me, until he saw the patient and then he leapt into emergency mode. In retrospect, due to his arrogant manner, and some insecurity on my part, I did not initially push the matter, causing the patient to be placed in danger again, which could have been fatal. It made me wonder how many patients receive inadequate care due to nurse intimidation by physicians and other health-care workers? What else could I or should I have done? It is too bad issues of bullying and intimidation still exist in health care and can cause patient harm.

An ideology of caring characterizes the nursing practice, yet nurses are not immune to bullying from members of the health-care team, including not only other nurses, but physicians, pharmacists, supervisors, managers, and other disciplines. Lateral violence in the workplace is widespread and can result in low morale, high staff turnover, increased sickness, absence, and low productivity, and it can cause clinical errors.

BULLYING

Lateral violence is defined as any inappropriate behavior, confrontation, or conflict, ranging from verbal abuse to physical and sexual harassment. There are three categories of behaviors that are considered lateral violence: bullying, harassment, and discrimination. Bullying among health-care workers has been identified in both U.S. and international studies for the last three decades. Haselhuhn's review (2005) characterized bullying as "generalized workplace abuse" that is persistent, nonsexual, occurs without physical violence, involves an imbalance of power or privilege, escalates from less to more severe behaviors, and can result in a negative effect on the nurse. Harassment is a form of lateral violence, which is any type of unwanted behavior that may range from unpleasant remarks to physical violence. Sexual harassment is linked to gender or sexual orientation. Racial harassment is typified by behaviors that are linked to a person's skin color, cultural background, race, and so on. Harassment tends to have a strong physical component in manifested behaviors. Behaviors that include regular following and watching are termed "stalking." Discrimination is also considered a form of lateral violence and involves a person

being treated differently, and in particular, less favorably, because of her/his gender, race, sexual orientation, or ability.

Workplace bullying is characterized by many incidents of unjustifiable actions of an individual or a group toward a person or group over a long period of time. Bullying behaviors are persistent, offensive, abusive, threatening, and malicious in nature with the intent to do harm. According to the Center for American Nurses (2008), bullying can be associated with the initiator of the bullying at an actual or a perceived higher level or authority. The perception may be based on the seniority of coworkers, the status of the professional position within the organization, or the power of an individual.[1] These behaviors could also be labeled as abuse. In 2004, the International Council of Nurses (ICN) defined abuse as "behavior that humiliates, degrades, or otherwise indicates a lack of respect for the dignity and worth of an individual."[2]

PREVALENCE

There has been considerable research about the prevalence of lateral violence in the past few years. Health-care workers have the highest rates of workplace bullying.[3] In a 2006 online survey conducted by *Nurse Week* and *Nursing Spectrum*, 50% of respondents described a bullying situation they had encountered.[4]

In 2008, an American College of Physician Executives survey revealed that 97% of the nurses and physicians stated degrading comments, yelling, cursing, inappropriate jokes, and refusing to work with one another were common. The most common complaint was about degrading comments (86%) and yelling (73%). Physicians were cited as being the most common verbal abuse offenders (45%). Physicians are treated differently than nurses, perhaps because they are viewed as being less expendable. It is interesting to note that regarding termination of employment for their behavior, 61% reported that nurses had been terminated for their behavior, while only 22% reported that physicians were terminated for similar behavior.[5]

Case Study 1

I had worked for a while in the hospital when I decided to try home-care nursing. The environment is different; the nurse is more on her own in the field. When I started the new job, I asked my supervisor a lot of questions. She answered some questions, but her answers were short and snotty; I could tell she would get irritated with me. After a while, she told me she didn't have time for my questions and stopped answering my calls when I was in the field. My coworkers told me they were warned not to help me or answer my calls, but they took me aside and told me they would help me anyways. It shook me to my core. I will never forget how that experience made me feel. I know now I am a good nurse, but I was questioning myself deeply at that time. In retrospect, I don't know why I stayed in that job so long, being treated that way. When I precept a new nurse these days, I take more time with them so they will never feel the way I did back then.

The effects of bullying on the worker include:

- Sleep disorders
- Poor self-esteem
- Eating disorders
- Nervous conditions
- Low morale
- Apathy
- Disconnectedness
- Depression
- Impaired personal relationships
- Removal of self from the workplace

The physical and psychological effects of bullying can be debilitating and can drive a nurse to leave current employment to seek another job or leave the profession altogether. McKenna et al. (2003) found that 34% of bullied nurse respondents indicated that the problem was distressing enough to make them consider leaving the nursing profession.[6] Simons (2008) further demonstrated that the extent of bullying experienced by nurses can in large part explain their level of intent to leave their jobs.[7] Rosenstein and O'Daniel (2006) found that disruptive behaviors increased levels of stress and frustration, which impaired concentration, impeded communication flow, and adversely affected staff relationships and team collaboration.[8] Griffin (2009) stated that studies show that 60% of new nurses leave their first position within 6 months because of some form of verbal abuse or harsh treatment from a colleague.[9]

Research has shown bullying can increase physical symptoms as well. In 2008, Marras demonstrated the negative impact of aggressive communication on the back muscles of students while conducting studies in his patient handling and movement lab. Marras recorded data on human performance in relation to workload and measurement outcome on the spine during a specific job task in a socially comfortable situation and then in a socially adverse worker environment. The outcome revealed that under unpleasant social conditions the lumbar spine compression load response was adversely affected for some individuals.[10]

Poor self-esteem can cause someone to distrust his or her own judgments and skills, especially when there is little support from others in the workplace. Leadership needs to understand that the continued bullying behavior imposed on workers causes pain, which causes individuals to have diminished capacity to do their job. Often the bullies themselves do not have the skills to cope with job stress and may perceive others who are trying to deal with the situation at hand as a threat. In a 2003 VHA Inc. study, when the perceived impact of disruptive behavior on psychological and behavioral variables was surveyed, between 83% and 94% of respondents indicated that disruptive behavior had a significant effect on psychological and behavioral variables.[11]

According to Simons, Stark, and DeMarco, the past 10 years have revealed increased evidence that lateral violence has significant effects on both individuals and organizations. On an individual level, victims of bullying behavior have been

linked with adverse effects ranging from insomnia to self-hatred and depression as associated with levels of sickness-related absenteeism among hospital staff.[12] Some other effects of lateral violence are

- Marginalization of the competencies, intelligence, and integrity of others
- Reduced self-esteem
- Disconnectedness
- Apathy and low morale
- Depression, anxiety, and sleep disorders
- Difficulty with motivation
- Difficulty with emotional control (bursting into tears)
- Impaired personal relationships—trust is destroyed further eroding relationships in the workplace and creating a major obstacle to team building

Targets of bullying experience stress from the attacks and have to constantly readjust their behaviors in an effort to avoid being revictimized. The time and energy invested in the pursuit of avoiding another attack have both physical and psychological effects on the individual. These symptoms impact the health-care provider's ability to provide high-quality care.[12]

In 2010, the authors concluded after their study of verbal abuse in nursing that this form of bullying is costly to the individual nurse. The effects of verbal abuse are often manifested as job stress, job dissatisfaction, missed work, and perhaps decreased quality of care. Their qualitative study involving 29 nurses' experiences of aggression found that "horizontal violence" was more distressful than being assaulted by a patient.[13]

INSTITUTIONAL BULLYING

The next confounding factor is what is termed "institutional bullying" or "organizational lateral violence." This occurs when everyone is witness to the egregious behavior, but nothing is done to stop it; thus, the message sent throughout the organization is loud and clear: no one is safe. The inappropriate behavior may continue for many reasons. One of the most common reasons is that many people do not know how to react to bullying behavior. The spectators as well as the target are traumatized by the negative behavior. Allowing disruptive behavior to continue is harmful to both workers and patients. It is the responsibility of the leadership representing the organization to ensure a safe workplace for workers, which in turn will create an environment in which quality, patient-centered care can occur. Too often those in authority (e.g., supervisors, nurse managers, and others in leadership positions) state, "I am not getting in the middle of this. It is not my job; this is between the two people or group to work out between themselves." Those in authority representing the organization need to stop making excuses. Stereotypical statements such as "I have seen this before, it goes on between women all the time" need to be replaced with a response based on proven effective tools of communication and strategy similar to a root-cause analysis as to why the situation is happening. It is time that those assigned leadership positions be given guidance and tools to deal with this issue in

a positive and productive manner. The first step is to recognize and understand what is contributing to the problem. Once the situation is seen clearly, only then can it be dealt with. The old attitude of denial and doing nothing to fix the situation in a constructive manner confirms a culture of abuse and disruptive behavior.

OPPRESSIVE GROUP BEHAVIOR: IMPLICATIONS FOR IMPROVEMENT IN HEALTH CARE

One model used to explain how individuals within a group respond to domination is the theory of oppressed group behavior. In his study of European-dominated Brazilians, Paulo Freire (1971) believed the cause of horizontal violence is found within the cycle of oppression.[14] The oppressed or dominated group is instilled with the learned belief that they are inferior. This inferiority belief continues within the dominated group because the oppressor creates a culture with norms and values based on their choices reflecting their own image. Consequently, subordinate groups learn to hate their own attributes. A lack of pride leads to feelings of low self-esteem and compounds a lack of respect for each other and their attributes, when not valued by the power group. It is imperative that the dominated group feel inferior; this ensures continued submission to the dominant group. According to Memmi (1965), those who want to get ahead need to change and look like the oppressor. Individuals who are successful at assimilation become "marginal," as they are not full members of the dominate group and also operate on the edge of their own culture. Being in a marginal state or "marginality" is to be without a clear cultural identity. Being powerless and experiencing a lack of pride in one's own culture or group are factors contributing toward the cycle of subordination. The internalization of inferiority gives rise to a power differential, which exists even when there is no physical domination. The oppressed feel aggression toward the powerful, but their fear and low self-esteem make them submissive when confronted by authority and power.[15] In 1976, Carmichael and Hamilton posited that aggression and anger toward the powerful are often turned inward toward their own based on the same fear and low self-esteem.[16] Freire (1970) coined the term horizontal violence to explain this dynamic horizontal violence while Fanon (1963) called this "internalized oppression."[14,17]

OPPRESSION THEORY AND NURSING

Health care primarily has occurred in the hospital environment. Nursing as a group has been viewed as oppressed because of its lack of power and control in the hospital as the workplace. Following this train of thought, horizontal violence is the result of worker-on-worker frustration and or aggression. The assertion made in "oppression theory" is that frustration stems from nurses and other health-care workers who are not valued or are on the fringe of the greater group in power. They are "marginalized," not feeling they have a voice in the organizational power structure.

Roberts (1983) maintained the theory of oppressed group behavior was relevant to nursing because of the medicalization of health care.[18] Freshwater (2000) reiterated the connection of lateral violence in the nursing profession to the behaviors

of oppressed groups.[19] In 1997, Farrell said, "It is contended that because nurses are dominated (and by implication, oppressed) by a patriarchal system headed by doctors, administrators, and marginalized nurse managers, nurses lower down the hierarchy of power resort to aggression among themselves."[20] Griffin (2004) believed nurses have little control over their work environment and yet are held accountable, resulting in personal stress. The member of the oppressed group is abusive to peers and those individuals with lesser status because she/he fears addressing the source of the stress affecting her/him. Therefore, the nurse strikes out at peers, students, nursing assistants, and others who are perceived as having lesser status.[9]

SOME OF THE SIGNS AND SYMPTOMS OF A HOSTILE WORK ENVIRONMENT

Nurses and other health-care workers are often told by coworkers and managers that they are reacting to a situation that is not intended to be personal. Too often targets do not receive support from management or coworkers and are told that no one is attacking or picking on them. (For various reasons, that will be discussed later in the chapter.) It is important that we begin to differentiate between environmental stresses and recognize that bullying behavior is in fact just another type of hazard adding to stress. As evidenced by substantial research, workplace bullying has a profound negative effect on the health and well-being of individuals.[21]

The National Institute for Occupational Safety and Health (NIOSH) defines occupational stress as "the harmful physical and emotional responses that occur when the requirements of the job do not match the capabilities, resources, or needs of the worker." The strategies recommended by NIOSH to reduce worker stress include distribution of workloads that are matched with workers' capabilities and resources, clearly defined workers' roles and responsibilities, and methods to improve communication within the organization. NIOSH also suggests that workers be offered opportunities to participate in decisions and actions affecting their jobs. This process will reduce uncertainty about career development and about future employment prospects. Opportunities for social interaction among workers are encouraged.[22] The following is a list of common stressors found in health-care settings:

- Inadequate staffing levels
- Long work hours
- Shift work
- Exposure to infectious and hazardous substances
- Needlestick injuries
- Exposure to work-related violence or threats
- Sleep deprivation
- Injuries
- Role ambiguity and conflict
- Understaffing
- Career development issues
- Dealing with difficult or seriously ill patients[23]

Looking at the environment from a health and safety perspective, the hazard is often the very stressful work environment itself, compounded by those who may have difficulty coping with the stress in a productive manner. Some individuals strike out or begin to target others as a way to relieve their discomfort and to remain in control in an otherwise stress-filled situation.

TOXIC PERSONALITY AND MARGINALITY

Another component that workers are forced to deal with is the toxic personality, or bully who politically (marginally) is associated with the outer ring of the larger network. In the workplace, the toxic personality is generally not a good communicator with others. They can be very effective in pushing their own agenda but are not seen as willing to spend time with and for the work group or team. Their style is more telling people what to do. For some reason, the expectation is the whole world will operate based on what they think. In relation to a team approach, those with this style of communication seemingly do not have the ability to conceptualize and communicate their needs and the needs of those around them in the work environment. Nor do they want to; it simply appears that it does not seem relevant to them—after all they simply know it all. These individuals have been heard to say they never make mistakes. The other "mere mortals" are rather taken aback by such statements and have a hard time understanding how some individuals can actually operate on the false premise that they never do anything wrong.

If one applies the oppressed theory to those individuals who have brought into or adopted the dominant group thinking, at face value, they are operating on the premise that they are and know better than their peers. They behave as if they believe they belong to a higher status, therefore attached to the larger group. They continue to push their way of doing things and their view of the world on other workers. According to the oppression theory, their actions are all based on their low self-esteem. They will do anything to manipulate their surroundings for their own personal gain. More often this type of personality is known as blame assessment, elevating their stature at the expense of others. Health-care environments can provide the perfect setting for a bully. Bullying, which is systematic and primarily psychological in nature and can demean, devaluate, and humiliate, is four times more frequent than sexual abuse.[23]

It is the responsibility of leadership to recognize that individuals are not born with the social skills to manage the stress imposed upon them by the environment. Often toxic personalities are left to their own devices because they have mastered successful strategies within certain positions of authority. This becomes apparent when one looks at the indicators such as turnover, job satisfaction reports, complaints, and/or requests for transfers in certain units and departments. These red flags can act as indictors to warn upper management that there may be a fox in the henhouse.

The root of institutional violence is the absence of respect in the workplace. Because leaders set the tone, it is the leadership that must promote a culture of respect through their words and behaviors. According to Stokowski, the employer

is responsible for setting an example of harmony and collaboration with her or his staff.[24] In organizations where bullying is allowed, it is seen as the cultural norm in the workplace. Consequently, blaming the victim is a means for the employer to avoid responsibility for bullying. The nurse who is targeted may be told by her employer that it is her problem. Therefore, the nurse is held responsible to deal with her "stress problem" while the employer fails to address the institutional culture that supports the bullying of employees.

Structural bullying specifically involves supervisors or line managers taking actions perceived as inequitable or retaliatory involving scheduling, workload assignments, or pressuring nurses to not use their earned time. Where lateral violence is permitted, the institution permits or ignores these behaviors, resulting in a hostile work environment. Once again when this behavior is allowed and institutions sanction or turn their backs, they are sending an "it's OK" message to all.

EFFECTS OF INSTITUTIONAL LATERAL VIOLENCE

It is imperative that we begin to look at and listen to those workers with years of service in organizations experiencing problems with others. Workers are often isolated and do not know where to turn for assistance. A referral to employee assistance may help to clarify feelings, but it is not the cure for workplace dysfunction. The toxic environment is compounded by negative variables leading to an escalated destructive state for those administering care.

A MATTER OF TRAINING AND STYLE

This case study shows us that background, training, and communication style are important elements in the dynamics of nursing. Leadership must express clear expectations for professional behavior early on when a workplace conflict arises or it can deteriorate and become both painful and confusing for workers who may need assistance.

Case Study 2

Two LPNs had worked together for a period of 5 years with no incident. One is a male ex-police officer, and the other is a female who completed schooling and became a registered nurse (RN). Soon after she became an RN, she began to notice problems between her and her coworker, who threatened to write her up on more than one occasion. He told her he was going to report her for waking patients and improperly administering medication. An investigation proved that the complaints were not valid and the new RN was correctly following procedure in her job. However, the RN said, "the situation between me and my coworker became so bad, I had no choice but to leave. I love my job but I became afraid to go to work; I couldn't think straight and I was afraid I might give the wrong medication."

Without interventions from management, constant interruptions and ineffective communication can sometimes lead to a very destructive situation among some individuals. The opportunity to discover why there is a communication problem and/or misunderstanding with issues concerning practice is missed, allowing the situation to worsen.

PSYCHOSOCIAL AND ORGANIZATIONAL FACTORS DEMONSTRATED

What is clear here is that some people's ability to work is reduced by the inherent psychosocial stress in their environment. In the world of occupational health and safety, this is similar to a job-safety analysis. Needless to say, stress and its inducers become a hazard for many at the workplace. Leadership needs to recognize and be on the alert when individuals consistently add to stress because of inappropriate behavior. The toxic personality or workplace bully who is disruptive becomes a sort of hazard and needs to be dealt with as one would deal with any other workplace hazard.

The following case study involving a multiple systems error is a very typical medication error. Usually, multiple systems contribute to an error. By focusing on the "low hanging fruit," that is, the last person involved in the cycle of the error, and by assessing blame, the system that led to the error will not be improved; a root-cause analysis approach looks at the "systems" that need to be improved rather than focusing on the individuals that made an error.

Case Study 3

I found myself involved in this process last week when I administered a medicine that had been entered onto my medication administration record (MAR) by a pharmacist and had been acknowledged by a colleague, but actually constituted an overdose. The night nurse noticed it when she completed her 24-hour checks and noted that the order said to give 20 mg of the medicine, but the MAR read 120mg!

My nurse manager was upset with me and couldn't understand why I hadn't read the actual order myself. I told her that it had been acknowledged on the MAR, and it was not customary for me to double-check a colleague. When I asked her how the patient was doing, she found out and called me back in an hour, saying the patient was fine.

A hearing was held and I was nervous because of the confrontation by my nurse manager about the error. On my way to the hearing, I was in the elevator with someone I did not recognize, and after I introduced myself, he informed me he was the director of pharmacy, so I told him I was the nurse that gave the medicine and supposed we were going to the same meeting. He immediately apologized to me for the pharmacy error that contributed to this event and he said, "This is all about the process and what we need to do to improve our practice so

this does not happen again." I was so grateful, and said I believed this was the right way to deal with the situation.

Those at the meeting were the VP of risk management, the nurses on duty when the error was made, the physician, the nurse manager, the VP of nursing, the director of pharmacy, the pharmacist on duty, and our union rep. A discussion of what happened followed. At the end of the meeting, we talked about ideas to improve the processes that were problematic. Many processes for improvement were considered, including staff education about medication reconciliation, having a pharmacist investigate dosing parameters incorporated into the order entry system, variable hours for secretarial support and trending of admissions, peer education on order error identification, and decreased time for the submission of dictated notes to enhance communication. When we left the meeting, there was a plan for improvement with assigned tasks for several individuals. The general feeling was that everyone got their say, many good ideas were discussed and introduced to affect positive change, and no individual was targeted.

The process this nurse described is not what usually occurs, but this gives us a snapshot of how ineffectively a mistake or error can be handled (i.e., when the nurse supervisor expressed her frustration) and the effective way to handle a near miss or an incident without harm to the patient. The root-cause analysis that explored the reasons the error occurred followed by brainstorming from the entire group for solutions is an example of how effective an analysis of all of the factors leading to an error can be. Blame assessment typically points a finger at the nurse or the lowest-hanging fruit, but through root case analysis, multiple factors can be taken into account, which will affect a multilayered process improvement plan that will increase patient safety.

In 2007, when the newborn twins of actor Dennis Quaid and Kimberly, his wife, were hospitalized for a staph infection, they were accidentally given 1000 times the dose of heparin than the hep-lock flush that was ordered, to flush the IV lines. The twins nearly hemorrhaged to death. In his decision not to sue the hospital, he spoke about how the nurse who made the mistake is traumatized as well. Instead, Quaid tried to work with Baxter, the manufacturer of the drugs, in an attempt to differentiate the bottles of the two drugs, both of which had small printing on them and blue labels, though one was a slightly different color. Baxter, of course, concluded it was human error, and though they eventually changed the labels, would not recall the old stock. Quaid sued, and eventually the drugs were pulled from the market due to "contamination."

In a recent case in Seattle, a neonatal nurse committed suicide after being fired from her hospital position as a result of the nurse giving an infant an overdose while in her care. The nurse had an unblemished record and was being investigated by the state board of nursing when the suicide occurred. This is an example of "second victims," a term created by Dr. Albert Wu, a professor at Johns Hopkins Bloomberg School of Public Health. The term describes the two victims of a serious medical mistake: the person hurt or killed by a preventable error, and the person who has to live with the knowledge they hurt a patient who they were trying to help.

The Institute of Medicine's groundbreaking report *Crossing the Quality Chasm* (2001) on solutions to improve the health-care system and reduce errors stated "The biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm."[25] In the report, the Committee on Quality of Healthcare in America explained that the majority of quality problems and medical errors occurred "because of fundamental shortcomings in the ways care is organized"[25] and not by individual error or negligence.[26] Medical errors will happen; serious efforts must be made to reduce errors in health care by looking at root causes. As we saw in the last case study, patient outcomes can be improved without using a punitive approach. Failure to acknowledge and report errors impedes efforts to improve patient safety. Only when errors are openly recognized can the reasons for the errors be addressed and subsequent errors prevented.[27]

The following response is from a nurse educator who made the statement when asked if her hospital had incorporated or developed a risk-management tracking system for reporting incidents to help prevent medication or medical errors:

> Yes, we have an electronic system in place to report incidents. Historically, there has been a punitive connotation attached to incident reporting. Whether there was deleterious harm or no adverse results, management has held these things against nurses. Now with the advent of electronic incident reporting, quality experts want reporting to be "tools of improvement and learning." However, that history of punitive culture is difficult to change when it is so ingrained. How do you change this? Like most things, it will take a culture change. It will also take building of trust. Trust is earned; after years of being beaten down, trust comes hard. My position was an afterthought when they realized an educator was needed to bring individuals to report incidents.
>
> Nursing was brought in as an afterthought, as opposed to taking part in the conceptual planning and implementation stage of major changes in the hospital system. This is all too common—one more time nursing is given another job to do by administrators without any input from nursing during the initial phase of the project. Not to think about the largest segment of the work force responsible for using the new electronic quality patient safety tool is disturbing. Nurses will actually be best to make this effort a success and they are left out. What does this tell us about the lack of respect and consideration given to nursing, the largest group who will be using this tool within the hospital system?

Health-care systems are in a continuous state of change, creating a challenge for the most expert workers. From a systems perspective, there are many reasons for problems. The value of safe patient care needs to be the foremost thought for everyone when implementing new data-collection systems. Nurses spend more time than other professionals, including the physician, with the patients and have the greatest potential to improve quality outcomes of patient care. It appears that nursing was not considered or that aspect of patient care was not thought of when this recording system was put in place. Nurses need to be at the table when planning is occurring, along with the implementation and evaluation phase; it is what we do.

EFFECTS OF BULLYING ON PATIENT SAFETY

In today's complex health-care environment, administering safe patient care requires more than any one individual's skills and good intentions. Consistent, open, and collaborative communication among all health-care providers, administrators, and patients and families must be established and practiced to ensure quality patient-centered care. It is imperative that those providing care be able to focus on the task of the job.

In a recent article, Simons, Stark, and DeMarco (2011) found significant examples in the literature that revealed a direct relationship between positive nurse–physician relations and the quality of the work environment, enhanced patient safety outcomes, and decreased patient mortality rates.[11] In 2004, the Institute for Safe Medication Practices released a survey on workplace intimidation. Almost half of the over 2000 respondents, which included a variety of health-care providers as well as nurses, were verbally abused when contacting physicians about clarification or questions on a medication prescription and, as a result of feeling intimidated, they either did not question an order or sought ways to indirectly confront the prescribers.[28] In 2008, the Joint Commission published a Sentinel Event Alert as a response to increased acknowledgement that disruptive behavior in the health-care system adversely influences the safety of patient care.[29]

MANDATES

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recognized the lack of a constructive organizational response to bullying, lateral violence, and horizontal violence as one of the contributing links to decreased patient safety in the health-care environment. Many who work in health care have recognized intimidating and disruptive behaviors as a serious problem. The JCAHO accreditation standard that took effect on January 1, 2009 required more than 15,000 accredited health-care organizations to create a code of conduct and establish a formal process to define acceptable and unacceptable behaviors. Hospitals, home health-care agencies, rehabilitation centers, and laboratories must now manage inappropriate behavior. This applies to physicians, nurses, pharmacist, therapists, support staff, and administrators.[29]

JOINT COMMISSION LEADERSHIP STANDARD

- Provide the hospice will have a code of conduct that defines acceptable and disruptive and inappropriate behaviors.
- Leaders create and implement a process for managing disruptive and inappropriate behaviors.[29]

Some of the suggested actions include

- Provide training to educate all care team members about the practice of professional behavior as defined by the organization's code of conduct.
- Hold team members accountable for modeling professional behaviors.

- Develop policies/procedures that address zero tolerance.
- Implement complementary medical staff policies addressing the behavior of physicians.
- Include nonretaliation clauses in policies.
- Develop disciplinary actions.
- Develop a system of reporting.
- Develop education around the utilization of nonconfrontational interaction strategies to address behavior.
- Establish protocols to determine workplace actions to deal with bullying.[29]

Only when we begin to understand some of the many components that lead to and perpetuate the problem of workplace bullying can it be addressed. If the environment of the hospital or health-care institution will change, the administrative body of the organization will be involved and place this issue on the risk-management agenda throughout the entire organization. There is no boilerplate approach to this problem, but having a system in place for workers to report unsafe situations within the organization is a good place to start. Risk-management collaborative initiatives with workers could be developed with the human resources and occupational and employee health and education departments, to name a few.

INDIVIDUAL INTERVENTIONS

According to the Center for American Nurses, a few of the ways bullying can be handled are

- Recognize bullying behavior when it occurs and do not assume that it is normal or accepted behavior.[30]
- Confront the situation—avoidance is the number one means by which bullying behavior is handled in the workplace. However, the use of avoidance as a strategy only delays the inevitable recurrence of the behavior.[31]
- Acquire conflict engagement skills—learning to deal with bullying behavior incorporates the basic skills of self-awareness, building trust, listening, acknowledging, reframing, and generating options.[32]
- Speak out to support the person, or offer silent support, but do not pretend you do not see a target being abused.
- Confront the unacceptable behavior.
- Promote education of staff and managers.
- Advocate for written policies and procedures.[23]

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12 Special Populations
Medical Error and Infection

Susan Gallagher

CONTENTS

The Healthy Kidney Removed by Mistake

In St. Louis Park, Minnesota, a patient was submitted at Park Nicollet Methodist Hospital to have one of his kidneys removed because it had a tumor believed to be cancerous. Instead, doctors removed the healthy one.

"The discovery that this was the wrong kidney was made the next day when the pathologist examined the material and found no evidence of any malignancy," said Samuel Carlson, M.D. and Park Nicollet's chief medical officer. The potentially cancerous kidney remained intact and functioning. For privacy and family's request, no details about the patient were released.

INTRODUCTION

Medical errors and adverse events in today's health-care environment are occurring at an ever-increasing rate. In 1999, the National Institutes of Health (NIH) Institute of Medicine released the report *To Err Is Human*. In that now-famous report, the authors concluded that there were up to 98,000 preventable patient deaths due to medical errors every year.[1] To place this in context, the number of preventable patient deaths equates to a jumbo jet crash every day for a year.

Although the report set off widespread attention in many sectors, this sensational number is probably a low estimate because it fails to include errors in diagnosis, which lead to mortality or morbidity associated with skin injury and wound infections

among certain special patient populations. Experts explain that delayed or missed diagnoses are inevitable in some cases. However, in the area of skin and wound care, especially among obese people, diagnosis is rather straightforward. However, historically, skin injury related to chronic illness such as pressure ulcers and skin-fold challenges have seldom received the interest or concern of other medical conditions. A study that reviewed the evidence related to the frequency of manual turning revealed the alarming fact that up to 90% of acute care patients who need assistance in repositioning do not receive manual turning as needed.[2] Hospital-acquired infections as a result of skin injury have become a high-incidence, high-cost condition gaining attention from the Joint Commission on Accreditation of Healthcare Organizations through the 2011 National Patient Safety Goals. Additionally, reimbursement for avoidable hospital-acquired pressure ulcers and wound infections has been eliminated by the Centers for Medicare and Medicaid Services (CMS), putting pressure on hospitals to decrease incidents.[3] Authors contend that the health-care industry is not listening or learning, and whether because of a knowledge deficit or a lack of awareness, it is clear that the health-care industry is truly not listening or learning, especially regarding rescuing patients of size from the common, predictable, and preventable events that can result from an acute hospital stay.

Medline, CINAHL, PubMed, and government websites do not provide sources for studies or literature that break down data pertaining to hospital-acquired infections and the obese individual specifically. How can risks be managed if they have yet to be quantified? Further, few authors are even considering the relationship between safe patient handling and the immobility-related complications described herein. Little is discussed in the literature, which presents the downstream relationship between skin and wound care, bariatrics, safe patient handling, and liability risk. A first-person approach is used here to better understand some of the unique care issues that threaten patient safety and organizational risk by transecting the evidence pertaining to safe patient handling, bariatrics, and hospital-acquired skin injury and wound infection.

WHAT IS BARIATRICS?

"Bariatrics" is a functional term derived from the Greek word *baros* and refers to the practice of health care relating to the treatment of obesity and associated conditions.[1] The implication in health-care settings is that activities such as turning, lifting, and repositioning can predispose workers to physical injury. Additionally, immobility and failure to provide adequate patient activity lead to issues of patient safety and adverse outcomes. The phrase "special patient population" is enigmatic in this context because, as the most recent data suggests, at least 67% and as many as 80% of Americans living in the United States are overweight. Moreover, as many as 6.4% of Americans are severely or morbidly obese. The question this raises is: When does the exception become the rule? At what point do we recognize this is the patient population, not a *special* patient population? Hospital-acquired skin injury and wound infections may occur because of the failure to recognize the predictable, preventable, and costly consequences associated with patients of size, who comprise as

much as 80% of the general population. In the course of this chapter, a number of social, organizational, and economic issues will arise. The phrase "special patient population" and the definition of bariatrics are only the first. Although curiosity and exploration are good first steps in the process of bringing about change, they are just that: first steps. Few have taken this much further in the process of safely managing the complex needs of the special patient population known as bariatrics.

THE UNSPOKEN TRUTH

Despite National Patient Safety Goals, the quality movement, and other efforts to promote cost-efficient, timely, and appropriate care, most nurses agree that care for the larger, heavier person is challenging at best and often impossible. Even the most compassionate nurse will attempt to avoid assignment to an overweight individual because of the numerous care challenges. Certainly, there is the fear of personal injury, but nurses are also acutely aware of the threat of medical errors and adverse events. Consider Liz, a 28-year-old, 480-pound woman admitted through the emergency department for laparoscopic appendectomy. Liz never left the hospital. Liz was not a victim of a medication error, fall, or one of the many other measurable quality indicators. She simply was a morbidly obese woman. Hospital staff members were ill prepared to care for her, and she was unable to survive the numerous events that transpired.

Liz was admitted with chronic irritation in her abdominal skinfold, which was also the site of her trocar placement—the operative field. The wound became contaminated, and she developed a significant wound infection, which was not initially noticed because the infection was hidden deep in the folds. While treating her sepsis of unknown origin in intensive care, the staff members reported they were so concerned with their inability to provide basic care, they never considered she would be at risk for an atypical pressure ulcer over the buttock, which was not discovered until this full thickness wound had involved the muscle, bone, and surrounding tissues. The buttocks wound was overwhelmingly odorous and infected. Like 60% of nurses in the United States, the facility did not provide staff members with lifting equipment to safely position Liz.[4] Thus, even though she had a pressure ulcer on her buttocks, it was still nearly impossible to reposition Liz off the wound. Several nurses who felt committed to provide care to Liz developed back injuries. One nurse was unable to return to work because of continued back spasms. The nurses in intensive care were short staffed, and it is well documented that as registered nurses (RNs) deliver less direct care, outcomes suffer. For example, Lichtig, Knauf, and Mulholland report a significant inverse relationship between the percentage of care delivered by an RN and the incidence of pressure ulcers and postoperative infections.[5]

The unspoken truth is that Liz's story is not that unusual, yet data pertaining to the patient of size and relevant, measurable quality indicators are not forthcoming. A widespread failure to preplan and deliver size-appropriate care is a realistic threat to resolving the problem of skin injury and wound infections among Americans of size. Front-line health-care workers recognize this threat to safe, quality care.

HOSPITAL-ACQUIRED INFECTIONS

Hospital-acquired infections are considered "never-events" in some circles as this is a special situation where Medicare has specifically removed any financial incentive to health-care organizations that fail to address processes and procedures designed to prevent certain hospital-acquired conditions. In days past, health-care organizations would charge patients or private and public insurance carriers for care that emerged because of inadequate policies and procedures. Therefore, the point at which issues of the skin and bariatrics intersect with safe patient handling is increasingly more important in health care, especially in the face of medical error, adverse outcomes, and nonreimbursable events.

Who is the patient at risk for hospital-acquired infections? The obese individual is at greater risk for hospital-acquired infections. Health problems associated with obesity include diabetes, hypertension, lipid disorders, soft tissue infection, some cancers, impaired circulation, and others, each of which interferes with the patient's level of health, in general, and skin care, specifically. Additionally, deconditioned patients pose greater mobility risks and are often left to the hazards of immobility. Deconditioning refers to muscle weakness, respiratory compromise, and other physiologic changes that occur with significant immobility. It becomes imperative to understand comorbid conditions and their disproportionate effects on the morbidly obese patient, and at a younger age than their nonobese counterparts. Many authors contend that from the onset, the obese patient is at a disadvantage because diagnosis is difficult and procedures are technically more complicated if not understood properly.[6] Hospital staff members report concerns due to inadequate training, equipment, and personnel to accommodate the needs of larger patients.[7] Recent advances in information, intervention, equipment, and education have helped reduce some of these risks.[8] Yet many facilities fail to integrate these advances into practice; therefore, medical misadventure continues to plague care of the obese person, often times leading to hospital-acquired infections, particularly skin injury and wound infections.

THE SKIN

The skin is the largest organ of the body, both by weight and by surface area, accounting for 16% of the total body weight. The skin is at particular risk for injury in the health-care setting among the bariatric population. This dynamic, living organ behaves differently in the presence of obesity. For example, there is increased water loss throughout the skin with widespread inflammation and occasionally dry skin. Sometimes, the skin's pH is altered. Itching that leads to scratching leads to breaks in the skin surface where microorganisms can enter. These factors work together to increase the threat of skin injury, wound infection, and delayed wound repair. Hormonally, there are elevated androgens, insulin, growth hormone, and insulin-like growth factors. Subsequently, increased sweat gland activity occurs, which leads to an increase in the prevalence of inflammatory or noninflammatory pimples, cysts, or cyst-like growths over the head, face, neck, back, or arms.[9] Bariatric individuals have a different weight-to-skin ratio than their nonobese counterparts and perspire

more efficiently when overheated in order to cool the body adequately. This moisture can accumulate deep in the skinfolds and lead to intertrigo, which is a rash inside the skinfolds. When considering pressure ulcers, it is important to recognize that the skin is more resistant to pressure than underlying soft tissue, so pressure injury can occur deep within the tissues before breakdown at the skin level becomes evident. This is important as deep tissue injury can occur before a break in the skin surface is observed.

Intertrigo is an important and misunderstood condition when discussing hospital-acquired infections in obese people. It is a term that simply refers to inflammation within the skinfolds, which can be found any place where skin rests against skin.[10] The causative organism can be bacterial, viral, fungal, or any combination thereof.[11] Clinically, intertrigo is characterized by scaling erythema, and in some cases, small pustules or pus-filled satellite lesions may appear. Intertriginous involvement can affect larger, heavier patients across practice settings, so many obese patients are admitted to the acute care hospital with intertrigo in the skinfolds, placing the patient at risk for skin injury and infection. The condition is more often found among those who are overweight and/or have diabetes.

FIRST-PERSON APPROACH: REAL-LIFE CHALLENGES

Question One

Are processes in place to reduce surgical site infections among individuals of size? We have quite a few obese patients on our unit, and it seems to me just about every patient develops a surgical site infection.

Answer: According to the Centers for Disease Control (CDC), there are approximately 500,000 surgical site infections in U.S. hospitals annually, with a 13% mortality rate and a financial cost of more than $1 billion each year. A surgical site infection is estimated to increase a hospital stay by an average of 7 days. The frequency and severity of surgical site infections have become so significant that the CDC is collaborating with stakeholders with the goal of reducing nosocomial infection rates by 50% over the next 5 years. However, despite this alarming data, none relates specifically to the person of size. Few, if any, hospitals, clinics, and primary care practices address preoperative bacterial, viral, or fungal loads on the skin surface and within skinfolds. Obesity is a strong risk factor for skin injury, including intertrigo.[12] Understanding the specific risks of intertrigo in the morbidly obese individual is essential to understanding creative methods to control for surgical site infection. When intertrigo goes unchecked, the skin continues to deteriorate. Bacterial, viral, or fungal infection may develop in broken or denuded skin. This could progress to cellulitis, wound infection, sepsis, or death if left untreated.

Evidence is available to help us understand the risks inherent in prolonged hospitalization and, therefore, the increased risk for hospital-acquired infections. For example, the surgical experience predisposes the patient to skin injury simply because surgery increases the patient's length of stay and dependency or immobility because of pain, sedation, or the fear of falling.[13] There are a number of critical junctures where risk exists, including activities as common as transfers from the

surgical table. For example, the larger, heavier person who may also have a body maldistribution will require extra personnel and supportive equipment who must take care not to create shearing injury, which leads to pressure ulcers. Inappropriate or incorrectly performed lateral transfers can place undue stress on incisions, which leads to hematoma and subsequently a risk for wound infection.[14] A lateral transfer device may help.

Some patients will fail to progress postoperatively either because of surgical complications or a critical condition.[15] Unless the patient can be mobilized in critical care, deconditioning will occur very rapidly and, therefore, there will be greater risk for immobility-related complications, such as pressure ulcers or hospital-acquired infections. As mentioned earlier, mobility is especially challenging in the critical care area and often does not occur in the timely manner necessary to prevent pressure ulcers and other immobility-related events. Sadly, while 56% of physicians feel compelled to partially disclose the details of an event, 3% will make no reference to the adverse event or error.[16] Families and the patient may never know the reasons for the prolonged hospitalization and its corresponding emotional and financial cost.

Postoperatively, patients seem to breathe more easily when the bed is at 30° because this position prevents the weight of the abdominal adipose tissue from pressing against the diaphragm.[17] The issue is that many thinner clinicians continue to place patients at a 45° angle, not realizing the inherent risk. Certainly, for a lean individual without abdominal fat, this position is best. However, it can be deadly for a person with excessive abdominal adiposity. The challenge this poses in terms of skin care is that patients who fear shortness of breath may refuse repositioning from this 30° angle, sometimes referred to as a semi-fowler's position, thus placing them at risk for sacral pressure injury. Educating patients about their misunderstanding of the threat to their skin is imperative in order to prevent pressure ulcer development (see Table 12.1). Introducing therapeutic support surfaces early in the admission may reduce some of this risk.

Improper positioning leads to special respiratory challenges, which are common among obese patients.[18] This in turn can lead to the need for long-term ventilator support and subsequent tracheostomy, which can be especially challenging if the trachea is buried deep within fatty tissue. A large wound may be needed in order to locate the trachea. This larger wound can lead to complications such as bleeding, infection, or damage to the surrounding tissue. Postoperative tracheostomy care must therefore include steps to protect the peristomal skin, manage the tracheostomy, and contain wound drainage.[15] To compound this dilemma, standard-sized trach tubes may be inadequate for use with patients with larger necks. In addition, narrow cloth

TABLE 12.1
What Is Failure to Rescue?

Failure to rescue is a term originally from the lexicon of ethics and refers to a failure to prevent a clinically important deterioration resulting from a complication of an underlying illness or a complication of medical care. Failure-to-rescue rates are widely recognized and used as patient safety indicators and will soon be integrated into national data collection.

trach ties can burrow deep within the folds of the neck, further damaging the skin and leading to hospital-acquired infection in this vulnerable area. Herein lies the argument for timely, appropriate positioning and mobility to avoid this largely preventable cascade of adverse events. Hospital-acquired infections significantly delay postoperative recovery, which can become costly emotionally for the patient and costly financially for the organization and society in general (see Table 12.2).

Question Two

Are back-injury prevention efforts in place, which allow frontline caregivers to provide basic hygiene in an attempt to prevent Fournier's gangrene and others, which arise out of pressure and invasion by microorganism? There are several men who have been admitted in the past month with odor and inflammation under the abdominal panniculus or apron. Many of the nurses and assistants are not physically strong enough to safely provide basic hygiene after toileting or when providing a bath. One of our patients did not survive a case of Fournier's gangrene. Our team members are very concerned not only for their own safety but for the patients who develop this potentially fatal infection.

Answer: William Charney was the first scholar to connect caregiver injury to patient safety in his 2007 landmark study.[4] Since that time, there has been increasing awareness of the relationship between injury, fear of injury, and care of the patient of size.[19] To that extent, it unfortunately makes sense that caregivers who question their ability to turn, lift, or reposition patients simply refuse. One physical therapist explained the direct correlation between incidence of caregiver injury and increased patient body mass index (BMI), up to a point. She indicated that no therapist had been injured when moving a patient weighing over 500 pounds. She further explained that the team does not feel safe providing such tasks, so the activities are simply not performed. Not only are caregivers aware of this anecdotally, Drake and coworkers documented increased injuries among nurses caring for obese patients, at a disproportionate rate.[20]

It is no surprise that caregivers are reluctant to perform certain custodial tasks. Bathing poses unique challenges such as access to bathing facilities and access to all body surfaces, including skinfolds. Privacy and dignity are also of concern.

TABLE 12.2
Steps to Prevent Surgical Site Infections among the Obese Individual

- Abstain from all tobacco products 30 days before surgery.
- Consume adequate proteins, vitamins, and minerals for the 30 days preceding surgery.
- Maintain blood sugar control before, during, and following surgery.
- Eliminate intertrigo.
- Shower the night before surgery using chlorhexidine soap.
- Do not remove hair from surgical site using a razor.
- Talk with your provider if you are taking systemic steroidal therapy.
- Talk with staff members about ways to keep your length of stay as brief as possible.

Consider a walk-in shower and a walker for support. In the shower, consider a handheld showerhead and a shower chair for patients with compromised endurance. A long-handled, soft-bristle shower brush will help the patient reach not only their back but the underside of the buttocks, lower legs, and feet—all common sense ideas that can be life-sustaining among this special patient population.

The central issue, however, relates to the fact that many caregivers are more than willing to practice in a culture of sacrifice. Lifting, turning, and repositioning patients, important parts of health care in any clinical environment, are high-risk activities that most health-care workers provide without consideration of the long-term impact.[21] A study published as far back as 1997 indicates that during an 8-hour shift a nurse may lift a total of 1.8 tons.[22] This may be one of the reasons why health care is considered one of the most dangerous jobs in the United States.

Caregivers are not the only group at risk for injury in health-care settings. Obese patients in the clinical environment are reportedly at a higher risk for certain common and predictable complications simply because of their body weight and size.[23] For instance, patients weighing 45.4 kg (100 lbs) or more above the ideal body weight have exponential increases in mortality and serious morbidities as compared with their nonobese peers.[24] In many cases, safe care for larger, heavier patients can be more complicated and may be more difficult for health-care workers.[25] This research sets the tone for the pressing question "In what profession, other than nursing, is there such use of dissimilar skill sets?" Nurses are skilled and educated to manage complex medications and critical situations, yet share the actual physical burden of lifting extreme and unstable workloads, which over time create compression, shear, and anteroposterior lateral force so great as to create lifelong pain and suffering. The sad fact is that nurses and other caregivers are often more than willing to expose themselves to this harm, risking themselves and often their patients as well.

The next generation of safety and outcomes pertaining to the care of patients of size is here. Presently, many facilities and individuals understand the need for equipment, training, and administrative support. Yet injuries continue to occur, and worse yet, we may not even recognize accurate methods to meaningfully measure the human suffering that results from such injuries over time. Consider the following summary on the topic of ergonomics and the issue of nursing injuries in the long-term care setting, published a decade ago but which applies even more today. The summary recognized that the increasing number of injuries in nursing homes had gained Occupational Safety and Health Administration (OSHA) attention to the need for better ergonomics—the science of fitting the job to the worker—in long-term care settings. At the time, U.S. Secretary of Labor Elaine L. Chao stated that OSHA would develop the first industry-specific guidelines to reduce ergonomic-related injuries and illnesses for nursing homes. Dr. Chao also stated that during the time the guidelines were developed, there was both an opportunity and a need to provide training for nursing home administrators, nursing supervisors, risk managers, frontline workers, and staff development coordinators in controlling the risks associated with manual handling of residents. More than a decade ago, OSHA recognized that occupational injuries such as musculoskeletal disorders (MSDs) occurred when there was a mismatch between the physical capacity of workers and the physical demands of their jobs and when workers did not have the training or equipment

to perform routine activities. Repetitive actions, force, awkward positions, contact stress, and vibration all lead to MSD. Many routine activities associated with caring for larger, heavier individuals, regardless of the health-care setting, pose risks, such as transferring patients from one height to another or working in confined and awkward spaces. Not only can repeated strain endanger the worker, it can result in patient injury. For example, caregivers who fail to provide mobility tasks place their patients at risk for developing immobility-related events. This creates dilemmas for health-care workers. Yet many workers (1) are working with distracting levels of pain, (2) are medicating themselves and then are impaired and in pain, or (3) simply call in and leave the patient care area short staffed. Employers must address the risks of caregiver injury in order to manage the issues of patient safety and medical errors and/or omissions (see Table 12.3).

Question Three

Are acute, long-term, and long-term acute care facilities prepared to assess, plan, and carry out pressure ulcer prevention and treatment for at-risk obese patients? It seems to me that every larger, heavier patient who comes out of intensive care has a pressure ulcer. Some of these ulcers become so infected that I fear for the patients. This consequence of care has lead to increased length of stay, which exposes our staff members to increased risk of MSD injuries.

TABLE 12.3
Components of an Ergonomic Program

Management leadership and employee participation to
- Assign and delegate responsibilities.
- Designate persons with authority, resources, and the information to meet responsibilities.
- Report MSDs, their signs and symptoms, and hazards; promptly respond to these reports.
- Involve employees in program development, implementation, and evaluation.
- Make a financial commitment to allocate appropriate resources to prevent and/or reduce patient/employee injury.

Supervisor responsibilities:
- Identify conditions that could cause or contribute to MSDs.
- Implement recommendations to reduce or eliminate risk factors.
- Encourage staff to report MSDs.

Job hazard analysis and control:
- Include all employees who perform the same job where an MSD exists and observe them at work.
- Develop a job hazard analysis tool incorporating the risk factors.
- Rethink the job and make appropriate changes.

Training:
- Provide initial training for employees and supervisors to include the purpose of the program.
- Put safety measures in place for actions such as the purchase and use of mechanical lifts.
- Conduct risk factor evaluations and provide education for the proper use of equipment lifting alone, with assistance, and with mechanical devices.

Answer: It is estimated that 1–3 million adults have a pressure ulcer, with an estimated cost of $40,000 to heal a full-thickness ulcer. The incidence of pressure ulcers varies greatly by clinical setting. Incidence rates of 0.4%–38.0% for acute care hospitals, 2.2%–23.9% for long-term care, and 0%–17% for home care have been reported. Pressure ulcers in elderly persons have also been associated with increased mortality rates. Because pressure ulcers are now considered a good indicator of quality of care, the failure to prevent or heal them can leads to a number of reimbursement and liability risk concerns.

Pressure ulcers are a result of pressure, friction, and shear. Other contributing factors include moisture, dehydration, and malnutrition; however, immobility is at the heart of pressure ulcer formation. Pressure ulcers typically occur over a bony prominence and develop because of the inability to adequately reposition the patient; this is particularly true among very heavy patients. Obese patients can be at risk for atypical or unusual pressure ulcers, which occur due to pressure within the skinfolds, as a result of tubes or catheters, or from an ill-fitting chair or wheelchair. Because of the atypical nature of pressure ulcer presentation among the obese, these are often missed until the patient has developed a severe infectious process.[26]

Planning care for the bariatric patient population brings with it many specific concerns that need to be addressed in order to provide care that is safe and effective and does not ignore the patient's unique needs. Areas of particular concern include safety, both for the patient and the caregiver, accessibility for the patient, sensitivity of all caregivers and staff, the use of specialized equipment that will work for larger patients, and adequate staffing.[27]

A facility's readiness to provide for patient safety and comfort can be assessed by performing a survey of the facility, paying specific attention to weight limits of equipment, including chairs, beds, commodes, shower seats, physical therapy tables, lift/transfer equipment, carts, exam tables, wheel chairs, walkers, computed tomography scanners, magnetic resonance imaging scanners, OR tables, and any other equipment needed to provide care for any patient.[28,29] All equipment should be labeled in a way that makes it easier for staff to be aware of weight restrictions, while not publicizing that it is "bariatric equipment." Check to see if toilets are floor or wall mounted. Standard wall-mounted toilets can be adapted to accommodate bariatric patients by using a relatively inexpensive support that is available commercially. Additionally, it is necessary to look at the width of doorways, to ensure that larger equipment will fit into and out of the room. There should be room for a patient to walk through the doorway with a larger walker, and with a health-care professional on either side for stability, since this may be what is needed for safety.[30] Consider the width, length, and weight limits of elevators. Larger sized personal items such as gowns, robes, slippers, identification bands, blood pressure cuffs, antiembolus stockings, sequential compression devices, and even gait belts need to be available for patients so that they can be cared for with dignity and safety.[31,32] It is not acceptable to snap together two standard gowns to fit around an obese patient. The purpose of ensuring accommodation in diagnostic, treatment, and care practices is to control for those common, predictable, and preventable complications associated with the failure to provide safe, reasonable care. Preplanning is at the heart of seamless care. Seamless care is at the heart of a manageable length of stay and control of immobility-related complications.

Caregiver safety is of critical importance since back injuries are often career ending.[33] A shortage of nursing personnel cannot be corrected if we risk the personnel we currently have. As mentioned earlier, many health-care workers are unwilling to care for bariatric patients in part because of concerns for their own safety.[34] Equipment is available to protect caregivers and must be utilized in all areas of health care in order to provide dignity and remove this negative association with larger patients.[35,36] A well-functioning lift team can ensure mobility for a patient whose size threatens activity.[37] A lift team is certainly a more cost-effective alternative to denial of services as a result of the CMS "never events."

Criteria-based protocols for use of equipment and care of bariatric patients can make your facility safer for patients and for staff.[8] Attention to hygiene, mobility, and more can provide an avenue to better prevent and treat issues of skin injury and wound infections. Staffing at health-care facilities is often determined by acuity, but bariatric patients' acuity is not the only factor in determining their care needs. Mobility and BMI factor into the number of staff members needed and the amount of time it takes to perform care.[38] It takes more caregivers to change the dressings of someone who has a wound in a skinfold, for example. Failure to provide this type of care leads to increased presence of microorganisms and subsequent wound infections. If the facility does not have a lift or mobility team, then extra caregivers are needed to walk a patient of size, and the process will take longer.

When addressing the prevention of skin injury and wound infections, consider conducting a survey to determine the actual learning needs of health-care workers. Do frontline caregivers understand the role of intertrigo in the wound field and the impact this situation has on wound infections? The value of a diverse, interdisciplinary bariatric task force is that it serves to provide a pool of experts to develop lesson plans and education to address patient care. For example, assuming clinicians are seeking information pertaining to skinfold management, an infectious disease expert, physician, vendor representative, therapist, nurse expert, and patient member of the task force could develop a 20-minute training module on assessment, treatment, and specific techniques to access skinfolds.

Sensitivity to the special needs of bariatric patients cannot be stressed enough.[39] Obese people often face humiliation because of their size, and this in turn may prevent timely, appropriate access to health care, which leads to greater emotional and economic expense.[40] Many patients are afraid they will break equipment, inconvenience staff, or embarrass themselves by asking questions about their care. They have been taken to loading docks or laundry rooms to be weighed on commercial scales, having been unable to receive treatment because facilities are not equipped with necessary scanners or equipment. Worst of all, they are often ignored altogether, treated as if they do not exist because of others' discomfort with their size. Ongoing sensitivity training for all personnel in a health-care facility should be provided.[41]

Bariatric patients do not need more care or better care than any other patient. What this special population needs are resources to level the playing field, so all patients receive the same quality of care regardless of size, weight, or weight maldistribution. In order to fully understand the risk for skin injury and wound infection, it is imperative to have a collaborative partnership with the patient. Insensitivity

threatens a collaborative partnership. Both caregiver and patient must feel at ease with communication. Patients must be willing to allow a comprehensive physical assessment in order to ensure early identification of skin and wound changes. To that same extent, patients should feel comfortable drawing attention to themselves if they believe there is a change in an existing wound or a change in the intact skin.

CONCLUSION

There is no reason patients of size should fear the care and treatment they are provided, regardless of the health-care practice setting. Mutually responsive decision making that lends itself to open dialogue is imperative. However, few clinicians can embrace the care of this at-risk, complex patient population without the appropriate tools and resources to accomplish the tasks. To that extent, in order to ensure dignified care with an element of sensitivity and empathy, health-care workers must feel safe and confident in their skills. Skin injury and wound infection can be costly emotionally and economically. Patients and their advocates are demanding strategies to address these unnecessary costs by addressing each of the steps that cause the downstream harm to this special patient population.[42]

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13 Personal Protective Equipment
Patient and Worker Safety

Thomas P. Fuller

CONTENTS

The Surgeon Who Removed the Wrong Leg

In what was perhaps the most publicized case of a surgical mistake in its time, a surgeon in Tampa, Florida mistakenly removed the wrong leg of his patient, 52-year-old Willie King, during an amputation procedure in February 1995.

It was later revealed that a chain of errors before the surgery culminated in the wrong leg being prepped for the procedure. While the surgeon's team realized in the middle of the procedure that they were operating on the wrong leg, it was already too late, and the leg was removed. As a result of the error, the surgeon's medical license was suspended for 6 months and he was fined $10,000. University Community Hospital in Tampa, the medical center where the surgery took place, paid $900,000 to King, and the surgeon involved in the case paid an additional $250,000 to King.

INTRODUCTION

This chapter highlights the relationship between the use of personal protective equipment (PPE) and patient infection rates in health care. After a review of the most significant infectious agents and their transmission pathways, the chapter provides a history of the use of PPE to minimize the spread of infection to patients.

The continuous and thorough use of PPE has been shown to have a positive influence on the reduction of hospital-acquired infections (HAIs). However, the data presented indicate that PPE is not being used consistently or effectively in many health-care settings. When PPE is not used appropriately, hospital infection rates in patient populations increase. Failure to use PPE also increases the likelihood that the worker will become infectious and a source of potential spread of disease to their patients. Many of the shortcomings in the use of PPE are identified. The reader is encouraged to think beyond blaming the health-care practitioner and try to think of other solutions to PPE inadequacies.

IMPORTANT AGENTS AND PREVALENCE

Each year, HAIs affect 13% of the worlds' hospital populations (WHO 2006). And worldwide, there are 1.4 million HAIs per day (Lynch et al. 2007). These multidrug resistant organisms (MDROs) contribute to HAIs as well as occupational infections of hospital personnel. One of the most common infections that patients catch during their visit to the hospital is *Clostridium difficile*. One study showed that 1.3% of all hospital patients are infected with *C. difficile* and that 72.5% of those patients acquired the infection while under the care of the hospital (APIC 2008). Another study showed that up to 20% of all hospital patients are infected with *C. difficile* (Gould 2010). In a Canadian study, attributable deaths to hospital-acquired *C. difficile* averaged 5.7%, with an attributable mortality in the province of Quebec at 14.9% (Gravel, Miller, and Simor 2009). Overall, *C. difficile* patients add a total of approximately 40,197 extra days to their hospital stays, just to clear up and treat their infections. The cost to the U.S. health-care system is estimated at $32 million per year (APIC 2008).

Another common agent acquired by patients and workers within the health-care system is methicillin-resistant *Staphylococcus aureus* (MRSA). One recent study showed that 4.6% of all hospital patients are infected with MRSA and that 23% of those cases were acquired during the hospital stay (APIC 2007). In a 2004 study, 36% of all *S. aureus* in hospital patients' infections were resistant to methicillin (Diekema et al. 2004). In intensive care units (ICUs), it was shown that 0.5%–1.5% of the patients become colonized (are exposed) with MRSA each day they are in the ICU. And overall, 0.4% of ICU patients actually become infected with MRSA each day they are patients in the unit (Gidengil et al. 2010).

Enterococcus spp. is a gram-positive cocci, which often occur in pairs and is difficult to distinguish from streptococci. It is a genus of bacteria of the phylum Firmicutes, which are generally facultative anaerobic organisms, but which can also survive in the absence of oxygen. Occurrences have risen in recent years to become the third most common source of HAIs (Wisplinghoff et al. 2004). Although not particularly virulent, the organism typically infects debilitated or immunocompromised patients and results in elevated morbidity, mortality, and increased hospital stays in this population (Rice 2001).

In recent years, an antibiotic resistant form of *Enterococcus* has become particularly troubling. Vancomycin-resistant *Enterococcus* (VRE) has been shown to comprise 30% of all enterococci infections (CDC 2004). In a 2006 study, the overall

prevalence rate of fecal VRE colonization in hospital patients was 13.6% (Freitas et al. 2006). The prevalence of VRE ranges from 3.4% in liver transplant patients on the waiting list (Hagen et al. 2003) to as high as 44% in patients after receiving their transplant (Bakir et al. 2001).

PATHWAYS OF TRANSMISSION

The transmission pathways for most of the MDROs presented above are generally assumed in the health-care community to be through direct contact with the organisms on surfaces or the patient or by contact with droplets expelled by the patient into the immediate surrounding environment. In a study of *C. difficile* in six health-care facilities, spores were shown to contaminate the hospital environment in 27% of the cultured samples (Dubberke et al. 2007).

The main reservoir of MRSA in hospitals is the patients themselves. MRSA colonization predominates in the nares of the nose; however, it can also colonize the patient's skin and is considered to be a significant source of cross contamination to health-care workers (HCWs) from these other surfaces (Boyce et al. 2004). In a study by Collins in 2010, it was shown that the emergency department (ED) staff were colonized by MRSA at significantly higher rates than the general population, indicating a clear link with workplace exposures to the agent (Collins 2010).

VRE is understood to be typically transmitted throughout the hospital nosocomially through contaminated HCW hands (Hayden 2000). Transmissible gastroenteritis virus has been shown to survive on porous and nonporous materials for up to 24 hours (Casanova et al. 2010). Staphylococci and enterococci have been shown to survive on polyester and polyethylene for as long as 90 days (Neely and Maley 2000).

Although not directly linked to the most significant patient infection rates or outcomes, some other relevant information is important to the discussion about infectious agent pathways in health care and hospitals. Infectious agents are always changing and mutating in ways that affect not only their modes of infection, virulence, and infectivity but also their transmission pathways. Often their ability to survive in the environment, survive cleaning and disinfection, and move through the environment changes when they mutate. A lot can be learned universally by looking at other interesting infectious agents.

Hepatitis A virus and human rotavirus have been shown to survive up to 30 and 60 days on porous and nonporous materials, respectively (Abad, Pinto, and Bosch 1994). The implications of this information for occupational and public health are clear. A dried drop of blood on the wall of the hospital room or the shoes of an operating room surgical intern sitting on the subway are both potential sources of infection for anyone who may subsequently come in contact with it under the right circumstances.

The severe acute respiratory syndrome (SARS) outbreak in 2003 demonstrated that early assumptions about how an infectious agent is spread in the environment can be wrong and result in dire consequences for patients and workers. Initially, it was assumed that the agent was only transmitted through patient contact. As the epidemic progressed, it was realized that droplets from the patient could also be infectious and that the virus could be transmitted nosocomially in environmental pathways.

SARS can contaminate environmental surfaces and be transmitted through fomites (Dowell et al. 2004).

The SARS virus was subsequently found at nursing station keyboards and break rooms. SARS CoV (coronavirus) has been shown to survive 1 hour on cotton gowns and up to 24 hours on impervious disposable gowns and other environmental surfaces (Lai, Cheng, and Lim 2005; Dowell et al. 2004). Finally, we learned that the agent can also be transmitted via the airborne route to infect adjacent patients and workers by inhalation of the virus from the breathing air. A study by Chan-Yeung documented clear associations between inefficient use of PPE and HCWs with SARS. It should always be remembered that 800 people died during the 2003 outbreak and that between 20% and 40% of those were unsuspecting HCWs (Chan-Yeung 2004; Liu et al. 2009).

Another agent whose medical or epidemiological significance has yet to be determined but poses a potential threat to patients and workers is respiratory syncytial virus (RSV). This agent is most commonly associated with newborns and pediatrics and can survive on fomites and environmental surfaces for up to 8 hours; nosocomial transmission can be its significant mode of transmission to patients and workers (Hall, Douglas, and Gelman 1980). This continually reemerging agent also serves as a flag for the need to be vigilant and continuously search for new risks and agents.

HISTORY OF TRANSMISSION-BASED PRECAUTIONS

Over the past four decades, the medical infection control community has continuously developed and revised the recommended precautions to prevent the spread of infectious agents in the health-care environment. Yet this approach appears to be inadequate given that HAI rates, as well as occupational infectious exposures, have risen during this timeframe.

Going as far back as 1970, the infection control community practiced a concept commonly known as "isolation." This was a system based on seven color-coded cards that explicitly described what the HCW was to use for each patient in each case. They were divided into the categories of precautions known as strict, respiratory, protective, enteric, wound and skin, discharge, and blood.

In 1983, the Center for Disease Prevention and Control (CDC) published a guideline for isolation to help health-care practitioners with transmission control. This guideline included two systems for isolation. One was category-specific and the other was disease-specific. Categories included strict, contact, respiratory, acid fast bacilli (AFB), enteric, drainage/secretion, blood, and body fluids. This program emphasized decision making by users and required them to consider the agent, the activity that they were performing, and the proximity to the patient in their decisions to don relevant PPE.

In 1985, to some extent in response to the HIV/AIDS epidemic, the CDC revised its recommendations to include blood and body fluid protections to all patients regardless of their infection status. At this time, they developed recommendations for the handling and disposal of needles and other sharps. The term "universal precautions" was coined by the CDC in 1987 and emphasized the avoidance of contact with all moist and potentially infectious body substances except sweat.

The Occupational Safety and Health Administration (OSHA) promulgated the Blood-Borne Pathogen Standard in 29CFR1910.1030 in 1991. These regulations set up clear and concise practices to be implemented to protect workers from exposure to potentially infectious agents in health care and other settings. Unless clear differentiation was possible, all blood and body fluids were considered to be infectious and warrant protection through the use of engineering controls and PPE. The use of mask, gowns, gloves, aprons, and other PPE was explicitly described as related to protecting workers from potentially lethal infectious agents.

In 1996, universal precautions were expanded to be used with all patients at all times and were renamed standard precautions by the CDC. This new system also included a three-pronged approach to transmission precautions: airborne, droplet, and contact. This model described discrete clinical syndromes that warranted the use of precautions until etiological diagnoses established the exclusion of specific infectious agents. These standard precautions attempted to address some of the shortcomings of universal precautions, reduce confusion in workers, and increase compliance (Ronk and Girard 1994; Williams et al. 1994; Leliopoulou, Waterman, and Chakrabarty 1999). Standard precautions also began to address some other new areas of suspected transmission and consider protection from unrecognized sources of infection in hospitals. An example of pathways that had not been considered fully in previous guidelines included such practices as linen and environmental waste management (Hinkin, Gammon, and Cutter 2008).

In 2007, the Health Care Infection Control Advisory Committee of the CDC issued a new document entitled *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. The section of the nearly 200-page document that describes the PPE to be worn by HCWs is six single-spaced pages. The section describes a variety of barriers and respirators used alone or in combination to protect mucous membranes, airways, skin, and clothing from contact with infectious agents. The PPE described includes gloves, face shields, gowns, masks, goggles, and respirators to be used in a broad variety of combinations to address numerous infectious agents in different patient and worker settings (Siegel et al. 2007).

After 4 decades, today's terminology has reverted to the 1970 wording "isolation precautions." Despite the change, the World Health Organization, Joint Commission, and the CDC themselves still use the old terminology "standard precautions" in numerous published documents and a variety of places on their public websites. The OSHA still refers to the controls to minimize the spread of infectious agents in health care with the 1987 terminology, "universal precautions."

As a result of all the terminology changes, it is truly difficult to determine what the precautions should be called in 2011, but more importantly what the consensus is on the appropriate PPE to be worn for any given health-care situation and suspected agent. Thirty years of experience in health care and a review of hundreds of articles have shown that nurses, doctors, and other practitioners in the field are routinely confused about the appropriate guidelines to refer to, what the precautions are called, and what PPE should be worn. Health-care administrators are equally ill informed about the technical aspects of patient and worker protection, and despite their responsibilities as health-care providers and employers, information and real materials are often deficient.

BENEFITS OF PPE

Employment in the health-care industry has been found to be associated with increased deaths due to exposure to blood-borne pathogens (Luckhaupt and Calvert 2008). It makes sense that during the course of treating patients, HCWs become contaminated with infectious agent, and scientific studies have shown that this is the case and that contaminated clothing becomes a potential source of cross infection on hospital wards (Loh, Ng, and Holton 2000). In one study of HCW clothing contamination, clothing was clearly shown to be a possible vector of transmission. In this study, 23% of white coats worn by grand rounds attendees were contaminated with *S. aureus* and 18% of those were with MRSA (Treakle et al. 2009).

The importance of PPE to the issue of patient infection rates has been demonstrated in a few studies. In a review by Muto et al. in 2003, it was shown that several studies have demonstrated that the use of gloves dramatically reduces hand contamination and the resulting transmission of hospital-acquired pathogens to other workers and patients (Muto et al. 2003). It has also been documented that the use of gowns decreases nosocomial transmission of VRE in the ICU (Srinivasan et al. 2002). Other studies have demonstrated an association with PPE and reduced transmission of VRE in health-care settings (Ostrowsky et al. 2001; Montecalvo et al. 1999). In a 2009 study by Daugherty et al., it was shown that workers who practiced poor PPE compliance were at increased risk of developing and/or transmitting nosocomial respiratory viral infection (Daugherty et al. 2009).

Going back to lessons learned from the SARS outbreak in 2003, it was clearly demonstrated that multiple layers of face protection and eyewear, in addition to adequate training, protected workers from exposure to SARS (Liu et al. 2009). A study of two different Vietnamese hospitals during the SARS outbreak indicated that the hospital that used N95 respirators had significantly fewer HCWs who acquired the disease (Ha et al. 2004). The risk of contracting SARS was significantly reduced by the consistent use of an N95 respirator over the use of a surgical mask (Loeb et al. 2004). Multiple layers of face protection and eyewear, in addition to adequate training, were shown to be protective from worker exposure to SARS (Liu et al. 2009). In addition, it has been shown that workers were significantly protected from patients with SARS by routine hand washing and wearing an N95 respirator (Teleman et al. 2004).

SHORTCOMINGS IN EXISTING SYSTEMS AND PRACTICES

Despite decades of directives from governmental and professional organizations regarding the importance and correct application of PPE in health care, there are still several glaring deficiencies. These are evidenced, in part, by the continued growth of HAIs for agents and organisms spread by cross contamination from patients to workers to patients, and in part by scientific studies that indicate the use of PPE is, in fact, neither universal nor standard. It should be noted that these directives do not carry the weight of law for worker protection, as requirements for protecting workers from workplace toxins like asbestos and toxic chemicals do. Health-care directives are promulgated as guidelines that are "recommended" by agencies but not "required"

by law; thus, many health-care facilities choose to ignore the recommendations, putting both workers and patients at risk.

Numerous studies over the past several years indicate that HCWs do not routinely or correctly use PPE on a regular basis. Multiple studies have shown that only 66% to 75% of the nurses observed or surveyed use PPE on all occasions or practice full compliance consistently (Knight and Bosworth 1998; Evanoff et al. 1999; Sadoh et al. 2006). Another study done in 2007 showed that only 5% of surgical nurses wore all components of PPE when in contact with potentially infectious material (Ganczak and Szych 2007). Another study of hospital trauma resuscitations showed that even when visible blood was involved, only 38% of the HCWs observed wore appropriate barriers (Madan et al. 2001). Orthopedic trauma teams were shown to only wear eye protection 21% of the time and face masks 18% of the time when working with blood and potential splash situations (Sundaram and Parkinson 2007).

In hospital EDs, where the patients often first arrive and precautions are often the most necessary, it has been reported that 4.3% and 9.8% of HCWs in the ICU and ED, respectively, never wear eye protection. Forty percent of the HCWs never wear face shields (Bryce et al. 2008). In a recent study by Swaminathan et al., it was determined that appropriate PPE was worn by ED personnel only 59% of the time (Swaminathan et al. 2007). In a 2008 study by Chiang et al., ED staff wore masks 90% of the time, but other required PPE had worse statistics. Eye protection was only worn 50% and gowns 20% of the time when they were appropriate for the patient and procedure. And perhaps even more alarmingly, these ED workers only wore gloves 75% of the time when they were required by isolation precaution protocols and policies (Chiang et al. 2008). ED personnel also consistently significantly overestimated their compliance with appropriate universal precautions, suggesting a lack of understanding regarding what appropriate universal precautions are (Henry, Campbell, and Maki 1992).

With the recent popularity of goatees, beards, and other facial hair in men's fashion, the ability to wear N95 respirators, when appropriate, has been diminished. When the ED has a staff of 10, three of them have facial hair, and it puts an undue stress and dependence on the availability of powered air purifying respirators (PAPRs). When an infectious agent develops that is transmitted via the airborne pathway, it is extremely important that all available HCWs be adequately protected and that adequate supplies and equipment are available. It is inappropriate and dangerous to try to train workers and perform respirator fit testing during an outbreak. It requires people to get together in close proximity for extended periods, thus increasing the risk of transmitting the disease to one another. Approximately 40% of HCWs surveyed do not receive annual respirator fit testing (Bryce et al. 2008). This is a condition that will exacerbate any airborne epidemic or pandemic in the health-care setting, and any methods to reduce the impacts should be planned for and addressed ahead of time, whenever possible. Annual respiratory protection fit testing is required by OSHA. Hospitals that do not conduct annual respiratory fit testing and training are breaking the law.

The lack of preparedness of the health-care community was perhaps most emphatically demonstrated during the 2003 SARS pandemic. HCWs accounted for 20%–40% of SARS cases in 2003 (Chan-Yeung 2004); 23% of SARS cases in Hong Kong

were HCWs; 40% and 41% of SARS cases were HCWs in Toronto and Singapore, respectively (Liu et al. 2009). Poor PPE implementation, including equipment removal, was a significant risk factor for SARS infection of HCWs (Lau et al. 2003).

Although large community outbreaks of SARS and other studies verified that SARS was easily spread via airborne pathways, there is still a lot of misunderstanding and confusion in the health-care profession about the routes of transmission (Yu et al. 2004). A year after the SARS outbreak, 33.3% of doctors and 55.9% of nurses working in Singapore EDs believed that a surgical mask provided adequate protection (Chia et al. 2005).

While ambulance workers are on the very front lines of an epidemic or pandemic, up to 80% of paramedics are not always provided with fluid-impermeable gowns or coveralls (Mathews et al. 2008). Paramedics who are not routinely provided PPE and whose supervisors do not emphasize universal precautions are at approximately twice the risk of nonintact skin exposure (Leiss 2009). And more than 20% of U.S. paramedics are exposed to blood each year (Leiss, Sousa, and Boal 2009).

Whether from apathy or ignorance, 35% of HCWs surveyed in one study were unable to articulate appropriate precautions for protection from nosocomial transmission of influenza (Daugherty et al. 2009). In a UK study, only 1.5% of workers adopted universal precautions for all patients irrespective of whether the patients' viral status was known (Cutter and Jordan 2004). And 44% of HCWs reported poor self-compliance with influenza PPE (Daugherty et al. 2009).

As all of these deficiencies relate to worker and patient contamination with infectious materials, it has also been scientifically proved that the failure to consistently and adequately use PPE has led to documented cases of contamination. In one study, it was found that the ineffective use of PPE was associated with 80% of observed and documented procedure contamination events during ED cardiopulmonary resuscitation (Chiang et al. 2008). Another study showed that gowns, gloves, respirators, and goggles donned by workers were easily contaminated with infectious agents and that the infectious agents were then transmitted to the worker's skin and clothing (Casanova et al. 2008).

The reasons for such poor compliance are due in part to the complicated aspects of infectious agents themselves. The particular agents mutate and change each year, and their modes of transmission, routes of exposure, virulence, and infectivity alter drastically over time. For practitioners with little time and for those who are not specifically trained in microbiology or infectious disease, it is difficult to keep up with these rapid and ongoing changes in addition to performing their normal jobs. Thus, in the workforce in general, understandably, there is little real comprehension about what the specific characteristics of the infectious agents are from year to year.

Federal and state government public health agencies try to analyze infectious agents as they mutate and emerge, but it is a difficult and time-consuming process. As information becomes available, these agencies put it forward in a variety of outlets including the Internet, print and audiovisual media, and reports. But, the information is often misinterpreted or misconstrued and misreported in some of these outlets. And over time, the original findings and reports change, and then there appears to be conflicting information regarding an infectious agent from a variety of sources, and sometimes even from the same source.

As information about the specific infectious agents changes over time, so do the logical methods of control and worker protection. In the case of H1N1, the first recommendations indicated that only droplet precautions were warranted for worker protection. But as the pandemic progressed, concerns arose regarding transmission via the airborne pathway, and several reports indicated that more substantial respiratory protection was appropriate to protect workers from transmission via the airborne pathway. Eventually, several organizations backed down either because they did not believe the airborne pathway was prominent or that the virulence/infectivity was lower than originally indicated, and they not promote the use of N95 respirators for H1N1; yet there are also a large number of equally reputable scientific and public agencies including the National Institute of Occupational Safety and Health and the Institute of Medicine, which still recommend a conservative approach to worker protection and still recommend N95 respirators for influenza control in the workplace (NIOSH 2011; Liverman et al. 2009). The American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) also recommends the use of N95 respirators for H1N1 pandemic flu exposure to HCWs (AFL-CIO 2009).

As the understanding about the specific infectious agents changes and the recommendations for PPE change with it, individual health-care organizations and clinics must disseminate the information; analyze their geographic location, patient population, medical services, and other factors; and make their own determinations regarding the PPE that will be appropriate to minimize exposure to their workers and the spread of contamination within their facilities. This is not an easy assessment and must include an interdepartmental approach. Of course nurses and physicians should be included in these assessments. However, other experts such as industrial hygienists, occupational health practitioners, facilities managers, environmental services, central sterile, and others should all be involved in the development of policies and procedures. These responsibilities and associations should all be formalized and implemented on an ongoing basis well ahead of each upcoming epidemic or pandemic.

REASONS FOR NONCOMPLIANCE WITH GOOD PPE PRACTICE

We have seen that the major shortcoming of PPE use in health care, as it relates to patient and worker infection rates, is that numerous studies have shown compliance with guidelines for isolation and prevention is abysmal. Workers complain that the use of PPE is inconvenient, it is often inaccessible, and they believe that it interferes with patient care (Daugherty et al. 2009). Home health-care nurses cited loss of dexterity as the main reason for not wearing gloves (Bennett and Mansell 2004). Other stated reasons for not wearing appropriate PPE included the belief that the PPE does not work and the perception that the patient represented a low risk (Ferguson et al. 2004; Cutter and Jordan 2004).

Workers reported that the level of their supervisor's oversight had a lot to do with whether they wore PPE or not. The organizational safety climate and supervisory expectations are two of the most important factors in adherence to PPE policies (Daugherty et al. 2009). In a study by Scott, Hughes, and Hall in 2005, it was observed that organizational factors and management support play key roles in HCW

compliance with infection control policies (Scott, Hughes, and Hall 2005). Hospital guidelines that are unclear and do not assign responsibility tend to lead to poor compliance to PPE practices (Gurses, Seidl, and Vaidya 2008). Lombardi et al. (2009) showed that a lack of comfort/fit, fogging and scratching, and lack of supervisory oversight were significantly related to the failure to wear protective eyewear.

RECOMMENDED IMPROVEMENTS FOR PPE PROGRAMS

Regardless of the PPE program, better awareness of when and what PPE is necessary is the first way to improve the effectiveness of PPE as a barrier to other patients and to workers. More comprehensive screening of both patients and workers leads to better understanding of possible infectious agents that they may be harboring. This understanding then leads to a better assessment of what PPE would be appropriate.

Studies have shown that better awareness and communication of infectious patients greatly improve the effective use of PPE and minimize the spread of infection to patients and workers (Aziz and Murphey 2009). Selective screening and isolation of MRSA carriers greatly improves the ability of HCWs to take appropriate actions to minimize the spread to other patients (Chaix et al. 2011; Girou et al. 1998; Wernitz et al. 2005). Timely and accurate information about the patients provided to the staff allows more intelligent decision making and timely responses to changes and the need for PPE.

In order to be effective, programs, policies, and procedures for PPE must be in writing and clearly address a broad variety of possible infectious agent scenarios. Workers need to be made aware of the role of clean uniforms, the use of appropriate PPE, and their professional responsibility for maintaining compliance with administrative requirements (Jackson and Cole 2010). Workers must receive associated training on a regular basis, and they should be tested on PPE awareness and requirements periodically (AORN 2007). Infection control training must be ongoing to ensure that workers maintain confidence and adherence to recommended practices (Phin et al. 2009).

Inconsistent terminology for isolation precautions contributes to variations in practice. Wherever possible, these standardized definitions should be consistent with international categories to improve adherence to the recommended methods (Landers et al. 2010). And whenever necessary, individual health-care systems should clarify expectations, requirements, and terminology within their institutional procedures and policies.

The availability and placement of PPE is of primary importance in its use by workers (Lymer 2004). HCWs are already under extreme time pressures in stressful working conditions. The need to take extra time to track down the "right" PPE can be a critical factor in whether it is worn or not. PPE should be available in a variety of appropriate sizes and combinations in locations easily accessible to the workers.

A review study by Ward (2006) indicated several specific areas for improvement in the general worker adherence to general infection control practices, including

- Training
- Upgraded facilities
- Written policies
- Increased staffing levels
- Management support

Management organizations should provide decisive leadership and support the written PPE policies and programs. The development of control programs, including PPE, should be interdisciplinary to ensure understanding and compliance throughout the organization (Lai et al. 1998). Workers should be a part of the PPE development team because their involvement in a well-developed management system will most likely lead to higher levels of work safety behaviors (Karasek and Theorell 1990).

Opportunities should be provided to employees to provide feedback regarding the use of PPE and associated programs. When audit or other deficiencies are identified in the programs, management should create and promote practical interventions to correct the problem areas. A culture of constructive feedback, a team approach, and continuous improvement are all important factors in a successful PPE program that minimizes the spread of infectious agents. Timely and adequate health information, readily available PPE, and affirmative social and organizational factors are the most significant factors in the appropriate use of PPE in the work environment (Torp et al. 2005).

Other future needs to improve the use of PPE to minimize the spread of infectious agents in health care include more and better information about the microbes, including transmission, incubation, infectious dose and period, virulence, sensitive populations. A better understanding of airborne hazards and the various available types of respiratory protection for patients and workers will also help reduce HAIs. Better engineering controls and behavior modification strategies have also been suggested (Williams et al. 1994).

The medical surveillance of workers is a controversial topic. Individuals, labor organizations, and health-care institutions each have good reasons (privacy, worker rights, and cost) for not spending time and money evaluating worker health status. But, it is difficult to argue that more and better information about the health status of workers would not provide useful information in the battle against HAIs. Do the costs of this surveillance outweigh the benefits? Do individual privacy rights outweigh the benefits of more information about infectious agents?

More timely and accurate information about infectious agents from federal, state, and international sources would improve the use of PPE and adherence to appropriate PPE procedures in health care. Expanded national databases of worker exposures and outcomes would be useful but, at this time, are generally unavailable except for specific outbreaks, and not generally through government sources. Better financial or regulatory incentives for work and patient protections could also lead to reductions in HAIs and in worker exposures.

SUMMARY

HAIs have been increasing in number, severity, and cost over the past 2 decades. This is despite a variety of programs and policies for the use of PPE written and disseminated by governmental and nongovernmental organizations over the years. Although much data was presented here to indicate that HCWs do not wear PPE consistently and effectively, it is important not to focus only on those shortcomings. If workers will not wear the PPE, then that should also be considered one of the major problems. In many industries, workers do not like to wear PPE, and it is a

constant struggle to maintain compliance. It should then be a major goal to develop and design PPE that is easy and comfortable for workers to wear and is still an effective barrier to the transmission or spread of infectious agents.

Rather than just blaming the workers, I would like to call upon the reader to begin to consider other alternatives to the same policies and procedures that we have been using and encouraging for the past 20 years. If workers do not or will not wear PPE routinely or effectively, then it is time to consider drastically different measures. A new approach to PPE is needed. New materials that can be easily washed or decontaminated should be developed. New methods that can allow workers to wear PPE throughout the day, without donning and doffing between each patient, should be researched. Comfortable PPE that can be decontaminated without removing it through the use of surface cleaners or disinfectants, or even germicidal ultraviolet radiation, should be considered as a way to reduce the likelihood of noncompliance with procedures for both donning and doffing PPE.

Manufacturers and designers should focus on other engineered solutions to "better" PPE systems and operations. Workers and worker organizations should seek new solutions to PPE, and administrators should seek new PPE solutions to replace the decade-old systems that are not meeting the expectations of the public and allow infectious agents to spread throughout their facilities at alarming rates.

Novel approaches to an old but growing problem are sometimes difficult to see, or embrace. Many notions about patient protection and PPE may have to be deeply reconsidered by workers, regulators, administrators, and the public themselves. New PPE may not be demanded by any of these groups mentioned above, but more so by the new insidious infectious agents emerging on the horizon.

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14 Legal Issues

Barbara Machin

CONTENTS

Disclosing Medical Errors Can Lower Liability Lawsuit Expenses

Many risk management officials see the financial benefits of the practice, says the author of a new report. Disclosing medical errors to patients mitigates medical liability lawsuits, increases safety and ensures long-term financial benefits for medical practices, according to a new report.

The report, released online May 12, 2011 by the privately-owned international insurance broker Lockton, reviewed previous studies on error disclosures between 1987 and 2010 and analyzed the financial impact of such disclosure on health-care professionals.

The Lockton report cited an analysis of the University of Michigan Health System's 2001 medical disclosure approach. The study, in the Aug. 17, 2010, issue of *Annals of Internal Medicine*, showed

- About 20 fewer lawsuits each year were filed after the program's implementation.
- Lawsuit resolution time went from 1.36 years before the program started to 0.95 afterward.
- The average cost per lawsuit decreased from $405,921 to $228,308.

The *Annals* study is online (www.ncbi.nlm.nih.gov/pubmed/20713789/). Research shows that disclosure programs make the best financial sense for health-care organizations.

Alicia Gallegos, amednews staff
http://www.ama-assn.org/amednews/2011/05/30/prsd0601.htm

INTRODUCTION

With more than 16% of the nation's gross national product dedicated to health care,[1] federal and state governments and the general public are demanding lower health-care costs along with improved quality. Statistics supporting the need for improved quality tell a dramatic story. HealthGrades, a national hospital rating organization, estimated in 2004 that 195,000 Americans die each year due to preventable errors. In 2008, the Centers for Disease Control and Prevention (CDC) estimated 99,000 deaths resulting from hospital-acquired infections (HAIs), the most common being methicillin-resistant *Staphylococcus aureus* (MRSA). According to a Kaiser Foundation study, nearly 7000 people per year are estimated to die from medication errors alone. Hospital errors, depending upon the study, rank between the fifth and eighth leading cause of death, affecting more Americans than breast cancer, traffic accidents, or AIDS. The cost of treating these preventable errors is estimated to be as high as $20 billion annually.[2]

Perhaps in the best position to influence both the cost of health care and the quality of services delivered is the Center of Medicare and Medicaid Services (CMS), in view of the fact that more than 60% of the U.S. population is a recipient of one or the other and the number can only continue to grow with the baby boomer generation coming of age. Increased quality and lower costs, on the surface, appear to be two incompatible concepts, given the rapidly escalating cost of the technology, which is often tied to the advancement of health-care services. In tandem with improving quality, hospitals and physicians are being asked to share with the public more and more information about their outcomes in treating a particular disease or injury, the options for available treatment, and the costs. This focus on quality and transparency is unfolding in an environment of revising coverage and payment policies to make health care more efficient and to provide incentives for reducing the incidence of serious adverse consequences during inpatient hospital stays. A significant policy question is the impact that transparency and improved quality will have on the traditional methods of monitoring the components of patient care.

The focus of this chapter is to explore the continuing viability of state laws, reinforced by federal mandate, that appear to contradict, if not contravene, the

movement toward transparency and, commensurately, quality improvement. Ironically, the public policy underlying these statutes is touted as improving the quality of patient care. The statutes in question are commonly referred to as "peer review" statutes, which provide a process for reviewing professional competency and conduct by one's peers in an environment free from exposure to civil liability for damages arising from or because of the decisions made. These statutes typically provide both a privilege against disclosure of the records provided to and emanating from the peer review body and immunity for those involved in the peer review process. Every state has adopted some form of "peer review" protection although the statutes vary somewhat from state to state based on its language and judicial interpretation. The underlying question is whether these statutes, in the modern health-care environment, are fulfilling their purpose and, if not, what actions should be taken by state legislators, federal, state and local government agencies, professional organizations, medical care facilities, and professional groups who either legislate or perform medical peer review functions and create the first line of defense against incompetence and unprofessional conduct.

STATE PEER REVIEW STATUTES

Initially, it is important to understand the peer review process and what may or may not fall within its scope. The principal underlying peer review in the medical profession is that the public goal of improved health care is best served when physicians and other health-care professionals monitor themselves. They can most effectively do so when those involved in the process are unencumbered in their investigation and implementation of corrective action without concerns that they may be incurring liability for their actions. As explained by one Arizona court of appeals, "[t]he statutory privilege furthers important public policy. The 'confidentiality of peer review committee proceedings is essential to achieve complete investigation and review of medical care'" (*Humana Hosp. Desert Valley v. Superior Court*, 154 Ariz. 396, 400, 742 P.2d 1382, 1386 [App. 1987]). Because "[r]eview by one's peers within a hospital is not only time consuming, unpaid work, [and] likely to generate bad feelings and result in unpopularity," it is imperative to preserve the peer review privilege (*Id.* quoting *Scappatura v. Baptist Hosp*., 120 Ariz. 204, 210, 584 P.2d 1195, 1201 [App. 1978]. *Sun Health v. North*, SA 03-0018 (AZ App. 1), pg. 5).

Peer review statutes typically break down into three components: (1) the confidentiality of any reports, data, records, or proceedings received or generated by the peer review committee; (2) a prohibition against subpoenaing documents generated by the peer review committee or eliciting testimony from participants in the peer review process in a subsequent civil action; and (3) immunity from civil or criminal processes related to those who participate in peer review as a result of their involvement or testimony provided.[3] The general rule is that a record or report of a medical peer review committee is privileged or confidential and not subject to subpoena or admissible as evidence in any civil action, including a medical malpractice action arising out of the same subject matter as before the peer review committee.[4]

Certain exceptions to complete confidentiality or immunity are found in most state statutory schemes, including (1) a limitation on the privilege of nondisclosure to documents actually generated within and by the peer review committee, excluding data and reports presented to it by an outside original source, such as the hospital's business records or patient records, and (2) rejecting immunity for one who is not truthful in his or her testimony before the committee or who testifies in bad faith or one who participates in the process with malicious intent. Judicial interpretation of what, on the surface, appears to be common language across the board has led to wide variation among the states in determining what entities or subcommittees of the entities are entitled to peer review protection.

For instance, Hawaii recognizes peer review committees subject to the privilege and immunities to include those of professional societies, licensed hospitals, clinics, health-maintenance organizations, and preferred provider organizations and networks whose function is to maintain the professional standards of persons engaged in that profession, occupation, specialty, or practice.[5] North Carolina defines a medical review committee as one of a local professional society, a medical staff of a hospital, a committee created by the hospital's governing board, or of any peer review corporation or organization.[6] Even more broadly, West Virginia defines a review organization as any committee or organization engaging in peer review, including a hospital's utilization review committee, tissue committee, medical audit committee, health insurance review committee, health-maintenance organization review committee, nursing advisory committee, medical assistance program committee, and so on.[7] At the same time, states like North Dakota interpret the peer review privilege more narrowly to apply solely to specifically enumerated committees and only to proceedings and records generated by those committees.[8] The wide spectrum of committees and organizations falling under the peer review umbrella recognized by the different states, either through their statutory pronouncements or through judicial interpretation, has led legal commentators to conclude that "no two statutes, or courts' interpretations of them, are alike" (*Trinity Medical Center*, 544 S.W.2d at 153).

In 1986, Congress enacted the Health Care Quality Improvement Act of 1986, which reinforced state peer review statutes by acknowledging a need to encourage professional peer review by removing the threat of monetary liability.[9] While most states had some form of a preexisting peer review process in place, typically reporting through the respective state licensure boards, the lack of a standardized, mandatory reporting process led to the federal enactment. One significant development brought about by the Act of 1986 was the creation of the National Practitioner Data Bank.[10] Health-care entities, including hospitals, physician groups, state boards of medical examiners, professional societies, and other entities, such as insurance carriers who make payments on medical malpractice claims, became subject to mandatory, detailed reporting of all but *de minimus* claims.[11] Hospitals and other health-care entities are required to report any adverse action impacting clinical privileges,[12] and medical licensing boards are required to report any action taken on the license of a physician, dentist, or other medical practitioner.[13] Enforcement powers are in the form of sanctions, including civil penalties or removal as the designated reporting agency, for failure to report a change in licensure or clinical privileges.

Effective March 2010, reporting was significantly expanded when the Department of Health and Human Services published its final rule under §1921 of the Social Security Act to include any negative action or finding by a state licensing agency, peer review organization, or private accreditation organization against any health-care practitioner or entity. This expansion added nurses, nurse practitioners, nurse aides, physical and respiratory therapists, physician assistants, social workers, and other allied health-care professionals to the Data Bank for inquiry. The purpose was to create a resource to enhance the hiring process and increase the health-care organization's efforts toward patient safety.

Despite the Data Bank's ability to compile a massive amount of information, public access is limited. Those entities authorized to query the National Practitioner Data Bank remain significantly restricted to hospitals and other health-care entities with formal peer review processes; state and federal agencies administering health-care programs such as Medicare and Medicaid, including their fraud and law enforcement units; quality improvement organizations; health-care practitioners themselves in performing a self-query; and plaintiffs' attorneys under severe limitations.[14] Attorneys who have filed a medical malpractice claim can seek information from the Data Bank regarding the physician or other health-care practitioner involved, but only if they are able to provide evidence that the hospital failed to request information regarding the physician or other health-care provider in the credentialing process.[15] The latter expressly serves as an inherent sanction against hospitals who fail to consult the Data Bank prior to granting staff privileges or every 2 years thereafter in the recredentialing process.[16] Absent one of the specified exceptions, the information compiled by the Data Bank remains confidential,[17] in keeping with the underlying principle of the federal act, that physician incompetence and inappropriate conduct giving rise to malpractice actions can best be managed by colleagues within the profession.

There are some states whose legislatures and/or courts have been reluctant to embrace the concept of keeping the peer review process behind a cloak of confidentiality. Early on, the Supreme Court of Kansas announced that there was no statutory or evidentiary privilege protecting the confidentiality of peer review records or proceedings (*Wesley Medical Center v. Clark*, 669 P.2d 209 [Ks. 1983]). However, upon federal enactment of the Health Care Quality Improvement Act of 1986, the state adopted Kansas statutes §65-4915 and §65-4925, which are fairly representative of the privilege and immunity statutes found in a majority of the states.[18] Louisiana's statutes carve out an exception to confidentiality of peer review records when sought in the context of authorized discovery of investigative records directly related to the type of injury sustained by the patient at issue.[19] In Kentucky, peer review materials are discoverable in medical malpractice actions.[20] In Massachusetts, records obtained from an original source other than the peer review process are not immune from discovery and can be used against a member of the review committee to establish a cause of action for bad faith.[21]

Most states recognize a privilege regarding the proceedings and records emanating from the proceedings but do not recognize a privilege for data, reports, and other information provided to the peer review committee that originate from an outside source, that is, records kept in the ordinary course of the hospital's

business.[22] Similarly, no immunity exists for those who testify before or provide information to the peer review committee as long as it does not involve revelation of what was disclosed to the committee and is limited to the elicitation of facts of which the individual has personal knowledge.[23]

Five states statutorily require the disclosure of an adverse medical incident resulting in injury or harm to the patient.[24] Idaho's statute[25] is applicable to civil actions brought against a physician, hospital, or emergency medical technician and requires disclosure of whether there was an inquiry into the event and whether any disciplinary action was taken, its disposition, and those individuals with direct knowledge of the incident. Florida's Patients' Right to Know about Adverse Medical Incidents Act[26] applies to any adverse incident causing injury or death reported by any facility to a peer review, risk management, quality assurance, or credentialing committee. The final report of any adverse medical incident is discoverable but whether it is admissible is governed by existing state evidentiary law. In 2009, Pennsylvania adopted a different approach when it enacted provisions in its Health and Safety Code prohibiting a health-care provider from knowingly seeking payment from a "health payor" or patient for treatment related to a preventable serious adverse event.[27] However, any information provided to the patient or his or her medical insurance carrier in reporting a preventable serious adverse event or in providing the refund is not discoverable or admissible in any subsequent civil or administrative proceeding.[28]

DOES THE CLOAK OF CONFIDENTIALITY SURROUNDING PEER REVIEW PROCEEDINGS AND RECORDS FOSTER OR HINDER IMPROVEMENTS IN THE QUALITY OF HEALTH CARE?

The Dilemma of the Peer Review Committee

Few instances when a physician's competence is subject to question are cut and dry. More frequently than not, there are mitigating circumstances, which come into play and make what appears on the surface to be a clear case of physician incompetence not so clear. To further complicate the analysis, medicine is not an exact science. While one physician may prefer performing a particular procedure one way, another specialist in the same field may prefer another. Standard jury instructions include a statement that because two physicians differ in a course of diagnosis or treatment for a particular medical condition, without more information, the trier of fact cannot infer negligence. When the outcome is good, there is no question. When the outcome is poor or unanticipated, the physician's methods, judgments, demeanor, and attention to detail all come into question. Medical malpractice trials more often than not turn into a battle of the experts, with the defendant physician's expert defending the course of treatment as falling within standards of care. The patient's expert will opine to the contrary, equally as vigorously and with factually based reasoning as to how the physician deviated from standards of care. The jury verdict may well turn on which expert is more persuasive and more believable, even though the research and medical literature may lend greater support to the opposite conclusion.

A hospital's internal peer review or quality assurance committee, whether of the medical staff or a special committee of the board, faces a similar dilemma. They are asked to weigh the professional judgments of their colleagues, especially when the outcomes are adverse or the physician exhibits an outlier trend. Even if the majority of those on the committee are physicians, their area of specialty may have little in common with the colleague whose practice has come under scrutiny. They are sensitive to the fact that any decision could well affect the physician's reputation and livelihood. With smaller, independent hospitals, especially those in rural areas, the physician's partners or practice group or those in direct competition may be the only other similar specialists in the geographic area, thereby creating a conflict of interest mandating removal from the peer review process. Sending out reviews is not only costly but time-consuming and may be counterproductive to obtaining an expeditious assessment when the safety and physical well-being of patients are at stake.

When the issue of incompetence is not clear but patient safety concerns abound, the initial tendency is one of intervention, such as informally urging the physician to take a voluntary leave of absence to assess the situation before any investigation is initiated. Once an inquiry is initiated, any action becomes reportable to the National Practitioner Data Bank. If the inquiry or investigation results in a denial, suspension, or revocation of privileges, the practitioner, under most medical staff bylaws, is entitled to a due process or fair hearing. At this juncture, if not before, both sides engage legal counsel, and a mini-trial ensues that can easily consume, if not divide, the entire medical staff.

Issues of physician behavior that undermine a culture focused on patient safety have become more prominent with both the American Medical Association and the Joint Commission on the Accreditation of Hospital Organizations (JCAHO). Effective January 1, 2009, JACHO adopted a new leadership standard to address disruptive and inappropriate behavior for all accredited programs. It requires the hospital or health-care organization to implement a code of conduct that defines acceptable and unacceptable, disruptive, and inappropriate behaviors and create a process for reporting, monitoring, and management.[29] If a physician or other health-care practitioner shows up at the hospital inebriated or otherwise under the influence of drugs, if he or she engages in unexplained emotional outbursts, or if they so intimidate the staff that nurses refrain from contacting the physician when a patient concern arises, there is no question that the quality of patient care can be seriously affected.[30]

The JCAHO Leadership Standards adopted in 2009 recommend a zero tolerance policy for intimidating and disruptive behavior, reinforced by policies protecting from retaliation those who report or cooperate in the investigation, methods of communicating with patients and their families who witness such behaviors, and triggers for implementing disciplinary action.[31] Negative physician conduct impacts not only patient safety and well-being but also every member of the hospital staff who works with or otherwise comes into contact with the perpetrator. Ultimately, it will be the peer review or quality assurance and perhaps credentialing committees of the medical staff and hospital board who will act on the investigation or inquiry, thereby bringing conduct issues within the privileges and immunities provided by the state statutory scheme.

GIVEN THE COUNTERVAILING FACTORS, CAN PEER REVIEW COMMITTEES FULFILL THE ROLE OF POLICING THEIR PROFESSION WHEN IT REQUIRES WEEDING OUT THE INCOMPETENT AND THOSE WHO MISBEHAVE?

In this age of hospital transparency and reporting of quality measures, including outcomes, for the purpose of making the health-care consumer more knowledgeable, a legitimate question arises as to whether the health-care profession can police its own to weed out the incompetent and the misbehaving practitioners or whether the privileges and immunities associated with the peer review process simply act as a shield for their protection. The most important variable internally is the leadership of the peer review committee, and the concomitant support of the hospital's or organization's administration and board. Externally, as health-care consumers become more proficient in use of the Web to discover the positives and negatives of treatment at a particular hospital or by a particular physician, the market alone will force health-care providers to remove the outliers. In the interim, state legislators need to closely review and monitor their peer review privileges and immunities to determine if express exceptions need to be introduced to expand the scope of both records and testimony that are subject to discovery and are admissible in a subsequent civil action for medical malpractice. Taken one step further, as in Idaho, Florida, New Jersey, Nevada, and Pennsylvania, legislators should weigh the necessity in their respective states for mandating the disclosure, upon request, of whether an inquiry or investigation occurred as a result of a reported incident or seminal event and whether a final report of the inquiry should be subject to subpoena and admissibility at trial in accordance with the state's existing evidentiary rules.

Additionally, nearly half of the states recognize a common law cause of action for corporate negligence of a hospital or other health-care entity resulting from failure to conduct a thorough investigation into the credentials of a practitioner before awarding staff privileges or before biannual or more frequent recredentialing.[32] Ohio law goes so far as to create a presumption within its peer review immunity statutes that a hospital is not negligent in the credentialing of an individual who has applied for staff privileges if the hospital was accredited by JCAHO or other national accrediting agency at the time of the alleged negligence, unless the hospital's governing staff or medical executive committee knew that a previously competent physician would provide fraudulent medical treatment to the plaintiff-patient.[33] Federal law provides a further hurdle in proving the corporate negligence of a hospital or other health-care entity by mandating that hospitals request information from the National Practitioner Data Bank when initially credentialing a physician, dentist, or other health-care practitioner for staff privileges and every 2 years thereafter. On the other hand, federal law statutorily permits the hospital to rely on the information obtained, with immunity from civil liability unless it knew the information was false.[34] In light of the privileges and immunity surrounding the peer review process, a medical malpractice plaintiff has difficulty obtaining even an acknowledgment that a peer review, quality assurance, or risk-management inquiry was initiated into the adequacy or appropriateness of services he or she received. Consequently, these claims have proven difficult to pursue and are frequently dismissed prior to trial.

VOLUNTARY DISCLOSURE OF MEDICAL ERRORS

At the other end of the spectrum is a policy, which has slowly evolved over the past decade, of encouraging physicians, hospitals, and other medical providers to voluntarily disclose medical errors leading to unanticipated outcomes. The JCAHO adopted a standard for the disclosure of medical errors in July 2001 and published a subsequent interpretation in May 2002, which narrowed the application to sentinel events considered reviewable by the Joint Commission.[35] The disclosure of medical errors and unanticipated outcomes is not new to the health-care profession, in that the American Medical Association's Code of Ethics has long adhered to the fundamental ethical requirement that physicians should, at all times, deal honestly and openly with patients. Yet significant obstacles, the most prevalent of which is the fear of being named in a malpractice action, have more often than not deterred physicians from acknowledging an error, even one resulting in little or no adverse impact.

Legislatively, in an effort to overcome this obstacle, a majority of states have enacted "apology laws," the enunciated purpose of which is to encourage the disclosure to patient and family of medical errors that cause harm based upon the belief that honest and forthright disclosure will reduce the number of malpractice actions.[36] While most of these statutes were enacted in 2005 and later so that there has been little opportunity to do any type of long-term study of their effectiveness, current research indicates that voluntary disclosure is as rare today as it was a decade ago when the Institute of Medicine report triggering the concept of voluntary disclosure was released.[37] An excellent bibliography summarizing more than 65 articles relating to the disclosure of unanticipated outcomes and medical errors, revised in January 2008 by Daniel O'Connell, PhD, for the Institute for Health Care Communication, is available on the Web.[38]

The reasons voluntary disclosure has not become more accepted despite statutory protections are multifold. As noted by William McDonnell, MD, JD, in his 2008 article in the *Annals of Internal Medicine*, "Do state laws make it easier to say 'I'm sorry'?"[39] very few of the states enacting "apology laws" have structured them to prevent the use of a voluntary acknowledgement of error as an admission against interest in a subsequent malpractice action. Too often, the "apology law" only provides immunity for an expression of sympathy, thereby creating a thin line, easily crossed for the erring physician or hospital and discouraging both, usually on legal advice, from providing a complete voluntary explanation of the factors giving rise to the unanticipated outcome.

In addition to the fear of litigation, other reasons recited for nondisclosure include fear of harming one's reputation with patients and colleagues,[40] the emotional distress of admitting error,[41] and institutional culture, that is, whether the hospital encourages open disclosure. Perhaps the most significant negative factor preventing open and honest disclosure is the unknown factor of how the patient and/or his family will respond, especially if the relationship is long-standing and built on years of trust and confidence. Surveys, on the other hand, reveal that patients and the public generally favor full disclosure of medical errors.[42]

With the objective of determining the impact of full disclosure on the patient's likelihood of changing physicians, seeking legal advice, satisfaction, trust, and

emotional response, an empirical study of 400-plus members of a New England health maintenance organization provided hypothetical scenarios involving a physician's failure to detect an allergy and a failure to monitor a patient properly. The study revealed that full disclosure of the medical errors resulted in a more positive patient response to the predictors of satisfaction, trust, and the decision to retain the physician. At the same time, there was no detectable impact on the decision to seek legal counsel. Overall, the results suggested that full disclosure had a positive impact or no impact on patients or family members and that there was no evidence it increased the likelihood that patients would seek legal advice.[43]

While the jury is still out on the "efficacy" of the so-called apology laws, it seems obvious that as the general public becomes more knowledgeable about and responsible for the costs of their health-care and the options available to them, there is going to be a growing, market-driven emphasis on the transparency of a health-care provider's quality measures. CMS is already posting certain quality measures on its website, www.hospitalcompare.hhs.gov.

THE FOCUS ON QUALITY IMPROVEMENT AND EFFICIENCY IN THE HEALTH-CARE INDUSTRY IS SLOWLY PROGRESSING TOWARD GREATER TRANSPARENCY THAT WILL CONTINUE TO ERODE THE CLOAK OF CONFIDENTIALITY SURROUNDING THE PEER REVIEW PROCESS

In the current health-care environment, the combined efforts of CMS, the Joint Commission, the American Medical Association, and other medical professional societies, along with the federal and state governments, are all advocating for greater transparency in the health-care industry. Caps on spending coupled with consumer expectations demand that change occur. While the rationale underlying the peer review privilege has been the belief that confidentiality fosters the free exchange of information, leading to improvement in the quality of care, the staggering numbers of preventable medical errors resulting in patient harm belies the rationale. The question remains whether state peer review privileges and immunities truly serve the public interest of improving patient safety and the quality of patient care. The numbers suggest they do not.

Both Congress, in enacting the peer review enabling provisions in the Health Care Quality Improvement Act of 1986, and the state legislatures who have enacted peer review privilege statutes, need to take a hard look at whether this legislation is serving the purpose for which it was intended. Would it be more effective, if improving the quality of health care is truly the goal, to create an administrative process at the state level for adjudicating medical malpractice claims administered by trained medical professionals? This may eliminate the fear of litigation, the accompanying threat of the loss of reputation, and the huge verdicts and potential loss of employment underlying the perceived need for confidentiality, and put the focus instead on identifying and eliminating the root causes of harmful medical errors. The Pennsylvania statutory scheme is perhaps a step in the right direction, whereby medical errors resulting in injury or harm to the patient can be disclosed and fair compensation

provided without fear of lengthy and costly legal proceedings and the attendant emotional, reputational, and financial consequences. Regardless, change is coming and coming rapidly, change which will force the elimination of confidential processes if not eliminated voluntarily beforehand.

APPENDIX I: STATUTES BY STATE

Alabama

*Alabama Code §22-21-8(1981)**: Confidentiality of accreditation, quality assurance, and credentialing materials; applies to written reports, records, correspondence, materials of accreditation, quality assurance, or like committee of a hospital, clinic, or medical staff. Materials to be held in confidence; not subject to discovery or admissible in any civil action against the health-care professional or institution arising out of the matters that are the subject of review. No person involved in the review is permitted to testify about the proceedings, evaluation, or opinions expressed therein. Information and documentation from other sources not unavailable for discovery in a civil action because it is introduced before the committee and witnesses may testify in a subsequent civil action but cannot be asked about their testimony or data provided to the review committee.

Alaska

Alaska Statutes §18.23.020(2002): Confidentiality of review organization's records applies to all data and information acquired in the review process. No disclosure to anyone outside the review process. Information is not subject to subpoena or discovery. No one is permitted to reveal what occurred in the proceedings. Documents and data otherwise available from another source are not immune from discovery. An individual who testifies before the committee is not precluded from testifying in a civil action regarding matters within his or her personal knowledge but cannot testify as to testimony given before the committee. Exceptions: materials are discoverable (1) by health-care provider who claims disciplinary action unreasonable; (2) by health-care provider who claims information given to committee was false; or (3) health-care provider under review. Information or reports submitted to the state medical board are not discoverable until and unless it takes action to suspend, revoke, or limit the license.

Arizona

Arizona Rev. Stat.§36-445.01(2001): Confidentiality of information and conditions of disclosure. All proceedings, records, and materials prepared in connection with a review are confidential and not subject to discovery except by the state medical board or by the health-care provider in an action against the hospital for refusal, termination, or suspension of privileges. Members of the committee and those who appear before it are not subject to subpoena in any quasi-judicial or judicial proceeding if

* Date current statute initially enacted.

the subpoena is seeking peer review information. There can be testimony that peer review occurred in a subsequent legal action against the hospital but the contents of any records are confidential and inadmissible.

A.R.S.§36-445.02(2001): Immunity from liability for civil damages of those on the review committee for furnishing records or information to the committee from liability for civil damages. The only legal action available is one for injunctive relief to correct an erroneous decision or record.

A.R.S. §36-445.03(2001): Review is subject to publication only for purpose intended.

A.R.S. §36-445(2001): Mandates the existence of a peer review committee in every hospital and surgical center.

Arkansas

Arkansas Code §20-9-501(1975): Defines a peer review committee as one formed to evaluate and improve health care; determines that health services delivered were appropriate and within standards of care and that costs were reasonable.

Arkansas Statutes §20-9-503(1975): Peer review committee proceedings and records are confidential and not subject to subpoena or discovery in civil action arising out of the same matter. One who appears before the committee can testify in subsequent civil action about matters within his or her personal knowledge but not about testimony given to the committee. There is no waiver of confidentiality when the peer review report is submitted to the hospital's board.

California

California Business & Professions Code §809-§809.9 (1999): Outlines peer review policy and process applicable to healing arts practitioners, including physicians, surgeons, podiatrists, dentists, marriage and family therapists, clinical psychologists, and clinical social workers.

California Evid. Code §1157(2001): Proceedings and records of any peer review committee responsible for evaluating and improving the quality of health care are not subject to discovery and no person in attendance may be required to testify about the proceedings. An exception arises when the health professional who was the subject matter of the review is a party in the subsequent action, is requesting hospital privileges, or has brought a bad faith claim against an insurance carrier.

Colorado

Colorado Statutes §12-36.5-104(1989): Defines and establishes professional review committee and its functions and rules. Subsection 10(a) provides that records are not subject to subpoena or discovery and are not admissible in any civil suit against a physician who is the subject of the review. Exceptions include an appeal of the decision of the committee or by the physician or governing board seeking judicial review. The proceedings are exempt from any public meetings requirements and are deemed confidential.

Connecticut

Connecticut Statutes Chapter 368A §19a-17b(1976): Peer review statute defines health-care provider and provides immunity to one who provides testimony or information believed to be true to a peer review committee and immunity to those who participate on a committee as long as action is not taken with malice. Proceedings are not subject to discovery, and no person can be required to testify in a subsequent civil action about the proceedings. Statute does not preclude the subsequent admissibility of a writing recorded independently of the proceeding or the testimony of a witness who has personal knowledge of the underlying cause. The fact that privileges have been terminated or suspended may be disclosed in a subsequent civil action.

Delaware

Delaware Statutes Chapter 17 §1768(1953): Provides for immunity from any civil action of those on the peer review committee as long as they acted in good faith and without gross or wanton negligence. Those providing information to the peer review committee are also immune. The records and proceedings of the committee are confidential and can only be used to review the committee's functions. They are not public records, are not subject to subpoena, and are not discoverable. Nothing in the statute prevents a committee or board from sending the records to a state licensing board. Disciplinary action issued by the state board is a public record except for patient identification information contained therein.

Florida

Florida Statutes §395.0193(1982): Peer review of licensed facilities is required. There is immunity from civil action for damages of those on committee absent evidence of fraud. The records and proceedings of the peer review committee are not subject to inspection; meetings are not open to public. Investigation, proceedings, and records are not subject to subpoena or introduction into evidence in any civil or criminal action. Those present cannot testify to the proceedings or evidence introduced, but records can be obtained from the original source, and witnesses can testify from personal knowledge, but not concerning opinions and evaluations given. If a health-care provider sues a hospital or health-care entity in subsequent civil action over discipline and loses, he or she pays the reasonable attorneys' fees of the health-care facility.

Georgia

Georgia Code Chapt 7, Art. 6A §31-7-140(2001): Defines medical review committee as one whose duty is to evaluate and improve the quality of health care or to determine if the services rendered were professionally indicated or performed within the standards of care or that the cost was reasonable.

Georgia Code Chapt. 7, Art. 6A §31-7-15(2001): Review of professional practices by a peer review committee. Requires a hospital to provide a peer review process. Subsection (d) renders records and proceedings generated by the duties of a peer

review committee not subject to subpoena or discovery (immunities of Chapt. 14 and Art. 4 of Chapt. 18 of Title 50).

Hawaii

Hawaii Statutes §624-25.5(1971): Proceedings and records of peer review and quality assurance committees created to maintain the professional standards of persons engaged in that profession. The quality assurance committee of the hospital board functions to monitor and evaluate patient care and identify, study, and correct deficiencies in the delivery system to reduce the risk of patient harm. Proceedings are not open to the public and records are confidential. Proceedings nor records are subject to discovery but are limited to records generated by the committee. Does not include incident reports or records otherwise kept in the ordinary course of business of the hospital. Original sources of records are not immune from discovery because they were the materials presented to peer review committee. No testimony is permitted in subsequent action as to what occurred in the committee but testimony as to the personal knowledge of the underlying incident is permitted. Provides that information and data relating to a medical error submitted by a health-care provider to the committee is not subject to discovery.

Hawaii Statutes §663-1.7 (1970): Defines peer review and quality assurance committees. There is no civil liability for any member of the committee unless he or she acted with malice or for any one who gave testimony or information to the committee unless he or she knew it was untrue.

Hawaii Statutes §453-17 (1982): Allows for discovery pursuant to the subpoena of a final report of a peer review committee, including the committee's decision and the basis for the decision solely for use by the Department of Commerce and Consumer Affairs, with patient-identifying information redacted.

Idaho

Idaho Statutes §39-1392b(2003): Peer review records are confidential and privileged; not subject to subpoena or discovery; inadmissible as evidence in any judicial or administrative action for any purpose, as is related testimony. There is no order of censure, suspension, or revocation of license admissible in a civil proceeding seeking damages or other civil relief against the physician or health-care organization that is a defendant. Nothing in the statute affects the admissibility of patient care records.

Idaho Statutes §39-1392c(2003): Immunity from any liability for monetary damages or other legal or equitable relief for those furnishing information or opinions to a health-care organization for peer review purposes.

Idaho Statutes §39-1392f(2003): Every licensed hospital is required to have a medical staff committee charged with reviewing the professional practices of members of the staff to reduce morbidity and mortality and improve the quality of patient care.

Illinois

Illinois Compiled Statutes §210 ILCS 85/10.2(1999): Enunciates a policy of candid and conscientious evaluation of clinical practices essential to adequate hospital

care resulting in a state policy to support peer review. Provides immunity from civil action for the damages of those who participate unless conduct is willful or wanton. Applies to any internal committee involved in quality control, improving patient care, or professional discipline.

Illinois Compiled Statutes §225 ILCS 450/30.5 (1988) [scheduled to be repealed eff. 1/1/14]: Provides for the confidentiality of peer review records, which are privileged and not subject to discovery, subpoena, or other legal process in a civil action. No member of a peer review program can be required to testify on matters disclosed in the peer review context. No privilege attaches to documents or information otherwise publicly available because the record was introduced in a peer review proceeding.

Indiana

Indiana Statutes §34-30-15.1(1998): All peer review proceedings are confidential. The final report can be released to hospital board, health maintenance organization, and state agency; may report to state department of health without waiving confidentiality.

Indiana Statutes §34-30-15-8(1998): Records and determinations of the peer review committee are confidential, with limited disclosure allowed to the state board of licensure, hospitals, preferred providers, nonprofit health-care organizations, and so on. The health-care provider can waive confidentiality.

Iowa

Iowa Statutes §147.135(1977): Peer review committees. Provides immunity from civil liability for participants unless they acted with malice. Peer review records are defined to include complaint and investigation files, reports, and related information, all of which is privileged and not subject to discovery, subpoena, or other means of legal compulsion other than by the licensee who is the subject of the inquiry or peer review committee; not admissible in any civil action other than one brought by licensee. A person who testifies before committee cannot be compelled to testify in a subsequent judicial or administrative proceeding unless it is related to disciplinary action taken. Information obtained from other sources is not privileged by virtue of the fact it was introduced in peer review proceedings. Statute does not preclude discovery of the identity of witnesses or documents known to the peer review committee. If the licensee appeals, the entire case record is submitted to the reviewing court. The hospital is required to submit any final report invoking discipline to the state medical board within 10 days, but the report remains confidential. Persons participating in any subsequent investigation conducted by the state retain immunity from liability.

Kansas

Kansas Statutes §65-4915(2003): Defines peer review as any committee having the function to evaluate and improve the quality of health-care services and determine that those provided were professionally indicated and performed within standards of care and that costs were reasonable. Findings and records submitted to and generated by a peer review committee are not subject to discovery. The information contained in reports cannot be elicited through the testimony of a participant in a peer review

proceeding. An exception exists where the health-care provider contests the disciplinary action or in subsequent administrative action before the licensing agency.

Kansas Statutes §65-4925(2003): The reports of a peer review committee of a medical care facility are confidential, including those submitted to a state licensing agency. Participants in the peer review process cannot be compelled to testify in any civil, criminal, or administrative action other than a disciplinary proceeding of the appropriate licensing agency.

Kentucky

Kentucky Statutes §311.377(1990): Waiver of anyone applying for staff privileges at licensed health-care facility of any claim for damages for a good faith action taken by a member of any board or committee who furnishes information to or serves on an authorized committee reviewing the credentials or evaluating the competency of professional acts or conduct. The proceedings, records, and conclusions of the committee are confidential and privileged, not subject to discovery or subpoena or admissible in any civil action or administrative proceeding. Adopts immunity provisions of the federal Health Care Quality Improvement Act of 1986. Presenting information to or serving on a committee does not preclude testimony in subsequent civil action other than the opinions given to the committee. The health-care entity can reveal its actions if related to the denial of staff membership or privileges.

Louisiana

Louisiana Statutes §13.3715.3(1983): Applies to records, notes, data, studies, analyses, exhibits, and proceedings of a public hospital committee, JCAHO, or similar nationally recognized peer review/quality assurance agency, risk-management committee, medical staff executive committee, or any committee whose duty is to study the root-cause analysis of sentinel events; all such records are not subject to discovery or subpoena except by a health-care provider whose privileges are the subject of the inquiry. Statute does not preclude discovery that can be obtained from an original source or disclosure to an appropriate state licensing agency. There is immunity from civil liability for participants unless they acted with malice. Nothing in the statute precludes the release of patient records to the patient or his or her agent. There is no waiver of confidentiality by disclosure to any board conducting an investigation or fulfilling an adjudicatory function.

Maine

Maine Rev. Statutes §8754(2001): Reporting of sentinel events. All notices, reports, and information collected or developed are privileged and confidential, not subject to discovery or subpoena or admissible as evidence in civil, criminal, or administrative undertakings.

Maine Rev. Statutes §3293(1971): Immunity of physician who serves on a peer review or disciplinary committee that is required for accreditation by JCAHO.

Maine Rev. Statutes §3292(1971): Disclosure to state licensing board for purposes of conducting an investigation limited to purpose of its function.

Maryland

Maryland Code Health Occupations §1-401(2002): (1) Defines medical review committee. (2) Defines the functions of the evaluation of level of performance, qualifications, and credentials of health-care providers and evaluation in disciplinary matters. (3) Provides for the confidentiality and nondisclosure of records, files, and proceedings of the committee except for disclosure to the aggrieved health-care provider or disclosure of documents otherwise available from the original source. (4) Provides immunity from civil liability for those providing information to or participating in committee proceedings.

Massachusetts

Massachusetts General Laws §111.204(2001): Proceedings, reports, and records of a medical peer review committee are confidential and exempt from disclosure, not subject to subpoena or discovery nor admissible in judicial or administrative proceedings except before the board of registration for the profession. No person in attendance can be required to testify but for proceedings before the board of registration or depart of public health as to the proceedings, the findings, or the recommendations of the committee. Records obtainable from the original source are not immune from discovery and can be used in a proceeding against a member of the committee to establish a cause of action for bad faith. Statute grants authority to the court or administrative body to put reasonable restrictions on disclosure.

Massachusetts General Laws §111.205(2001): Defines medical peer review committee and records to which confidentiality and privilege against disclosure apply.

Michigan

Michigan Compiled Laws §331.531(1967): Lists organizations to which information may be provided regarding the physical, psychological, or health care of a person or the qualifications of a health-care provider, which includes a safety committee of a hospital collecting data on serious adverse events. No civil or criminal liability exists for providing information to a review committee unless an act is committed with malice. Disciplinary action is to be reported to state board within 30 days.

Michigan Compiled Laws §331.532(1967): Limitations on publication of peer review proceedings; only permissible to maintain standards of health-care profession, advance research, protect financial integrity, provide evidence of discipline of a health care provider, review qualifications, and monitor the competence of health-care providers.

Minnesota

Minnesota Statutes §145.63(1971): Provides immunity for participants from civil liability for actions taken or recommendations made in a reasonable belief that they were warranted, unless motivated by malice. Immunity also applies to governing body. An exception exists if a health-care provider required to be under scrutiny provides unnecessary or inappropriate care.

Minnesota Statutes §145.64(1971): Data and information acquired by reviewing organization in the scope of its duties is held in confidence and not subject to subpoena or discovery. Participants may not be required to testify concerning testimony given to the review committee but are not precluded from testifying to their personal knowledge of underlying facts. Documents otherwise obtainable from an original source are not precluded from use in subsequent civil action because of their introduction in the review process. Applies to data and incident reports electronically submitted. There is no waiver of confidentiality by a referral from the review committee to the governing board. If a public governing body can close the meeting to discuss, they must tape record it and maintain the recording for 5 years. Can release nonidentifiable aggregate date on medical errors and iatrogenic injury.

Mississippi

Mississippi Code §41-63-9(1977): Peer review proceedings are confidential, not subject to subpoena or discovery in a civil action arising out of matters that are the subject of the review. Participants cannot be required to testify regarding the proceedings but are not precluded from testifying from personal knowledge as to the underlying facts or other matters. Documents available from an original source are discoverable. Confidentiality does not apply to civil action in which the aggrieved physician challenges the action of the review committee as malicious. The legislative purpose is to promote quality patient care through medical and dental peer review activities.

Mississippi Code §41-63-12(1977): Accreditation and quality assurance materials are similarly confidential and not discoverable or admissible in subsequent civil action. Participants of the committee cannot be required to testify in any civil action as to the findings, evaluations, opinions, or recommendations of committee. Documents otherwise available from an original source are discoverable, as is testimony within witness' personal knowledge. Witness cannot be asked about opinions or data given to the committee or given to the participant to evaluate or review accreditation or the subject of the quality assurance review.

Missouri

Missouri Statutes §537.035(1973): Defines health-care professional to include physicians, surgeons, dentists, optometrists, pharmacists, psychologists, nurses, social workers, and mental health professionals. Defines peer review committee as one with the responsibility to evaluate, maintain, and monitor the quality and utilization of health-care services and which may arise within state, corporations, or partnerships of health-care professionals, hospitals and their medical staff, and any other organization under state or federal law. Participants are immune from civil liability as long as the acts are performed in good faith, without malice, and are reasonably related to the scope of the inquiry. Records that are privileged and not subject to discovery or subpoena or admissible in evidence in any judicial or administrative action include notes, interviews, memos, findings, deliberations, reports, minutes, and so on. Participants cannot be required to disclose information acquired within the scope of the peer review proceeding or any opinion or recommendation discussed therein but can obtain documents from the original source.

A witness cannot be questioned about his or her testimony before the committee. The prohibitions do not apply to a subsequent judicial or administrative action challenging the disciplinary action imposed by the committee. The appropriate health-care licensing board can obtain information by subpoena from a peer review committee.

Montana

Montana Statutes §50-16-201(1969): Defines "data" as that used exclusively in a peer review, quality assurance context and expressly excludes incident or occurrence reports and patient health information used to make decisions regarding care. Defines "medical practitioner" as one licensed by the state of Montana, and includes physicians, surgeons, pharmacists, nurses, and so on, and physician assistants.

Montana Statutes §50-16-202(1969): Provides for access to information relating to the condition and treatment of patients within the health-care facility to evaluate for research, morbidity and mortality, and prevention and treatment of diseases, illnesses, and injuries available to peer and utilization review, medical ethics review, quality assurance, or improvement committee within the facility.

Montana Statutes §50-16-203(1969): All health-care information and records described in §50-16-202 are deemed confidential to the peer review committee.

Montana Statutes §50-16-205(1969): All "data" is confidential, not discoverable or admissible in evidence in any judicial proceeding.

Nebraska

Nebraska Statutes §71-2046(1971): Requires each hospital licensed by the state to have a medical staff committee and utilization review committee for maintaining high standards of medical care and the most efficient use of hospital.

Nebraska Statutes §71-2047(1971): Obligates every physician, surgeon, nurse, hospital administrator, or technologist of a licensed hospital to report any knowledge of facts relating to hospital care, when required, to medical staff or utilization review committees. Privilege exists against disclosure to any other person.

Nebraska Statutes §71-2048(1971): Proceedings, minutes, records, reports, and communications originating in one of the above committees are privileged and not subject to disclosure unless: (1)the patient waives privilege and (2) a court orders disclosure for good cause shown under extraordinary circumstances. Statutes do not preclude the disclosure of hospital records kept in the ordinary course of business or patient records. Statute's notes point out that it does not protect antecedent factual reports given to the committee, but only the communications and deliberations within the committee.

Nevada

Nevada Statutes §49.265(1971): Privilege for proceedings and records or organized hospital committee evaluating and improving the quality of hospital care and peer review committee, and those in attendance are immune from testifying unless they are a party to an action that is the subject of the meeting or there is a bad faith claim against an insurance carrier. The statute does not preclude the disclosure of health-care records.

New Hampshire

New Hampshire Statutes §151:13-a(1992): Defines records subject to privilege as interviews, reports, statements, charts, and other documentation used by a hospital committee to evaluate matters relating to the care of patients, morbidity, and mortality; not subject to discovery, subpoena, or admissible in evidence. Statute does not preclude the discovery of documents from an otherwise original source. Participants cannot testify reproceedings before the committee but may from personal knowledge of the underlying facts. Records are discoverable in a subsequent proceeding to revoke or restrict privileges or alleging repetitive malicious action against a physician or surgeon. The privilege can be waived by the hospital board. Immunity from civil liability exists for committee participants.

New Hampshire Statutes §151-D: 1 and 2(1995): Essentially the same provisions apply to ambulatory care clinics providing outpatient services.

New Jersey

New Jersey Permanent Statutes §2A:84A-22.8(1970): Provides for the confidentiality of information and data secured and in possession of a utilization review committee. May be disclosed only to (1) the patient's attending physician; (2) the chief administrative officer of the hospital; (3) the medical executive committee; (4) a federal or state agency; or (5) an insurance carrier.

New Jersey Permanent Statutes §2A:84A-22.9(1970): Immunity of participants in the utilization or peer review process, including committee members and those providing information.

New Jersey Permanent Statutes §2A:84A-22.10(1970): Defines professional review committee as involved in credentialing, peer review, utilization review, medical ethics, grievances, or otherwise related to controversy with patient over diagnosis, care, or fees charged. Participants are immune from civil liability for any action taken or recommendations made, if made without malice and in reasonable belief after reasonable investigation that their actions were warranted.

New Mexico

New Mexico Statutes §41-9-2(1978): Definitions of health-care provider, health-care services, and review organization dedicated to gathering information relating to the evaluation and improvement of the quality of health-care services, reducing morbidity and mortality, developing and publishing guidelines of norms for health-care services within reasonable costs, credentialing, and providing professional standards review.

New Mexico Statutes §41-9-3(1978): Provides immunity to those providing information to a review organization unless they the information is false or the person had reason to believe it was false.

New Mexico Statutes §41-9-4(1978): Immunity from subsequent civil action for those involved in the review process unless they participated with malice toward subject. No civil liability for damages if he or she acted under a reasonable belief that the action or recommendation was warranted.

New Mexico Statutes §41-9-5(1978): All data and information acquired by the review organization is held in confidence and only subject to disclosure to the extent necessary to carry out the committees' functions. No one is to disclose the activities of the committee. Documentation submitted to the committee can be discovered from its original source, and participants can testify from personal knowledge of the underlying facts but not of opinions formed in the committee proceedings.

New York

Consolidated Laws of New York §2805-J(2001): Requires hospitals to maintain a coordinated program to identify and prevent malpractice, including a quality assurance committee, periodic credential reviews, staff privilege sanction procedures, patient grievance procedures, and monitoring of experiences with negative outcomes. Provides immunity from civil liability for a person who provides information in good faith to a quality assurance committee or who participates on a committee that takes action on a review.

Consolidated Laws of New York §2805-K(2001): Documentation required of a physician, dentist, or podiatrist for credentialing or recredentialing. Proof of submission can be requested by the state Department of Public Health.

Consolidated Laws of New York §2805-L(2001): Incident reporting of patient deaths or impairments of unanticipated outcomes, fires, equipment malfunction, poisoning, disasters affecting hospital operations, and death of a minor under 18.

Consolidated Laws of New York §2805-M(2001): Provides confidentiality of reports emanating under §§2805-J through L with release only to the state Department of Public Health. They are not subject to discovery, and participants on various committees cannot be required to testify as to what transpires within the committee. This does not preclude a party from testifying in subsequent action if he or she was the subject of the review. Immunity from liability for participation on one of the respective committees or providing information to a committee regarding the fitness, qualifications, or professional conduct of a medical professional or to a state agency unless the information is untrue or given with malicious intent.

North Carolina

North Carolina Statutes §131E-76(1947): Defines hospital medical review committee as evaluating the quality of and necessity for hospitalization.

North Carolina Statutes §131E-95(1973): Medical review committee. Provides immunity for participants from liability in subsequent civil action. Proceedings and records are confidential; not public records. No participant can be required to testify as to the proceedings, opinions, or recommendations. Documents otherwise available from an original source are not immune from discovery. Records can be released to a professional standards review organization.

North Carolina Statutes §131E-96(1987): Required hospital risk-management programs to identify, evaluate, and manage risk of injury to patients, visitors, employees, and property.

North Carolina Statutes §131E-97(1993): Confidentiality of credentialing and peer review information. Confidentiality attaches to documents obtained for credentialing and recredentialing for staff privileges. Information otherwise available as a public record does not become privileged because of use for this purpose.

North Dakota

North Dakota Statutes §23-01-02.1: Provides for the immunity and confidentiality of the quality assurance review committee. Repealed in 1997.

Ohio

Ohio Revised Code §2305.24(2003): Information furnished to quality assurance or utilization committees is confidential and can only be used by the committee to carry out its functions. A cause of action exists against any member of the committee who misuses or publicly discloses information.

Ohio Revised Code §2305.25(2003): Defines peer review committee of health-care entity organization, insurance carrier having credentialing, or quality review activities. Hospital incident report involves an injury or a potential injury to a patient as a result of the care or treatment provided by a health care provider for use by a hospital, physician group, or insurance carrier.

Ohio Revised Code §2305.251(2003): Immunity from civil liability for work performed within the scope of peer review functions. There is a presumption against negligence in credentialing if the hospital or health-care entity is accredited by a professional association, that is, JCAHO; can be overcome with proof that the hospital took no action to curtail the privileges of a health-care provider it knew to be incompetent or providing fraudulent care. No participants are required to testify regarding the findings or evaluations of committee. Documents are discoverable from an original source, and participants can testify to personal knowledge of underlying facts.

Ohio Revised Code §2305.252(2003): Confidentiality of peer review proceeding and records; not subject to discovery or admissibility of evidence arising out of matters that are the subject of a review.

Ohio Revised Code §2305.253(2003): Incident or risk-management reports are not subject to discovery nor admissible. Does not limit the discovery or admissibility of testimony from those with personal knowledge of the facts.

Oklahoma

Oklahoma Statutes 76 O.S. §24(1987): Definitions. A professional review body is organized for the purpose of maintaining standards of conduct and competence for multiple professionals, including physicians, psychologists, nurses, pharmacists, dentists, and others.

Oklahoma Statutes 76 O.S.§25(1987): Immunity of participants on a professional review body from civil liability for actions taken in good faith.

Oklahoma Statutes 76 O.S. §26(1987): Immunity from civil liability for those supplying information to a professional review body in good faith.

Oklahoma Statutes 76 O.S. §27(1987): Protections of §25 and §26 do not apply to actions for violation of civil rights or antitrust.

Oklahoma Statutes 76 O.S. §28(1987): Protections conditioned on reasonable belief that action was taken to enhance the quality of professional standards, after a reasonable effort to obtain facts, after adequate notice and opportunity to be heard, and that the facts warranted action. Provides review process.

Oregon

Oregon Statutes §41.675(1963): Defines peer review bodies as involved with quality assurance, utilization review, credentialing, education, and training of physicians and other health-care providers, their supervision, discipline, or the grant or denial of privileges. Data defined as all records, reports, communications to the peer review body, or notes and reports generated by it. All data is privileged and not admissible in any judicial, administrative, arbitration, or mediation proceeding. Nondisclosure does not apply to patient medical records. A person on the committee cannot be examined as to the communications or findings of the committee unless the health-care provider who is the subject of the review subsequently contests the denial, restriction, or termination of clinical privileges, or membership in a professional society.

Pennsylvania

Pennsylvania Statutes 62 P.S. §444.2(1967): Physicians serving on a hospitalization utilization review or similar committee are immune from liability for civil damages arising from the acts or decisions of the committee unless they are grossly negligent.

Pennsylvania Statutes 35 P.S. §449.92(2009): Defines health-care facility, health-care provider, and preventable serious adverse events.

Pennsylvania Statutes 35 P.S. §449.93(2009): Provides payment policy for preventable serious adverse events and renders any reporting to the health payor or patient nondiscoverable or admissible in any civil or administrative action.

Pennsylvania Statutes 40 P.S. §1303.746(2002): Mandatory reporting of settlement in medical malpractice action to appropriate licensure board. Person reporting in good faith immune from civil or criminal liability arising from report.

Rhode Island

Rhode Island Statutes §5-37.3-7(1978): Medical peer review boards. Providers can make confidential health-care information available to a peer review committee without authorization. The information remains strictly confidential, and proceedings and records are not discoverable nor admissible in evidence. No participant can testify to the committee's actions, evaluation, and recommendations. Documents obtainable from another source are discoverable. Participants can testify to underlying facts about which they have personal knowledge. They cannot be questioned regarding their testimony before the committee. Confidentiality protections do not apply to a legal action brought to restrict or revoke clinical privileges or an action brought by the subject of the review against the hospital for the disciplinary action taken.

Nothing precludes the state licensing board from requesting records or obtaining information regarding the committee's proceedings that impacted licensure. No criminal or civil liability attaches to participants for action taken or information given without malice and based on a reasonable belief that the action was warranted.

South Carolina

South Carolina Code §40-71-10(2003): Defines professional society. No civil liability attaches to a member of an appointed committee to maintain professional standards or review patient records to study causes of death and disease, as long as the committee member acts without malice, made a reasonable effort to obtain facts, and took action that was warranted.

South Carolina Statutes §40-71-20(2003): Confidentiality of proceedings, data, and information acquired by review committee unless the respondent waives the privilege. Data is not subject to discovery or subpoena and is not admissible but for an appeal from the committee action. Statute allows the testimony of those with personal knowledge regarding the underlying facts. No waiver in reporting incidents to the state Department of Health.

South Dakota

South Dakota Statutes §36-4-42(1998): Defines peer review committee as one engaged in peer review activities.

South Dakota Statutes §36-4-43(1998): Defines peer review activities to include matters affecting membership on staff of health-care facility; the grant, denial, revocation, suspension of clinical privileges, matters affecting membership in a professional society, or employment in a professional group; the review and evaluation of the quality, character, conduct, and competency of like professionals and review of the services provided.

South Dakota Statutes §36-4-25: Immunity from civil liability for participants in peer review, including physicians, hospital governing board, and so on, for actions taken within the scope of its function if taken without malice and with reasonable belief the action was warranted.

South Dakota Statutes §36-4-26.1: The records, reports, and statements of peer review committee are not subject to discovery and not admissible as evidence in any action unless needed for the defense of an action against that person. Participants cannot be required to testify about committee proceedings.

Tennessee

Tennessee Statutes §63-6-219(1967): States policy of encouraging candid, conscientious review of peers' professional conduct. Defines peer review committee as one with a function to evaluate and improve the quality of health care; provide support and intervention to professionals; determine if services are professionally indicated; and determine if services are performed within standards of care. Participants are immune from civil liability to any patient, individual, or organization for providing

information to the committee and from damages resulting from actions taken without malice and based on facts known or reasonably believed to exist. Extends immunity to any individual or entity giving assistance or counseling to a licensee. Also extends immunity to anyone giving information concerning the competency or conduct of a professional unless the information is false. A presumption exists that members of the committee acted in good faith. Privilege attaches to all information, incident, and other reports furnished to the committee and to its findings, conclusions, and reasons, which can only be used in the exercise of its functions. The records of the committee are not public records nor subject to subpoena or discoverable. Statute does not preclude discovery of records otherwise maintained in the ordinary course of business.

Texas

Texas Statutes and Code §160.006(1999): Records, reports, or other information received and maintained by a medical peer review board and materials developed in its investigations and/or hearings are confidential and can only disclosed in a subsequent disciplinary hearing or appeal, or before the state licensing authority, pursuant to a court order or for workers' compensation purposes or research (if personal identifying information is redacted). Records are not admissible in any action for damages, including subsequent medical malpractice arising out of the occurrence or services subject to the inquiry. Records remain confidential and under seal in any subsequent administrative or judicial process. Confidentiality does not extend to patient records or records otherwise discoverable as records maintained in the ordinary course of business.

Utah

Utah Statutes §26-25-1(2003): Immunity from civil liability for providing information, data, interviews, reports, statements, or any other documentation relating to the care or treatment of an individual to a professional review organization, society, organization, or in-house peer review committee of a health-care facility for the purpose of reducing disease, morbidity or mortality, and evaluating and improving the health care rendered by the facility.

Utah Statutes §26-25-2(2003): Information described in §26-25-1 provided to entities described therein is only to be used in accordance with the chapter. Information may only be published for the advancement of medical research or education to reduce disease, morbidity, and mortality.

Utah Statutes §26-25-3(2003): All information furnished to peer review organization or committee and the findings, conclusions, or communications of the committee are privileged and not subject to discovery or evidence in any legal proceeding.

Utah Statutes §26-25-4(2003): Information described in §26-25-1 is to be held in strict confidence and only released for the functions described in the statute.

Vermont

Vermont Statutes §1441(1975): Defines peer review committee as formed to improve and evaluate the quality of health care rendered by providers of health services,

ensure that the services are professionally indicated and performed within standards of care, and ensure that costs are reasonable.

Vermont Statutes §1442(1975): Immunity from civil liability for members of a peer review committee or those providing it information or otherwise assisting with peer review process for any act or proceeding related to peer review activities, provided that it was not done with malice and was done after a reasonable effort to obtain facts and under a reasonable belief that action was warranted.

Vermont Statutes §1443(1975): Proceedings, records, and reports of peer review committees are confidential and are not subject to discovery or admissible in any civil case against the health-care provider arising out of matters that were the subject of a review by the committee. No participant can be required to testify in any civil action as to the findings, recommendations, conclusions, and opinions. Statute does not preclude discovery of documents from the original source. Participants are not immune from testifying as to their personal knowledge of the underlying facts. The peer review committee is required to provide the entity's board with all supporting information and evidence, and likewise to the state Department of Health. Information may be used for disciplinary and enforcement purposes, but is not subject to disclosure.

Virginia

Virginia Statutes §8.01-581.17(1950): Privileged communications of credentialing, peer review, quality assurance committees. Covers proceedings, records, reports, and communications originating in or provided to the committee. Cannot be obtained by legal discovery proceedings unless ordered by the Circuit Court for good cause arising from extraordinary circumstances. Oral communications concerning a specific medical incident involving patient care to a quality assurance or peer review committee are only privileged if made within 24 hours after the occurrence. Statute does not preclude the discovery of patient records or records otherwise kept by the hospital or other covered entity in the ordinary course of business or to facts contained within records. Reports or patient safety data in the possession of a patient safety organization are not subject to discovery by civil, criminal, or administrative subpoena or admissible in proceedings but are discoverable from the original source. Patient identification is at all times to remain privileged. There is no waiver of confidentiality when reports are exchanged between health-care providers as long as patient identity is redacted. Reports for self-assessment in compliance with JCAHO requirements remain confidential and are not subject to discovery; release does not constitute a waiver of the privilege.

Washington

Washington Revised Code §4.24.250(1971): Immunity from civil liability for a health-care provider who supplies information and/or documents to a committee charged with reviewing and evaluating the quality of patient care, under the presumption of good faith. Presumption overcomes with clear and convincing evidence that the information was knowingly false. Proceedings, reports, and written records of the committee are not subject to disclosure, subpoena, or discovery in any civil proceeding except for an action arising out of the recommendations or actions of the committee resulting in the restriction or revocation of clinical privileges.

The committee may share information, including complaints and incident reports, within and between coordinated quality improvement programs for the purpose of improving the quality of patient care and preventing medical malpractice. The committee is required to comply with state and federal laws regarding the privacy of patient information. Any information shared between coordinated programs retains confidentiality and is not subject to the discovery process.

West Virginia

West Virginia Statutes §30-3C-1(2003): Defines "health-care professional"; "peer review" as the procedure for evaluating a health-care professional's quality and the efficiency of the services ordered or performed; and "review organization" as any committee or organization engaged in the peer review process, including a hospital's utilization review, medical audit, tissue, health insurance, and health maintenance organization review committees; a nursing advisory committee, medical assistance committee; JCAHO; and any federal or state committee created for peer review functions, identified as improving the quality of health care, reducing morbidity and mortality, and establishing and enforcing guidelines of a reasonable cost structure.

West Virginia Statutes §30-3C-2(2003): Immunity from civil liability for persons providing information to a review organization, unless it is knowingly false. Participants of the committee are immune from liability for loss or injury to the person reviewed unless acting with malice.

West Virginia Statutes §30-3C-3(2003): Proceedings and records are confidential, not subject to subpoena or discovery or admissible as evidence in any civil action arising out of matters that are the subject of review. Participants cannot be required to testify concerning committee activities, findings, recommendations, evaluations, or opinions. Statute does not preclude discovery from other sources nor testimony as to matters within the participant's personal knowledge. Participants cannot testify to the opinions or testimony given to the committee. The subject of the peer review can waive the privilege. Discovery of records and proceedings is available upon appeal or subsequent action brought by the individual reviewed.

Wisconsin

Wisconsin Statutes §146.37(1975): Defines health-care provider and peer review. Provides for immunity from civil damages for participants in a review or evaluation furnished for the purpose of improving the quality of health care and reviewing the reasonableness of charges for services, as long as it is done in good faith. Protected activities of peer review committee include censuring, reprimanding, limiting, or revoking staff privileges; taking disciplinary action of any nature; or notifying the medical examining board. Good faith is presumed but can be defeated with clear and convincing evidence, such as the actions of the medical director or health-care facility in preventing the subject of review to inspect the records and documents submitted to and considered by the committee. The statute expressly extends to psychiatrists.

Wisconsin Statutes §146.38(1975): Confidentiality of records. Participants may not disclose any information acquired in the committee proceedings. They are

required to keep a record of the investigation and inquiry, but not for release, and such records cannot be used in any civil action for injuries to a health-care provider. Records are not immune from discovery solely because they were presented before the committee, and participants can be required to testify as to their personal knowledge of the underlying facts. Unless the patient has waived the privilege, documents can only be disclosed with patient-identifying information redacted.

Wyoming

Wyoming Statutes §35-2-609(2002): Hospital can disclose patient health-care information without authorization for quality assurance, peer review, administrative, legal, financial, or actuarial purposes. Medical staff is to have access to patient records for supervision, discipline, or evaluation of the privileges of members of the staff, evaluating and reporting on matters affecting patient care, research, reducing mortality and morbidity, prevention and treatment of disease, and utilization review. All reports, findings, and proceedings against a hospital or member of the medical staff related to the denial, suspension, or termination of staff privileges are confidential unless actions were arbitrary, capricious, or without foundation in fact.

Wyoming Statutes §35-2-910(2002): Licensed health-care facilities must implement a quality management function to evaluate and improve patient care and services. Information related to this function is confidential. Participants in a quality management function acting in good faith are immune from civil suit arising from the performance of their functions. The statute does not apply to negligent or intentional acts or omissions in the provision of care. Hospitals are required to have a program for the review of professional practices to be licensed by the state or relicensed. The review is to include the quality and necessity of care, prevention of complications, review of the medical treatment, diagnosis, and surgical procedures, and evaluation of the professional competency and conduct of those performing services, and is to be performed by the hospital's governing body or duly appointed peer review committee, a state or local medical society, or an organization of physicians with quality review as its function.

Wyoming Statutes §35-2-912(2005): Requires reporting of safety events, defined as unexpected occurrences involving death or serious physical or psychological injury, to Department of Public Health and Safety. Occurrence must be reported to the designated safety officer within 24 hours of notice and reported by the safety officer to the state Department of Public Health and Safety within 15 days. Reports do not identify the patient, employee, or health-care professional involved. The notices, reports, and other documentation are confidential and not discoverable or admissible in any legal proceeding; not a public record. The state expressly adopted the immunity policy of the federal Health Care Quality Improvement Act of 1986 to govern immunity, confidentiality, and whistle-blowing provisions in §35-2-910.

Wyoming Statutes §35-17-105(2002): Reports, findings, proceedings, and data of a professional standard review organization are confidential, not subject to discovery or introduction into evidence in any civil action. No participant can be required to testify in any civil action as to evidence introduced during the proceedings or as to the findings, recommendations, evaluations, or opinions of the committee. Documents available from the original source are discoverable. Participants can

testify to facts within personal knowledge but not regarding testimony before the review organization or opinions formed as a result of the proceedings.

APPENDIX II: JURISPRUDENCE BY STATE

These are decisions recognizing the independent duty of a hospital to its patients to assure the competence of its medical staff and personnel through its selection and review processes. Claims asserting this duty are frequently identified as corporate negligence or negligent credentialing.

Alabama. *Clark v. Allied Health Care Products, Inc*., 601 So.2d 902 (Ala. 1992); *Humana Medical Corp. of Alabama v. Traffanstedt*, 597 So.2d 667 (Ala. 1992).

Arizona. *Tucson Medical Center, Inc. v. Misevch*, 113 Ariz. 34, 545 P.2d 958 (1976).

California. *Elam v. College Park Hospital*, 132 Ca. App.3d 332, 183 Cal. Rptr. 156 (1982).

Colorado. *Kitto v. Gilbert*, 39 Colo. App. 374, 570 P.2d 544 (1977).

Florida. *Insinga v. LaBella*, 543 So.3d 209 (Fla. 1989).

Georgia. *Mitchell County Hospital Authority v. Joiner*, 229 Ga. 140, 189 S.E.2d 412 (1972).

Illinois. *Darling v. Charleston Community Memorial Hospital*, 33 Ill.2d 326, 211 N.E.2d 253 (1965), cert. denied 383 U.S. 946, 86 S.Ct. 1204, 16 L.E.2d 209 (1966).

Michigan. *Ferguson v. Gonyaw*, 64 Mich. App. 685, 236 N.W.2d 543 (1975).

Missouri. *Gridley v. Johnson*, 476 S.W.2d 475 (Mo. 1972).

Nebraska. *Foley v. Bishop Clarkson Memorial Hospital*, 185 Neb. 89, 173 N.W.2d 881 (1970).

Nevada. *Moore v. Board of Trustees*, 88 Nev. 207, 495 P.2d 605, cert denies 409 U.S. 879, 93 S.Ct. 85, 34 L.Ed.2d 134 (1972).

New Jersey. *Corleto v. Shore Memorial Hospital*, 138 N.J. Super. 302, 350 A.2d 534 (Super Ct. Law Div. 1975).

New York. *Raschel v. Rish*, 110 A.D.2d 1067, 488 N.Y.S.2d 923 (App. Div. 1985).

North Carolina. *Blanton v. Moses H. Cone Memorial Hospital, Inc*., 319 N.S. 372, 354 S.E.2d 455 (1987).

North Dakota. *Benedict v. St. Luke's Hospital*, 365 N.W.2d 499 (N.D. 1985).

Ohio. *Albain v. Flower Hospital*, 50 Ohio St.3d 251, 553 N.E.2d 1038 (1990).

Oklahoma. *Strubhart v. Perry Memorial Hospital Trust Authority*, 903 P.2d 263 (Okla. 1995).

Pennsylvania. *Thompson v. Nason Hospital*, 527 Pa. 330, 591 A.2d 703 (1991).

Texas. *Park N. General Hospital v. Hickman*, 703 S.W.2d 262 (Tex. Ct. App. 1985).

Washington. *Pedroza v. Bryant*, 101 Wash.2d 226, 677 P.2d 166 (1984).

West Virginia. *Utter v. United Hospital Center, Inc*., 160 W.Va. 703, 236 S.E.2d 213 (1977).

Wisconsin. *Johnson v. Misericordia Community Hospital*, 99 Wis.2d 708, 301 N.W.2d 156 (1981).
Wyoming. *Greenwood v. Wierdsma*, 741 P.2d 1079 (Wyo. 1987).

APPENDIX III
State "Apology" Statutes

Arizona	Ariz. Rev. Stat. §12-2605 (2005)
California	Cal. Evid. Code §1160 (2000)
Colorado	Colo. Rev. Stat. §13-25-135 (2003)
Connecticut	Conn. Gen. Stat. §52-184d (2005)
Delaware	Del. Code Chapt. 10 §4318 (2006)
Florida	Fla. Stat. §90.4026 (2001)
Georgia	Ga. Code §24-3-37.1 (2005)
Hawaii	Haw. Rev. Stat. §626-1; Rule 409.5 (2007)
Idaho	Idaho Code §9-207 (2006)
Indiana	In. Code §34-43.5-1-4 and 34-43.5-1-5 (2006)
Iowa	Iowa Code §622.31 (2006)
Louisiana	La. Rev. Stat. §13.3715.5 (2005)
Maine	Me. Rev. Stat. Chapt. 24 §2907 (2005)
Maryland	Md. Code Cts. & Jud. Proc. §10-920 (2004)
Massachusetts	Mass. Gen. Laws Chapt. 233 §23D (1986)
Missouri	Mo. Stat. §538.229 (2005)
Montana	Mont. Code §26-1-814 (2005)
Nebraska	Neb. Rev. Stat §27-1201 (2007)
New Hampshire	N.H. Rev. Stat §507-E:4 (2005)
North Carolina	N.C. Gen. Stat §8C-2, Rule 413 (2004)
North Dakota	N.D. Cent. Code §31-04-12 (2007)
Ohio	Ohio Rev. Code §2317.43 (2004)
Oklahoma	Okla. Stat Chapt. 63 §1-1708.1H (2004)
Oregon	Or. Stat §677.082 (2003)
South Carolina	S.C. Code §19-1-10 (2006)
South Dakota	S.D. Cod. Laws §19-12-14 (2005)
Tennessee	Tenn. Code Rule of Evid. 409.1 (2003)
Texas	Tx. Civ. Prac. & Rem. Code §18.061 (1999)
Utah	Utah Code §78B-3-422 (2006)
Vermont	Vt. Stat. Chapt. 12 §1912 (2006)
Virginia	Va. Code §8.01-52.1, §8.01-581.20:1 (2005)
Washington	Wash. Rev. Code §5.64.010 (2006)
West Virginia	W.Va. Code §55-7-11a(b)(1) (2005)
Wyoming	Wyo. Stat §1-1-130 (2004)

Source: Wm. M. McDonnell, MD, JD; Elisabeth Guenther, MD, MHP. "Narrative Review: Do State Laws Make it Easier to Say 'I'm Sorry?'", *Annals of Internal Medicine*, Vol. 149:11 (December 2, 2008).

ENDNOTES

1. Centers for Medicare & Medicaid Services, Office of the Actuary. National Health Expenditure Accounts—Projected, Table l: National Health Expenditures; Aggregate and Per Capita Amounts, Percent Distribution, and Average Annual Percent Growth, by Source of Funds: Calendar Years 2003–2018.
2. Agency for Healthcare Research and Quality [AHRQ]. "Advancing Patient Safety: A Decade of Evidence Design and Implementation" (2010).
3. Appendix I contains an alphabetical listing by state of the peer review statutes with a brief summary of each.
4. For example, see TX Statutes §160.006(c); PA Statutes 63 P.S. §425.4; LA Statutes §13:3715.3(A)(2); KY Rev. Statutes §3111.377(2); Alaska Statutes §18.23.030(a); Mass. Genl. Laws 111 §204(b); Ohio Rev. Code §2305.251; AZ Statutes §32-1451.01, §36-445.01; MS Code §41-63-9 & §41-63-23.
5. Hawaii Statutes §663-1.7.
6. N. Carolina Statutes §131E-76.
7. W. Va. Statutes §30-3C-1.
8. N.D.C.C. §23-01-02.1; §31-08-01.
9. 42 U.S.C. §11101, *et seq*.
10. 45 C.F.R. §60.1, *et seq.*
11. 45 C.F.R. §60.7.
12. 45 C.F.R. §60.9.
13. 45 C.F.R. §60.8.
14. National Practitioner Data Bank document 02449.02.00; 45 C.F.R. §60.11(a)(1)–(4).
15. 45 C.F.R. §60.11(a)(5).
16. 45 C.F.R. §60.10.
17. 45 C.F.R. §60.13.
18. See Appendix I, Kansas Statutes.
19. LA Statutes §13:3715.3.
20. KY Rev. Statutes §311.377(2).
21. Massachusetts General Laws §111.204. See Appendix I.
22. Va. Statutes §8.01-581.17; Nev. Rev. Statutes §49.265; Pa. Statutes 63 P.S. §425.4; La. Statutes §13.3715.3(F); Mass. Gen. Laws 111 §204(b).
23. See Appendix I.
24. Idaho Statutes §39-1392e(2003); Fl. Statutes §381.028(2005); N.J. Statutes §26:2H-12. 25(d) (2004); Nev. Rev. Statutes §439.855 (2002); Pa. Cons. Statutes §1303.308(b)(2002).
25. Idaho Statutes §39-1392e.
26. Fl. Statutes §381.028.
27. Pennsylvania Statutes 35 P.S. §§449.92 and 449.93(2009).
28. Pennsylvania Statute 35 P.S. §449.93(d)(2009).
29. JCAHO Leadership Standard LD.03.10.
30. Joint Commission. "Behaviors that Undermine a Culture of Safety," *Sentinel Event Alert* 40 (2008):1–3.
31. See note 30.
32. For a list of decisions in which a common-law theory of corporate negligence against a hospital or other health care entity has been recognized, see Appendix II.
33. Ohio Rev. Code §2305.251(B)(1)(a)-2(d).
34. 45 C.F.R. §60.10.
35. JCAHO Standard RI.1.2.2. At a minimum, the patient and, when appropriate, the patient's family are informed about outcomes of care that the patient (or family) must be knowledgeable about in order to participate in current and future decisions affecting the patient's care and unanticipated outcomes of care that relate to sentinel events

considered reviewable by the Joint Commission. The responsible licensed independent practitioner (LIP) or his or her designee informs the patient (and when appropriate, the patient's family) about these outcomes of care.

36. Appendix III contains a listing of states alphabetically that have enacted "apology laws."
37. L. T. Kohn, J. M. Corrigan, and M. S. Donaldson, eds., *To Err Is Human: Building a Safer Health System*, A Report of the Committee on Health Care in America (Washington, DC: Institute of Medicine, National Academy Press, 2000).
38. D. O'Connell, *Disclosing Unanticipated Outcomes and Medical Errors* (New Haven, CT: Institute for Health Care Communication, 2010).
39. W. M. McDonnell and E. Guenter, "Narrative Review: Do State Laws Make It Easier to Say 'I'm Sorry?'" *Annals of Internal Medicine*, 149, no. 11 (2008):811–6.
40. S. Fein, L. Hilborne, M. Kagawa-Singer, E. Spiritus, C. Keenan, G. Seymann, K. Sojania, and N. Wenger, "A Conceptual Model for Disclosure of Medical Errors," *Advances in Patient Safety,* Agency for Healthcare Research and Quality (Feb. 2005); see also, Frank Federico, "Disclosure: Challenges and Opportunities; Disclosure of Medical Error," *Forum* 23, no. 2 (2003):2–3.
41. J. F. Christensen, W. Levinson, and P. M. Dunn. "The Heart of Darkness: The Impact of Perceived Mistakes on Physicians," *Journal of General Internal Medicine* 7 (1992): 424–31; A. W. Wu, "Medical Error: The Second Victim: The Doctor Who Makes the Mistake Needs Help Too," *British Medical Journal* 320 (2000):726–7.
42. S. Fein et al. "A Conceptual Model for Disclosure of Medical Errors," citing studies by M. Hingorami, T. Wong, and G. Vafidis "Patients' and Doctors' Attitudes to Amount of Information Given after Unintended Injury during Treatment," *British Medical Journal* 318 (1999):640–1; A. B. Witman, D. M. Park, and S. B. Hardin, "How Do Patients Want Physicians to Handle Mistakes?" *Archives of Internal Medicine* 156 (1996):2565–9; K. M. Major, S. R. Simon, R. A. Yood et al. "Health Plan Members' Views About Disclosure of Errors," *Annals of Internal Medicine* 140 (2004):409–18; M. P. Sweet and J. L. Bernat, "A Study of the Ethical Duty of Physicians to Disclose Errors," *Journal of Clinical Ethics* 8, no. 4 (1997):341–8.
43. K. M. Mazor, G. W. Reed, R. A. Yood, M. A. Fischer, J. Baril, and J. Gurwitz, "Disclosure of Medical Errors: What Factors Influence How Patients Respond?" *Journal of General Internal Medicine* 21, no. 7 (2006):704–10.

15 Technology and Medical Errors

Shannon Gallagher

CONTENTS

> A recent study at the University of Michigan has found that over 1 in 6 older patients receive the wrong medications in emergency room visits. According to the study, which was published in *Academic Emergency Medicine*, nearly 19.5 million patients ages 65 and older received one or more potentially inappropriate medications (PIMs) in emergency visits from 2000–2006.
>
> *http://www.naturalnews.com/028590_hospitals_medical_errors.html#ixzz1ReDAmZB0*

Medical errors in the United States have long maintained a certain invisibility among the American public as they present a glaring contradiction. The field of medicine, in the imagination of the public, represents the pinnacle of human knowledge and achievement, in combination with an infallible precision driven by compassion. The idea of medical errors, separate from the statistics surrounding the topic, debases the public's trust in the larger system by challenging the confidence placed in medical professionals. In a sense, awareness of the epidemic of medical errors is as dangerous conceptually as statistically because it undermines the trust that must be present for the patient to truly benefit from health care. Additionally, caregivers feel a compelling urge to achieve perfection in care, and the advent of medical errors corrodes the satisfaction associated with the largely philanthropic work of health-care professionals. The ensuing disavowal of medical errors even silences discussion of this phenomenon as an "epidemic," though more Americans—between 44,000 and 98,000—die each year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).[1,2] There can be no doubt that these statistics surrounding other epidemics were chosen by the Center for Disease Control and Prevention in their discussion of medical errors precisely because of their visibility. Each of these categories exemplifies the act of bringing attention and action to the forefront of preventative efforts. Take the billions of dollars spent on engineering and testing automobiles, for example, or the philanthropic efforts surrounding the

funding of breast cancer research, or the sweeping education efforts around HIV/AIDS. All these strategies carry with them the seeds of a movement. This brings into question the previously mentioned invisibility of medical errors, which consistently rank between the fifth and eighth leading causes of death in America.[1]

Medication errors and adverse drug events (ADEs) present an additional level to the paradox of medical errors. This is due to the fact that the sheer number of available pharmaceuticals contributes to the likelihood of these events. That is, the range of available treatment creates a situation where the potential for confusion, conflation, dosage errors, and allergies increases with the availability of these treatments. From this perspective, there is a call to action to intervene in the phenomenon of medication errors and ADEs before the inevitable introduction of yet more pharmaceuticals to the market. To put this issue into perspective, it has been established that between 380,000 and 450,000 preventable ADEs occur annually in the United States, incurring costs totaling between $3 and $15 billion.[3–5] Beyond the staggering total of preventable ADEs, it is accepted that 7000 people die each year, while 1.5 million others are injured by medication errors.[6]

The use of information technology (IT) holds promise as the volume of information around prescription and administration of pharmaceuticals grows. This is not to say that technologies alone can abate this epidemic; rather, it is to suggest that the development of a unified, comprehensive, patient-centered health-care software is needed to address the situation. Additionally, development of such a tool would afford health care in general the opportunity to revise the system currently in place. This will not take place, however, if medical IT is "balkanized," or unnecessarily divided against itself, as it often is. This unnecessary division results in the new problems inherent in new solutions, existing as a barrier to patient safety.

The question looming large is now, "Is IT an effective intervention in preventing medical errors?" This question is exceedingly difficult to answer, given the volume and variety of medical ITs available. This creates a bipartite response. Certain technologies are effective at preventing errors pertaining to the task they manage. Other technologies cause errors because of their inability to interface with others. This is the point of "balkanization" at which the caregiver must transcribe, interpret, or otherwise interject the possibility of human error into a situation that has been largely dependent upon human judgment and technologically recorded memory. The departure from the unified process, in this case, is the new root cause of error itself.

COMPUTERIZED PHYSICIAN ORDER ENTRY

Computerized physician order entry (CPOE) systems and bar code verification have received much attention in recent years as the volume of available pharmaceuticals and number of patients continue to grow in parallel. These technologies aim to reduce the human error in the prescription and administration of medication, such as legibility issues or confusion over dosage. While studies consistently demonstrate their potential for reducing ADEs, they have not been implemented as widely as initially expected. As of 2009, only 17% of health-care facilities nationwide had implemented CPOE, with even fewer reporting implementation of comprehensive EMR systems.[7]

Like many technologies, early versions of CPOE fell out of favor with many physicians because of the limitations of the platforms and the software. Barriers to implementation include physician and organizational resistance, the immaturity of the vendor market, cost, and poorly defined interfaces.[8] Ross Koppel, PhD, a sociologist at the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine, is the primary author of a 2-year study that revealed 22 types of medication errors, including but not limited to

- Ordering the wrong medication dosage because pharmacy-purchasing dosage decisions were misread as clinical guidelines.
- Ordering new or modifying existing prescriptions without canceling old orders because viewing a single patient's medications could require looking at as many as 20 screens. The fragmented CPOE displays also led to delays of several hours in canceling medications.
- Causing gaps in antibiotic therapy because of a lack of coordination among information systems.
- Prescribing a drug for the wrong patient because the names of patient files and drugs were listed close together in small type and the patients' names did not appear on all screens.
- Ordering prescriptions for the wrong patient or not getting intended medication to patients because the previous physician had failed to log out of the computer.
- Losing data and delaying medication orders because the CPOE system crashed or was down for maintenance.[9]

Ten of the 22 (45%) types of medication errors identified were directly attributed to the CPOE system itself and its inability to consistently interface with other departmental information systems. According to Dr. Koppel, the system functions in a manner "that is not integrated with the way the hospital actually does work, using it where you're not constantly being vigilant about the way it's used and the way information flows within an organization."[10] Koppel's frustration is understandable, though, as the tools upon which he depends prove counterproductive to the larger project of delivering quality care.

Critics of this study are quick to point out the fact that the antiquated system at the heart of the study was developed in the late 1960s and that the study included no comparative rates of medication errors.[9] These points give rise to a universal question surrounding the intersection of IT and research on the prevention of medical errors: Is data gathered as a result of obsolete technology vulnerable to the same obsolescence? According to one report, it takes an average of 17 years for the findings of randomized clinical trials to be adopted into practice, and even then the application is highly uneven.[11] With this gap between research and practice, relevant clinical data pertaining to medical IT systems may always be a step behind the state of the art. This is problematic because the place of IT in health care is relegated to anachronism, creating a barrier to full integration with the system it is designed to serve. This is not to say this technology does not hold great promise for the prevention of ADEs; it is, instead, recognition of the work that lies ahead. In the words of

Dr. Koppel: "All systems are going to create changes and require extraordinary integration [of technology and workflow]. No matter how good the system, constant vigilance, constant analysis and constant tweaking are required to make them function effectively."[9] Affirming this position, at least one study has quantitatively described an increase in ordering errors immediately following implementation of CPOE in a neurosurgical intensive care unit (ICU), insisting upon the need for preemptive integration and thorough training to ensure patient safety.[12] The reality of this suggestion is that the facility implementing this technology may spend more money to get clinicians away from the bedside than for the technology itself.

Apart from this controversy, many clinicians are recognizing the various advantages of CPOE, and evidence-based support for this technology is growing. One trial, evaluating CPOE in medical and surgical ICUs, found that the frequency of preventable ADEs was reduced 17% while serious medication errors with the potential to cause ADEs were reduced by 55%. This drastic reduction in percentage may be contextualized by the actual reduction in the number of serious errors relative to patient days, in this case 10.7 versus 4.86 per 1000 patient days. In this trial, the specific CPOE system featured medication use guidelines, recommended typical doses, administration frequencies, and therapeutic alternatives—all supportive of best practices with regards to prescription.[13,14]

While these seemingly disparate data sets and professional opinions create confusion surrounding the efficacy of CPOE, the relatively limited implementation of these software systems at this point in time presents an opportunity for vendors and clinicians to turn a critical eye on the continual development of CPOE in health care. Dr. Koppel's vociferous criticisms of his dated system are not without value if the health-care community as a whole takes them into account as better technology arises. This proactive position cannot be abdicated as we take on the responsibility of constructively criticizing present technology in an effort to refine the concept for the future. It is essential that this position be defended because this process, like the development of new treatments and pharmaceuticals themselves, is never truly finished. This evolutionary process is complicated by the expansion of CPOE beyond inpatient ICUs that compose the majority of the case studies surrounding CPOE and into yet unsaturated areas of the market, such as family practice. The complication, in this case, stems from meeting the specific needs of many different types of physicians in many different types of practices while ensuring that this beneficial concept does not become prohibitively expensive. This situation would limit the ability of CPOE systems to deliver patient safety not because of their respective efficacies across practices, but because of their limited distribution. As it stands, early adopters of this technology bear a significant financial burden of progressive practice. This is evident in the assertion that it costs approximately $8 million to implement a CPOE system at a 500-bed hospital, with associated annual expenses thereafter totaling $1.35 million.[15] This is staggering in light of the fact that one study found losses per ADEs average $2,200, while losses per preventable ADE average $4,685.[16] This data is contradicted by Rothschild, who estimates that the average cost of defending medical malpractice cases due to inpatient ADEs is $376,000.[17] This second figure fortifies the business case surrounding CPOE, while the first does not.

Regardless of the barriers to success, endeavors aimed at improving patient safety can be viewed as struggles against time. That is, the longer the implementation of effective measures is postponed, the more patients pass through the larger the healthcare system without benefiting from these improvements. In terms of CPOE, there exists a call to action to continually optimize available technology with input from all disciplines involved and then implement this technology widely enough to have a significant positive human impact.

BAR CODE VERIFICATION

No discussion of CPOE systems would be complete without a consideration of the actual administration of medication pursuant to the orders generated by CPOE systems themselves. Without detracting from the importance of an effective CPOE system, it is important to recognize the urgent need to optimize the process of administration of medication at the bedside. This assertion is supported by Bates, who recognizes the fact that errors occurring in the ordering process are the most common type of medication error; however, 48% of these errors were detected and remedied prior to reaching the patient and expressing themselves as ADEs. This fact is set off by the additional findings of the same study, which found administration errors to be less common, but also far less likely to be intercepted prior to reaching the patient.[4] That is, as the process progresses closer to the actual administration of medication to the patient, the likelihood that errors will be detected and prevented decreases, though fewer errors are likely to originate during the administration stage. At this point, the danger lies not in faulty decisions, but in the challenge of remaining true to the clinical decisions already made.

This is not to say that errors result from negligence; That is, the sheer volume of information associated with administration of medication exists as a barrier to diligence. In light of this, it is important to keep in mind that IT complements the work of problem solving but substitutes for tasks that follow specific orders or guidelines that can be programmed directly into software programs. This positions IT perfectly to prevent medical errors originating in the administration process and resulting from the volume of information provided to caregivers so that they may properly administer medication. In this situation, the paradox is that the information intended to protect patients has the opposite effect as it becomes too extensive to diligently monitor in certain structural situations that offer little or no assistance to caregivers.

Several technologies exist to intervene in administration errors, including smart infusion pumps and bar code verification. Implementation of bar code verification has been expedited by the technology's wide use and long history in industries outside of health care. Beyond this long process of development, the Food and Drug Administration mandated in 2004 that all newly approved pharmaceuticals be packaged with a bar code on the label. This aids in the prevention of errors associated with dispensing medications to automated medication cabinets as well as caregivers for direct administration. One study found that the implementation of bar code verification technology reduced dispensing errors by 36% and reduced potential ADEs by 63%.[18] This type of automated recognition system becomes increasingly

important as the number of available pharmaceuticals increases. This is due to the fact that an increased variety of pharmaceuticals saturate the administration process with similar packaging and ambiguous abbreviations.

While bar code verification has proven effective, it does not exist in a vacuum. An effective system must first recognize the details of the physician order, then match the order with the bar code on the medication label, and then verify that bar code on the patient wrist bracelet. This complex process dictates that bar code verification exists as a component of a larger system, a fact that is often overlooked in discussions of this technology, especially in terms of business. Pricing for bar code verification systems ranges from $500,000 to $2 million,[19] while one study estimates annual savings due to prevention of medication errors to be $2.2 million.[15] These figures contrast those surrounding CPOE, presented previously. The perception generated by the separation of the business cases around these technologies is that bar code verification is more accessible than CPOE; however, the ideal system would incorporate all available technologies to ensure optimal patient safety across departments and shifts, from admission to discharge. This would mean CPOE, bar code verification, and smart infusion pumps would be developed in parallel, under the umbrella of electronic medical records.

Looking to the future, systems like electronic medication administration record (eMAR) are approaching this fully integrated model. The relative lack of clinical research surrounding eMAR complicates analysis and implementation of this integrated model, especially as many health-care facilities have invested countless hours and dollars in their existing technologies. At the same time, facilities still using a paper system may be suspicious of an integrated system that has not yet been established as an industry standard. These integrated systems hold the most promise for the prevention of costly medications errors and ADEs, but like any comprehensive system, they have the potential to overpower old workflow patterns in the clinical setting. For this reason, comprehensive systems must be developed with clinicians in mind while simultaneously improving old practices. This means that new systems should be viewed as an opportunity to reform a system conducive to medical errors without becoming the "next cause" of these errors. As a compromise, these systems must also focus on improving workflow and caregiver satisfaction by eliminating redundant data entry. Beyond these points, a comprehensive IT system designed for health care should be able to seamlessly integrate modules to accommodate the future needs of the clinician and the patient as treatments and best practices are continuously developed and improved.

Case Study: The Economics of a Medical Decision Support Tool[20]

While no technology can effectively exist as a substitute for the clinician's decision-making responsibilities, certain technologies can expedite these processes by making sure clinicians have the proper information available to make these decisions based upon all the facts at hand. The process of gathering all the facts at hand is often arduous, especially in a paper system where information is not continuously updated and made available to those charged with analyzing and interpreting this body of information.

This study, by Rebitzer et al., examines the financial impact of an IT support tool developed to notify physicians of impending medical errors in addition to deviations from evidence-based best practices. The premise of this technology is that one cause of medical errors is the sheer volume of information, which must be considered in making an informed decision regarding patient care. The logical solution in this case was to consolidate this information in one accessible place, with built-in warnings pertaining to drug recommendations, suggested tests, and recommendations on when to stop a drug. Additionally, the software operated on three levels of urgency: life-threatening issues, issues with a moderate effect on clinical outcomes, and preventative care issues. In this case, final discretion was, of course, left up to physicians.

Interestingly, the focus of this study was not exclusively clinical outcomes, as is the focus of most clinical trials concerning technology and patient safety. Instead, the focus of this study was the direct cost of patient care. The conclusion of the economic analysis of this decision-support software was that patients in the study group saw lower average charges by 6% compared with the control group. Furthermore, these savings were attributed to reduced inpatient charges for the most costly patients.

While maintaining a focus on the economic case supporting this software system, this study maintains an awareness of the correlation between outcomes and the financial health of the institution. The system itself was concerned primarily with identifying and reporting "remediable" errors, defined in the article as those occurring when physicians are not fully aware of all the available information concerning their patient or the state of relevant medical knowledge. The system safeguards against these types of errors with a built-in second opinion; when the software generates an error message, the data is manually reviewed by doctors employed by the software company. This accomplishes two things. First, it lends a level of legitimacy to the suggestions generated by the system. Second, it allows for human beings to assign a priority level to the error message and ensure that it is returned to the patient and physician for which it was generated.

Case Study: Radio-Frequency Identification Analysis of Human Contact and Infection Control[21]

Despite the complications surrounding the introduction of technology into the working world of health-care professionals, IT holds promise for turning a critical lens on the old channels of workflow. The grievances listed in the CPOE section primarily entail the shortcomings of IT as it fits into the larger scope of how "work is done." This is certainly a difficult obstacle to overcome, especially because predominant analyses of work and workflow rely on testimony, experience, and other qualitative measures that vary widely between facilities and individuals. This inherently varied experience impedes the development of evidence-based, user-friendly technology that is simultaneously implemented widely enough to follow patients throughout their life to ensure that their needs are met and their safety is prioritized. While the discussion thus far

has maintained a focus on health care at the macro level—reducing medication errors, maintaining patient records, and so on—we now shift to a micro-level discussion of creative uses of technology in examining human interaction in health-care facilities.

A 2011 study by Isella et al. employed wearable radio-frequency identification (RFID) devices to measure the frequency and duration of human interactions in a general pediatric ward of the Bambino Gesù Hospital in Rome, Italy. Because RFID technology recognizes proximity and time, it is useful in electronically recording contact conducive to the spread of nosocomial infections. The authors recognize that the knowledge of patterns of transmission is essential to identify specific mechanisms that favor transmission and thus to set up tailored intervention strategies such as social or physical barriers, targeted immunizations, pharmaceutical interventions, and other measures aimed at preventing transmission and controlling the spread of disease. This is vital to patient safety as well as the financial security of our health-care system. It has been suggested that infection control is one of the most cost-effective endeavors among today's public health projects.[22] The data gathered from this study included 119 individuals on the unit: 10 ward assistants, 20 physicians, 21 nurses, 37 patients, and 31 caregivers. This 1-week study recorded nearly 16,000 contacts.

There are three items to note about this study before continuing: (1) the RFID tags record only proximity—they do not record physical contact or the presence of any infectious material, so their utility in this case is limited to simulating the spread of respiratory infections; (2) even though the majority of patients were discharged with a potentially transmissible disease, no evidence of nosocomial transmission was reported during the study; and (3) infection control efforts during the study were greatly increased because the study coincided with the peak of A/H1N1v infections in Italy.

The relative paucity of adverse outcomes in this study and the associated absence of causality seem to negate the revolutionary nature of this work. While the aim of the study itself is the prevention of nosocomial infection, it accomplishes this goal through a proactive analysis of workflow. That is, the snapshot of human interaction equated with the potential for spreading nosocomial infections is the truly valuable data in this case. In this case, staffing procedures and patient movement strategies meant that the main finding of the study was that there was very limited interaction between pairs of patients and between pairs of patient care staff members. This is in opposition to physicians and nurses, who had regular contact with multiple patients and coworkers. Suffice it to say, these findings are facility-specific and result from respective policies and procedures; however, they present a technology with potential for assessing unit risk for adverse nosocomial events. This is exacerbated by the fact that the study considered multiple classes of employee within the unit instead of simply dividing subjects into employees and patients, allowing the heterogeneity of classes of workers to be identified as a passive barrier to infection.

This detailed, quantitative analysis of the relationship between something as loathed as nosocomial infection and something as necessary as staffing provides a new way to look at causality. If this approach is applied to units with

higher-than-average rates of nosocomial infection and frequency or type of interpersonal contact can be cited or (better yet) ruled out as causal to adverse outcomes, then focused action can be taken. In this, technology has provided the analytical tools to optimize something as quotidian as workflow, providing an evidence base for patient safety prioritization in staffing practices. It can be said here that the best uses of technology in health care emerge as responses to the daily needs of health-care staff, contextualized by the evidence base. This study by Isella et al. heeds the call of the *Study on the Efficacy of Nosocomial Infection Control* by addressing structure (generated by evaluating workflow data) and process (present in the RFID methodology)—two elements long associated with lowering infection rates.[23]

CONCLUSION

On September 12, 1962, John F. Kennedy, Jr. visited Rice University in Houston, Texas. He insisted that within 10 years of that date Americans would walk on the moon. In his exact words, "We choose to go to the moon. We choose to go to the moon in this decade and do the other things, not because they are easy, but because they are hard, because that goal will serve to organize and measure the best of our energies and skills, because that challenge is one that we are willing to accept, one we are unwilling to postpone, and one which we intend to win, and the others, too." On July 20, 1969, Neil Armstrong stepped out of the Apollo 11 spacecraft and onto the surface of the moon, in an event that culminated and certainly overshadowed the decades of work leading up to that moment.

On February 2, 2005, George W. Bush issued a similar call to action in his State of the Union address. He called for every American to have an electronic medical record within 10 years, citing the need for "improved IT to prevent medical error and needless costs." As we rapidly approach the 2015 deadline of this dream, we are forced to take inventory of our progress so far.

Perhaps, however, the appropriate perspective in this situation draws upon both Kennedy and Bush. In this case, the projection of the goal has once again overshadowed the process and the progress necessary to achieve this monumental national project. At the core of the issue is the hard work of interdisciplinary professionals and experts who stand to contribute to this great marriage of IT and medicine. This core concept—that technology is a constant process of development—must never yield to the ideology of the current age, which lauds technology as a solution rather than a tool. In upholding this idea, we may consider transposing the latter half of the Kennedy passage upon the lofty goals of the Bush speech, revealing that we do need national IT capabilities with regards to health care, but first we must recognize and respect the scope of the project ahead.

Beyond this recognition of the scope of the project itself, development and implementation of IT aimed at reducing the frequency and severity of medical errors must be viewed as an opportunity to reform the systems designed to deliver care in the first place. This begins with a thoughtful unification and standardization of available technologies, complemented by the ability to develop and integrate new components as the practice of medicine itself expands and improves. For too long, IT in medicine

has been "balkanized," divided unnecessarily according to the task at hand. This is in contrast to comprehensive integrated IT systems, which follow the individual patient from task to task. The "balkanized" model, on the other hand, features an unfortunate pattern of following the task from patient to patient, resulting in undue opportunities for errors of conflation or confusion. A truly effective IT system must be able to strike a balance between the task-oriented model and the patient-focused model to maintain established patterns of workflow and culture in facilities while following the individual patient across facilities, departments, treatments, and individual caregivers. Essentially, the largely divided channels of patient care stand to be unified in the service of the patient through comprehensive IT systems; however, the unification of technology itself is the immediate challenge.

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16 Nursing Injury Rates and Negative Patient Outcomes
Connecting the Dots

William Charney and Joseph Schirmer

CONTENTS

The connection between nursing injury rates and patient outcomes has not been totally grasped in the health-care occupational health setting. This article concludes that nursing injury rates are linked to the nursing shortage and less nursing time at the bedside, both of which have been scientifically linked to negative patient outcomes. Because nurses' working conditions affect patients' outcomes, more funding and changes are needed to improve these conditions.

Since an Institute of Medicine report describing nurses' work environments as a potential threat to patient safety, legislative campaigns focusing on nurses' working conditions have been successful in Washington, Texas, Maryland, Rhode Island, and Minnesota (Institute of Medicine 2004). Despite this progress, most of the ongoing work to improve safety in health care continues to focus on the patient side of the equation. Substantial research confirms the association between hospital nursing capacity and patient outcomes (Aiken 2005; Aiken et al. 2003; Aiken, Clarke, and Sloane 2002; Aiken et al. 2001; Aiken et al. 2002; Estabrooks et al. 2005; Rafferty, Ball, and Aiken 2001).

Also, many studies associate current nursing working conditions with medication errors, falls, mortality, and spread of infection (Alonso-Echanove et al. 2003; Amaravadi et al. 2002; Andersen et al. 2002; Archibald et al. 1997; Arnow et al. 1982; Fridkin et al. 1996; Haley et al. 1995; Harbarth et al. 1999; Knauf et al. 1997;

Kovner and Gergen 1998; Kovner et al. 2002; Lichtig et al. 2002; Needleman et al. 2002; Robert et al. 2000; Stegenga, Bell, and Matlow 2002; Vicca 1999).

Another Institute of Medicine report concluded that nursing is inseparably linked to patient safety, emphasizing that poor working conditions for nurses and inadequate staffing levels increase the risk for error (Institute of Medicine 2000). Nurses' working conditions are related to the risk of health-care-associated infections among patients and occupational injuries and infections among staff (Centers for Disease Control and Prevention 2004). The sidebar contains general categories of hazards that nurses face in health care.

GENERAL CATEGORIES OF HAZARDS NURSES FACE IN HEALTH CARE

- Communicable diseases: Blood-borne pathogen exposures, human immunodeficiency virus, hepatitis C virus, and hepatitis B virus due to percutaneous needlestick injury. Between 600,000 and 800,000 such injuries occur each year, with injections (21%), suturing (17%), and blood draws (16%) being the top three exposures (Perry, Parker, and Jagger 2003).
- Musculoskeletal injuries: Patient movement and handling. Thirty-eight percent of all nurses experience back injuries, 98% of which are due to lifting patients manually (Meier 2001).
- Violence: An estimated 9.5% of nurses in general nursing are assaulted annually (Gerberich et al. 2004; Wells and Bowers 2002). The Minnesota nurses' study (Gerberich et al. 2004) reported that both physical (13.2) and nonphysical (38.8) violence rates are on the rise for emergency department, long-term care, intensive care, and psychiatric–behavioral care nurses.
- Chemicals: Related to patient treatment and maintenance of proper environment (e.g., formaldehyde, glutaraldehyde, and waste anesthesia gases).
- Stress: In a recent American Nurses Association (ANA) survey, nurses cited stress and overwork as their top safety concerns (ANA 2004).

This chapter suggests that nursing injury rates contribute both directly and indirectly to negative patient outcomes. Nursing staff injuries (A) influence staff ratios, which (B) influence patient outcomes, and therefore (C) nursing staff injuries influence patient outcomes. Algebraically stated, if A changes B, and B changes C, and then A changes C. Negatively affected staff ratios produce negative patient outcomes. If nursing injury rates negatively affect patient outcomes, more resources and energy must be devoted to enhancing working conditions, reducing the physical demands of the job, and building a culture of safety.

NURSING INJURY RATES

When health-care industry acute-care lost-time injury rates are added to long-term care injury rates using the health-care standard industrial classification (SIC) and North American industry classification (NAIC) codes in each state, health care is one of the most dangerous industries (Bureau of Labor Statistics [BLS] 2002). National data compiled by the BLS indicate that the rates of work-related injury or illness requiring treatment or lost work time were 8.8 per 100 full-time hospital workers and 13.5 per 100 full-time nursing home workers in 2001. These rates contrast with national data indicating annual rates of 4.0 per 100 in mining, 7.9 in construction, and 8.1 in manufacturing. With approximately 2.8 million nurses and 2.3 million nursing assistants in the United States, these rates constitute a national epidemic (Institute of Medicine 2004).

Psychiatric facilities are a subset of dangerous health-care organizations, with high rates of nursing injury due to violence. In New York state mental health facilities, the nursing injury rate was 24 per 100 full-time equivalent employees in 2005. Therapy aides had a rate of 35 injuries per 100 full-time equivalent employees in 2005, and secure hospital treatment aides (those working with the criminally insane) had a rate of 94 per 100 full-time equivalent employees (anecdotal data from J. Rosen, personal communication 2006).

Musculoskeletal injuries often occur among nursing staff while they are moving and transferring patients and result in substantial losses to employers and employees in terms of time and money. In the private health-care industry, 435,180 lost-time musculoskeletal injury claims were filed in 2005. Although this number includes all health-care workers, based on other studies, it can safely be assumed that a high percentage of these claims were nursing injuries. A median of 10 days away from work per injury, or 4,351,800 lost days, was reported in 2003 (BLS 2003). In addition, the underreporting of these injuries, which have been reported to range from 50 to 76 per 100 annually (Nelson and Baptiste 2004), must be considered.

The authors suggest these high rates of injury are linked to the national nursing shortage and also to the high turnover rates experienced in both acute and long-term care facilities. The national vacancy rate for registered nurses (RNs) stood at 13.6% in 2003, more than twice the rate of 5.6% in 1998 (American Health Care Association 2003). The national turnover rate for RNs was 14.6% in 2003. Nationally, certified nursing assistant turnover was estimated at more than 71% in 2002. Harrington (2005) testified that turnover is directly related to heavy workloads and poor working conditions. She cited at least two Institute of Medicine studies to support her claim (Wunderlich and Kohler 2001). Staff shortages increase the risk of injuries.

Trinkoff and Johantgen (2005), examining the relationship between staffing and worker injuries, concluded that nursing homes with fewer nursing hours per resident-day were associated with significantly increased worker injury rates. Several studies equate a lack of nursing staff hours with negative patient outcomes, but studies evaluating the relationship between staffing levels and nursing injury rates are rare (Needleman et al. 2002).

In 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reported that low nursing staff levels in 1609 hospitals were a contributing

factor in 24% of patient deaths and injuries (JCAHO 2002). This same report also concluded that "physical working conditions" are key contributors to turnover and burnout associated with nursing shortages, but did not quantify the relationship.

Shamian et al. (2001) found that 44% of nurses reported missing work due to illness at least once in the preceding 3 months. This article concluded that injuries among nurses are costly to hospitals in terms of lost productivity and are implicated in the loss of qualified nursing personnel from the work force and the delivery of quality patient care.

Clarke, Sloane, and Aiken (2002) found that nurses working on hospital units with compromised organizational climates and lower staffing levels were substantially more likely to report risk factors associated with needlestick injuries. Nurses on units with lower staffing levels, less nurse leadership, and higher levels of emotional exhaustion were twice as likely to report staff carelessness and inexperience.

Currently, 90% of long-term care facilities lack sufficient nursing staff to provide even the most basic care (JCAHO 2005). Long-term care facilities also have one of the highest injury rates (13.8 per 100 full-time equivalent employees) and one of the highest annual turnover rates (50%–75%) in the nation due largely to heavy workloads, poor working conditions, and low wages (Harrington 2005).

The American Society of Safety Engineers reported that a critical nursing shortage loomed nationally (Ramsey 2005). Several factors, including the strong likelihood of experiencing severe occupational injury or illness (e.g., blood-borne pathogens) and workplace violence, are suspected causes.

The Workplace Safety and Insurance Board (2002) reported that nurses' injuries are costly to hospitals in terms of lost productivity, workflow disruption, and claims paid, and costly to nurses in terms of pain, stress, and possible employment loss. Protecting nurses from disabling injury will be key to recruitment and retention.

PATIENT OUTCOMES

Many studies have examined the impact of nursing care on patient outcomes. The ANA identified 10 patient outcome indicators particularly sensitive to the quality of nursing care (e.g., nosocomial infection rates, patient injury rates [falls], pressure ulcers, and patient satisfaction with overall care and with pain management) (Trossman 2000).

As RNs deliver less direct care, patient outcomes suffer. For example, Lichtig, Knauf, and Milholland (1999) found a statistically significant inverse relationship between the percentage of patient care delivered by RNs and the incidence of urinary tract infections, pressure ulcers, and postoperative infections. Blegen, Goode, and Reed (1998) found an inverse relationship between RN hours per patient and medication errors, decubitus, and patient complaints. Shamian et al. (1994) found that more nursing hours per patient resulted in shorter stays for patients in 10 of 11 units studied.

Needleman et al. (2002) examined nurse staffing levels and their association with risk to patients as measured by fatalities or complications. They studied 799 hospitals in 11 states to determine the relationship between the level of care provided by

nurses in the hospital and patient outcomes. Among adult nonsurgical patients, a higher number of hours of care per day provided by RNs was associated with shorter stays and lower rates of urinary tract infections, upper gastrointestinal tract bleeding, pneumonia, shock or cardiac arrest, and failure to rescue (i.e., lower rates of failure to resuscitate).

DISCUSSION

Due to more than 10% of nurses nationally submitting workers' compensation claims for injuries (based on adding NAIC codes 622 and 623) and millions of days lost to injury, less nursing hours are spent at the bedside and a national nursing shortage exists, both of which have been shown to result in negative patient outcomes. High nursing injury rates continue under the prevailing system, making it difficult to replace nurses and increase nursing hours at the bedside. Thus, nursing injury rates also result in negative patient outcomes.

Clarke and Aiken (2006) pointed out that a substantial body of research exists confirming an association between hospital nursing capacity and patient outcomes both within and across countries with differently organized and financed health care. They reported that recent studies conducted in the United States, Canada, England, Switzerland, and New Zealand revealed that the adequacy of nurse staffing and the quality of the work environment were associated with the quality of patient care. They found that patients tended to be at heightened risk in hospitals with poor work environments.

Nursing working conditions taken as a subset have a substantial effect on nursing injury rates, nursing shortages, and nursing hours at the bedside. On an ANA survey, nurses cited a disabling back injury (60%) followed by contracting hepatitis from a needlestick injury (45%) as their top safety concerns (ANA 2001). The survey also revealed that less than 20% of respondents felt safe in their current work environment. For years, the health-care industry has been aware of the dangerous conditions that nurses face on wards. Aiken et al. (2001) reported that one in three nurses younger than 30 was planning to leave his or her job within the next year. Burnout, back injury, infectious disease exposure, stress, violence on the job, and verbal abuse all contribute to the physical demands of nursing.

The top reason nurses leave the profession, aside from retirement, is to seek a job that is less physically demanding (JCAHO 2002). The ANA reported that more than 90% of the nurses surveyed indicated that health and safety concerns influenced the type of nursing work they chose to do and the probability that they would continue to practice nursing (ANA 2001). In this same study, 18% of respondents indicated that safe needlestick devices were not made available by their facilities, and nearly 60% said that patient lifting and transfer devices to prevent disabling back injuries were not provided by their organizations.

In a national survey by the American Federation of Teachers, 56% of nurses and 64% of x-ray technicians suffered lifting-related injuries, chronic pain, or both (Hart 2006). This study revealed their work has become so physically demanding that nurses and technicians report they have considered leaving patient care as a

result. Nelson found recruitment and retention of nurses to be an ongoing problem and the nursing shortage to have been exacerbated by occupational injuries (Collins 2006). Physical workload and fear for their safety are major reasons nurses leave the profession. The American Federation of State, County and Municipal Workers (2006) found that licensed nurses who are choosing to leave the profession (19.7%) cite concerns over workplace safety as a reason. The American Organization of Nurse Executives, on surveying 4910 RNs, reported that 43% planned to leave the profession within the next 3 years because of the work environment (Moses 1992). Moses (1992) found that 12%–18% of RNs will eventually leave the profession due to chronic back pain. In a recent Washington state survey, 55% of nurses reported they were so disheartened with the profession they would not recommend it to others as a career (W. Charney, unpublished data 2005). The hiring of temporary per diem nurses who may be less familiar with standard procedures and inadequately trained in workplace polices may also contribute to an unsafe working environment.

Powell-Cope et al. (2003) pointed out that an article on the nursing shortage by Berliner and Ginzberg (2002) did not address the physical demands of nursing. This has been the rule rather than the exception in the literature on the nursing shortage. Media coverage of the nursing shortage has mentioned pay, patient-nurse ratios, the aging nursing work force (average age of 46 years), and physician–nurse relationships as possible causes, often neglecting to mention occupational health and safety issues, risks that nurses face each shift, or national nursing injury rates.

Patient safety cannot be adequately addressed if employee safety is not being adequately addressed (Institute for Healthcare Improvement 2007). However, this concept has not taken a firm hold in the health-care industry, and in some instances, health-care workers become patients due to on-the-job injury. Few Occupational Safety and Health Administration (OSHA) regulations have been written specifically for the health-care industry, with the exception of the Bloodborne Pathogens Act, amended to include the Federal Needlestick Safety and Prevention Act (2001). OSHA conducted 413 inspections in SIC code 806 and (acute care) and 725 inspections in SIC code 805 (nursing homes) in 2005 (OSHA 2007), less than 3% of its annual projected inspection total of 37,500 (Snare 2005) in health-care facilities. JCAHO, in its environment of care sections, has standards for waste handling, safety committees, emergency preparedness, and written safety programs, but its standards are generic at best.

IN SUMMARY

Nursing injury rates and negative patient outcomes—connecting the dots shows

1. Nursing injury rates are directly connected to the national nursing shortage.
2. Nursing injury rates are directly related to a reduction of nursing hours at the bedside.
3. Nursing injury rates are a major reason nurses leave the profession.

When all of the above are combined, nursing injury rates yield negative patient outcomes (Charney and Schirmer 2007).

CONCLUSION

The association between nursing injury rates and negative patient outcomes could lead to substantial changes in occupational health nursing as nurses seek to protect the industry's human investments. The average hospital spends one-tenth of 1% (0.0001%) of its total operational budget on health and safety programs and systems (W. Charney, unpublished data 2005). This is much lower than expenditures on patient safety programs. If the health-care industry accepts the association between dangerous working conditions for nurses resulting in high injury rates and negative patient outcomes and if building a culture of safety will protect both employees and patients, more resources must be allocated to these programs.

It is clear that the nursing injury rate contributes to the nursing shortage and, in turn, the shortage contributes to the nursing injury rate. Investing in protecting the health and safety of nurses will in essence contribute to protecting patients. This means mechanizing patient lifting, reducing ergonomic stress through better architectural planning for both new construction and renovations, purchasing engineered needles to eliminate needlesticks, creating schedules that reduce fatigue and negative shift-work outcomes, and creating effective staffing ratios in nursing and ancillary departments.

The association between nursing injuries and patient outcomes is important to all health and safety departments, including occupational health, risk management, safety, and infection control. The final "dot" to be connected in the process of analyzing how to better protect patients is safety. Protecting health-care workers is directly connected to protecting patients, reducing nosocomial infection rates, reducing health-care errors, and yielding a balanced approach to the overall safety systems and culture. Budgets for occupational health in health-care institutions should be considered part of the overall plan for protecting patients.

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17 Industrial Hygiene for Health-Care Workers
Exposures Causing Injuries

John H. Lange, Giuseppe Mastrangelo, and Luca Cegolon

CONTENTS

SUMMARY

Industrial hygiene (IH) involves the prevention of disease and injury in the work environment. Traditionally, industrial hygienists worked in heavy and construction industries, but as these settings have changed, so has the role of IH. Diseases and injury in the health-care industry have become of greater concern, especially in light of increasing workmen's compensation rates and a rise in resistant pathogens (microbes). Today, other hazards are emerging as a concern for health-care workers, such as mercury, sharps, shift work, and antineoplastic agents. Few health-care workers have an understanding of IH and its role in disease prevention.

INTRODUCTION

IH, as a profession and occupation, is relatively new for a concept that has existed for millennia. This field is really not a primary scientific area of its own but rather a compilation of many areas of science and engineering, although one can say that it can include other subject areas, such as law, sociology, and psychology. Primarily, however, industrial hygienists concentrate in the areas of biology, chemistry, physics, statistics, and epidemiology. There are some areas that exist more strictly in the domain of IH, including personal sampling, respirator protection, other forms of personal protective equipment (PPE), and safety-related practices, for example. As mentioned, other areas such as ventilation, toxicology, management, ergonomics, biological monitoring, and the like cover a range of numerous other occupations including IH. This diversity makes IH a somewhat complex subject. Most industrial hygienists have been generally trained in a broad overview of IH and often develop an area of specialization or interest. Such specialization can be by type of activity (e.g., respirators) or industry (e.g., mining), or in some cases a combination. Here, the focus is on health-care workers (HCWs), who themselves are a highly diverse population, ranging from maintenance personnel to executives. However, some of the issues relating to HCWs are somewhat unique to this group (e.g., sterilization agents).

IH for hospitals, clinics, health centers, and HCWs can be considered very broad in scope since the activities of these occupational groups can include almost anything that can be imagined in an industrial setting, including new construction and renovation. However, in this chapter, there will be a focus on those hazards and activities more directly associated with work practices of HCWs. There will be a very limited discussion of ergonomics (Lorusso, Bruno, and L'Abbate 2007), although this subject area is of great importance to this occupational population and related legal concerns, specifically that of workmen's (workers') compensation. Such injuries can also impact the productivity of workers and how they work together. The major, more traditional hazards for HCWs are related to chemical exposure, including chemotherapeutic agents and infectious disease. Historically, these concerns were ignored, but as workers' compensation rates increase and the type of employment in communities changes, so does the view of occupational safety and health. With the outbreak of severe acute respiratory syndrome (SARS) (Lange 2005), concern about infectious disease in this population has rapidly emerged, although it always existed. That there is a high potential of disease(s) infecting not only the general public but HCWs as well has been further emphasized in the recent case of the person with tuberculosis traveling the world and the occurrence of swine flu (Sampathkumar 2007; Farley 2010). This raises the issue of antibiotic-resistant microbes, which are becoming of greater concern not only in hospitals and clinics but also for the general public (Barlow and Nathwani 2005; Jeyaratnam et al. 2006).

This chapter focuses on the hospital and clinic environment with general principles relating to this profession being extracted from the more traditional areas of IH, such as are observed in heavy industrial settings. For example, chemicals associated with exposure to HCWs are different in name; however, they can result in similar problems (e.g. cancer, dermatitis). There are also ergonomic problems for HCWs, such as those associated with lifting patients (Lorusso, Bruno, and L'Abbate 2007).

This is becoming one of the major issues related to health care, mostly associated with costs incurred as a result of workers' compensation claims (Occupational Safety and Health Administration 2005). However, most health-care settings have not fully considered or realized the hazards in this workplace, especially when discussing some of the chemicals (e.g., oncogenic substances) (Kosgeroglu et al. 2006; McDiarmid 2006) and biological hazards (tuberculosis) that exist (Tam and Leung 2006; Menzies, Joshi, and Pai 2007). Hazards from chemicals for the most part are more of a chronic problem, and the issues associated will not be realized for decades.

Some hazards for HCWs are somewhat unique to this industry, such as needlesticks and blood-borne pathogens. Psychosocial issues are also emerging as a major hazard among HCWs. Much of this relates to the stress of the working environment and shift work (Department of Health and Human Services/Centers for Disease Control and Prevention/National Institutes for Occupational Safety and Health [DHHS/CDC/NIOSH] 2002). This is emphasized by the suggestion that shift work can result in increased rates of cancer (Mead 2007). Certainly, this type of suggestion raises the issue as to whether activity like shift work can be labeled as a potential carcinogen. Issues of this nature may be the most popular, but overall are uncontrollable due to the nature of health care. Certain interaction with various agents will also impact diseases due to shift work. As this industry grows and more complex chemicals and agents are used in treating disease, the enormity of the hazards will increase as well. Issues such as shift work will also begin to impact HCWs and their health, and there must be a greater awareness of the changes that are on the horizon.

Changing conditions in health care, especially as related to reimbursement, will impact IH for HCWs. Today many are asked to perform multiple tasks and are receiving less training on secondary jobs. This can increase exposure and risk, along with decreasing the number of workers available to treat and provide support to patients and provide necessary services. Changing roles in health care make many functions more complex and difficult. Recently, there has also been a push to require lower-level personnel to be involved in treatment processes with less supervision. As health care changes, so will the risks and activities of protection and the role of IH.

HISTORY

Occupational protection, which is the basis of IH and can also be considered occupational safety and health, occupational hygiene, or health and safety, has been practiced since the beginning of time. In the Greek and Roman periods, various diseases were attributed to exposure that occurred during activity in one's occupation. For example, archers in the Bronze Age employed finger and wrist guards as a form of PPE (Gochfeld 2005), and later it was reported by Pliny the Elder that miners in an effort to prevent respiratory disease from dust used loose bladders as a form of a respirator (respiratory protection). It could be said that this was the first "functional" respirator. Thus, PPE, in some form, has probably been used since the beginning of man. It has been suggested that one of the first "reports" of issues with occupational health was by Edwin Smith Papyrus in around 1700 BC (Gochfeld 2005). After that Hippocrates (about 460–370 BC) recognized and discussed occupational

diseases (Rose 1997) as well as attempted to suggest solutions. He examined the relationship between air and water in creating an impact on health (Gochfeld 2005), which remains an important factor today although sometime it is forgotten in what is termed "modern technology."

In many ways, the initial scientific observation of occupational health hazards may have been started by Paracelsus and Agricola in the fifteenth century, when they noted and reported diseases related to mining and similar activities. The first "true" published account of IH, at least in reference to it, was by Bernardino Ramazzini, who published *De Morbis Artificum Diatriba* in 1713. Ramazzini is often considered to be the father of occupational medicine and, through his textbook, suggested mechanisms for reducing occupational exposure and disease. For the most part, this was the first textbook on occupational medicine and it can be said to have given rise to IH. After this, there were no notable published accounts on this subject until Charles Thackrah published a book on occupational diseases mostly related to the industrial environment in England in the 1830s. His work helped develop legislation in England that established worker protection laws and, in many ways, was a continuation of the Chimney-Sweep Act of 1788 that resulted from the work of Percival Pott. Practically, the modern view of occupational health began in England mostly as result of the hazards created through the industrial revolution (Carter 2004).

In the United States, IH emerged through the work of Alice Hamilton around 1910. She investigated working conditions in the United States. This investigation ultimately resulted in the formation of the Division of Industrial Hygiene in the United States Public Health Service, which later became the Nation Institute for the Occupational Health and Safety (NIOSH). NIOSH is the research arm of the Occupational Safety and Health Administration (OSHA). Various major industrial disasters, such as that at Galley Bridge in West Virginia, led to dramatic changes in standards and practices. These events lead to the ultimate formation of OSHA.

For those in health care, the history of IH is much shorter. Historically, one of the major hazards for those in health care was infectious disease. This is best exemplified with tuberculosis. Tuberculosis and mycobacteria-related diseases (leprosy) have been recognized as occupational risks since the time of Aristotle (Sepkowitz 1994). It was shown in the 1920s that there was a high risk of HCWs (e.g., nurses) contracting tuberculosis as a part of their profession (Heimbeck 1928). More recently, the outbreak of SARS further demonstrates the susceptibility of these infectious agents to HCWs (Lange and Mastrangelo 2006).

The importance of chemical exposure to HCWs is just beginning to be recognized. Many of these involve chronic scenarios and some appear to increase risks of cancer or other effects (Fransman et al. 2007). This along with ergonomic problems and the potential hazards associated with shift work are important issues to be addressed in the future.

HAZARDS ASSOCIATED WITH HCWs

A partial list of hazards for HCWs is shown in Table 17.1. The exact hazards encountered will depend on what type of activity the person does in a hospital or healthcare setting. The routes of exposure include inhalation, dermal, ingestion, and

TABLE 17.1
A Partial List of Some Common Hazards Encountered by Health-Care Workers and an Example of the Hazard

Chemical/Group/example	Hazard/Reference
Anesthetic agents[a]	Reproductive toxicity (Nayebzadeh 2007)
Disinfectants[b]	Contact dermatitis, asthma (Fujita et al. 2007)
Sterlizers	Ethylene oxide (Landrigran et al. 1984)
Ethylene oxide	Leukemia, spontaneous abortions (Landrigran et al. 1984)
Mercury	Congenital defects (Matte, Mulinare, and Erickson 1993)
Radionucleotides	Cancer (Shortridge-McCauley 1995)
Radiation[c]	Congenital defects (Matte, Mulinare, and Erickson 1993)
Formaldehyde	Contact dermatitis (Ravis et al. 2003)
Glutaraldehyde	Asthma (Cohen and Patton 2006)
Sharps (needlesticks)	Infectious disease (Gershon et al. 2007)
Antineoplastic agents	Cancer (Shortridge-McCauley 1995)
Biological agents	Infections (Shortridge-McCauley 1995)
Shift work	Cancer (Mead 2007)
Injuries (ergonomics)	Back pain (Lorusso, Bruno, and L'Abbate 2007)

[a] Example is nitrous oxide.
[b] For ortho-phthalaldehyde.
[c] Can be ionizing and nonionizing.

injection. These hazards include physical, chemical, and biological and can result in both acute and chronic effects. The discussion of these hazards will focus on examples from the general subjects of their chemical, physical, and biological properties. Ergonomics have become of great concern for HCWs along with issues relating to shift work. One difference between the health-care industry (HCI) and many other industries is that ingestion is a major concern. A brief discussion of these topics is presented.

A discussion of various topics will be presented as an attempt to illustrate the hazards and IH activities associated with HCWs and hospitals. However, many of these hazards can also be encountered in ambulatory health-care settings and related situations (e.g., dental offices). It must be remembered that a variety of different types of personnel can be exposed to any one of these agents and that a single substance is not restricted to one classification or occupational group.

Due to the complexity of the subject matter regarding IH and the HCI, only a limited number of topics can be presented. There are a large number of IH (Plog and Quinlan 2001) and toxicology (Klaassen 1996) books that can provide a fundamental discussion of general topics. In some cases, material safety data sheets (MSDSs) will provide useful information on substances that are encountered in the HCI. However, in many instances, this does not provide a detailed discussion of the general topic. This is mostly due to MSDS being prepared for legal protection for those using the substance rather than being informative on toxicology, safety, or IH.

Most HCWs have never been trained to understand MSDS or how information can be extracted and applied for practical application. Other informational sources such as that found on MEDLINE (PubMed) can also be useful.

ANESTHETIC GASES

There are a number of anesthetic gases that are commonly used in the HCI. The ones frequently used today include nitrous oxide (N_2O), enflurane, isoflurane, desflurane, sevoflurane, and halothane. It has been estimated that there are 200,000 or more HCWs routinely exposed to these agents, with some in nonhospital settings such as dental offices. There are a number of routes and mechanisms for these agents to leak into the atmosphere and result in exposure. Routes of exposure or leaks include spillage, poorly fitting masks, incomplete connections, and leaks in lines and connections. In small facilities, exposure may be totally unrecognized, especially since the gas is sometimes now administered by quasi-trained employees. Cross training is now becoming a common theme with HCWs. However, most do not have the basic background in science or health-related information (e.g., pharmacy) to understand and establish a high level of competence.

Exposure may also create added hazards due to the changing requirements of HCWs. This may become more critical and of greater concern as health-care dollars shrink and workers are required to take on a larger diversity of tasks. For example, medical assistants and others are now being asked in some facilities to maintain, clean, disinfect, and prepare agents and materials. Mostly this occurs in smaller facilities. Overall, many receive limited training in the area(s), usually from another coworker, and will work alone in conducting the activity. Although the volume of work may be small, short-term and chronic exposure could be great and is an unidentified hazard.

Many of those exposed to these gases, especially in excessive amounts, suggest that they feel like they are being anesthetized. This can result in confusion, depression, irritability, headaches, drowsiness, and poor coordination in the short-term. Overall, these effects can result in poor judgment and place patients at increased risk. It may also ultimately increase absences among employees, resulting in an increased cost to the health-care facility.

For long-term effects (chronic), studies have been less conclusive in regard to outcomes at low doses. However, there have been suggestions of increased risk for spontaneous abortions, congenital problems, liver and kidney disorders, and cancer (Ahlborg and Hemminki 1995; Szymanska 2001). For example, chloral hydrate has been suggested to increase the risk of cancer in patients at various sites (lung, stomach, prostate, skin, and mouth) after short-term application (Haselkorn et. al. 2006). Although this study was not directly related to HCWs, extrapolation of such cancers can easily be made to this population considering that their exposure would be chronic. Overall, such reports are consistent with other studies of those administrating anesthetic agents and suggest that some of these agents may be carcinogens. Most of the anesthetic gases do not have permissible exposure limits (PELs), although some, such as nitrous oxide, do have threshold limit value (TLV), which is 50 ppm-time weighted average (TWA). Halogenation with the gas should be considered in

evaluating the exposure level. If halogenated agents are used alone, Herr et al. (2008) suggest a value of 2 ppm. When combined with N_2O, this value should be lowered to 0.5 ppm, and the N_2O should be 25 ppm. It has been suggested that halogenated agents combined with other anesthetics can result in a synergistic effect, which is the reason for the lower value.

DISINFECTANTS

Use of disinfectants is a common and necessary practice in the HCI. Classification of this type of agent can be considered broad and include, for example, bleach, ethyl and isopropyl alcohol, petroleum products, quaternary ammonia, sodium hydroxide, phenol compounds, formaldehyde, and glutaraldehyde. The health effects from this group can be considered diverse, but in general, the major hazards encountered will be dermatitis and skin problems (Kampf and Loffler 2007). Other issues such as asthma, eye irritation, headache, and nausea may also occur. However, inhalation can also be a concern, especially in confined locations. When examined from a chronic point of view, effects on the hepatic, central nervous system, and liver must be considered, along with cancer. Noncancerous effects also likely occur but have not been very well studied or investigated.

As care extends out from centralized facilities, more HCWs are becoming involved in disinfectant activities. The diversity of disinfectants makes a list of health effects difficult if not impossible. This will also tend to make detection of problems, especially epidemiologically, difficult in disease events. This may place many HCWs at risk from disinfectant exposures, and in many cases, most will have little awareness of the hazards they encounter. In some case, HCWs do not know what products they are using. This occurs as a result of frequent changes in purchasing of materials due to cost. Here, cost may change, resulting in purchasing of different materials over time with little consistency. Such changes can dramatically vary exposure along with a difference in the "base" chemical or substance. This may be most critical in smaller settings in which disinfectants are used to "sterilize" instruments and equipment, with this work being conducted by personnel on a part-time basis. Awareness of exposure effects is likely not well recognized by this population of HCWs and likely constitutes an unknown and unrecognized hazard.

FORMALDEHYDE

Formaldehyde is a common chemical used in health-care situations. It is frequently used in pathology and hemodialysis and for the sterilization of instruments. This chemical can be a liquid but also exists as a colorless gas and is soluble in water. As a gas, it can cause irritation to the eyes and mucus membranes. In industry, it is mainly used to produce resins. Formaldehyde can enter the body through inhalation, ingestion, and dermal absorption. It can also be injected, but this is not a common route of exposure. Eye irritation and injury can occur from formaldehyde, mainly as result of direct exposure.

The current PEL is 0.75 ppm-TWA and an action level of 0.5 ppm-TWA. A ceiling limit of 0.3 ppm has been established by the American Conference of Industrial

Hygienists (ACGIH). High concentrations of 50–100 ppm have been reported to cause pulmonary edema and death.

Multiple exposures to this chemical can result in sensitization, which will result in the person not being able to detect the odor. Exposure(s) can result in an immunological response along with upper respiratory irritation, including sensation in the nasopharyngeal area. Dermatitis is a common condition associated with long-term exposure to liquid formaldehyde. One study suggested that about 13% of the U.S. population immunologically responded to formaldehyde when patch tested (Warshaw et al. 2007).

Historically, this chemical has been identified as a carcinogen, specially related to the nasopharyngeal area. This has been primarily based on animal studies. However, epidemiological studies have not shown an increased risk for such cancers, including the respiratory system (Bosetti et al. 2008). This study, along with others (Marsh and Youk 2005), suggests that there is a discrepancy between reported animal data and data from epidemiological studies, and that this substance does not cause nasopharyngeal cancer, for example. It is likely that this observed difference is due to the structure of the nose and mouth of humans and animals. However, reports, mainly review and regulatory, continue to be produced, which indicate that this substance is a respiratory carcinogen for humans. There does appear to be some relationship between this agent and cancer as related to the hematopoietic system (Bosetti et al. 2008).

GLUTARALDEHYDE

Glutaraldehyde is frequently used to sterilize equipment that is heat sensitive. This material is classified as a cold sterilant and is used for hospital equipment such as suction bottles and dialysis equipment. It is also used in pathology for preparing histology slides and for the development of x-rays. In general, it is used in strengths ranging from 1% to 50%. Exposure to this chemical can result in a large number of effects, including lung irritation, skin sensitization, nosebleeds, irritation of the nose, asthma, dermatitis, hives, nausea, and headaches. To prevent exposure, exhaust systems and PPE are required. If there is contact with skin, it should be washed thoroughly to remove the material. The current exposure limit established by the ACGIH-TLV is 0.2 ppm. There is no standard by OSHA at this time, although NIOSH has recommended the same values that have been set by the ACGIH.

SHIFT WORK

It has been known for some time that working various shift times disrupts circadian rhythms, and this has been associated with cardiovascular disease, metabolic problems, and cancer (van Mark et al. 2006; Pronk et al. 2010). However, there is considerable controversy as to shift work's importance in disease causation. Most recently, reports have indicated that this activity is both related and unrelated to cancer (van Mark et al. 2006; Kolstad 2008). Shift work and activity has been linked to heart disease, infections, metabolic disorders, and cancer. These increased health risks have been associated with changes in the sleep cycle, specifically melatonin. Recently, the International Agency for Research on Cancer has suggested that shift

work is a Group 2A carcinogen (i.e., possibly carcinogenic to humans). Although the types of cancer vary in the studies, it has been reported that increased risks occur for prostate, breast, thyroid, and colorectal cancers. Some have considered that the cause of these cancers, at least in part, is the disruption of circadian rhythms. With the recognition of the hazards related to shift work, considerable controversy will exist in regard to its application.

Since hospitals and many clinics operate 24 hours a day, shift work is required. Some people are able to function well in changing shifts, while others are not. It may be beneficial to evaluate each person to see if they can tolerate shift changes, especially those that occur overnight. However, such scheduling conflicts with the current demands of clinical work and the changing cost structures. It is likely that shift work also impacts performance, and more importantly, the rate of medical errors. How this can be handled in the future is unknown but is one of the most important issues facing HCWs and administrators. It can become a patient safety issue when workers are required to consistently change shifts. These activities can quickly result in fatigue and, in many cases, are not recognized or understood by administration.

ANTINEOPLASTIC AGENTS

Various cytotoxic drugs are used to inhibit cell division and are generally used in the treatment of cancer. There are five different categories of these agents: alkylating agents, antibiotics, antimetabolites, mitotic inhibitors, and miscellaneous compounds. Patients treated with these various drugs often experience secondary effects, including hair loss, other cancers, and malformation of children born to women at later times. Investigation has suggested that similar effects can occur in HCWs that handle and administer these antineoplastic agents.

Reproductive risks have been of great importance for HCWs handling and administrating these agents. There has been a report of fetal loss during the first trimester of pregnancy after exposure to these agents. Malformation of children born to woman working with antineoplastic agents has also been reported. Studies have shown that these agents are mutagens, teratogens, and are genotoxic, which is the basis of many of their actions. There have also been reported nonreproductive and noncancerous risks from these agents. Chronic exposure may result in headaches, nausea, diarrhea, vomiting, and dizziness.

The risk of cancer for HCWs from antineoplastic agents may be the greatest concern. There have been case reports of HCWs who fill antineoplastic prescriptions developing cancer that appears to be related to their occupation. Exposure studies have shown that there is an increased risk of HCWs developing cancer as a result of exposure (Testa et al. 2007).

MERCURY

Mercury is a common substance used in the HCI. Most exposures result from accidental releases, although some also occur during routine use, such as in histology. When mercury is spilled, the droplets can become trapped over a wide area and eventually become vaporized. Spilled mercury can be absorbed through the lungs

and skin (Rom 2007). In general, adverse health effects are related to chronic exposure; however, it is possible to have acute events. The best practice is to routinely monitor for mercury vapor and clean up spills that occur. At high doses, mercury can cause coughing, chest pain, salivation, kidney damage, and reproductive effects. One of the biggest risks associated with this heavy metal is that in many locations spills go unrecognized. This may be the biggest problem and may represent an unknown hazard. Today, activity of this nature has become even more critical since some HCWs are now performing multiple tasks and preparing/prepping tissues or fluids as partial task activities. In most cases, there is little or no exposure monitoring of these personnel. Thus, little information on exposure is available.

ETHYLENE OXIDE

Health-care settings use ethylene oxide (EtO) to sterilize materials that are sensitive to heat and moisture. This agent is a colorless gas at room temperature and pressure, although it can be a liquid at lower temperatures or high pressure. It will mix with water and most solvents and is highly flammable. If it comes in contact with alkali metals, it can explode. The OSHA PEL (TWA) is 1 ppm and it has an excursion limit of 5 ppm. OSHA requires those that use this material in the workplace to monitor the population for exposure levels (29 CFR 1910.1047). EtO has been identified as potential carcinogen, specifically associated with leukemia. Noncarcinogenic effects include spontaneous abortions, cytotoxic damage, cardiovascular and renal failure, nausea, and dizziness. Tissue irritation can also occur as a result of exposure. EtO can induce chromosomal aberrations and sister chromatid exchange in lymphocytes.

RADIATION AND RADIONUCLEOTIDES

HCWs can be exposed to both ionizing and nonionizing radiation. Most radiation (ionizing) is used for therapeutic and diagnostic activities, although some is used in the laboratory setting. The hazards of radiation have been well established, and it has been well recognized that there is a need for control. Nonionizing radiation is also used in health care, and consists of mostly UV radiation. However, other wavelengths can be used as well. Nonionizing radiation can cause skin damage and eye injury.

As drug-resistant microbes become more common, some facilities may begin to use UV light as a "sterilization" agent for general locations. UV light has been shown to be effective in killing microbes and has a long history of use in the prevention of tuberculosis. However, this type of "light" can also have detrimental effects in people, most associated with skin and eyes. Thus, even nonantibiotic agents are both a benefit and detriment as applied to health-care settings.

BIOLOGICAL AGENTS

Biological agents have been a traditional hazard to HCWs. In many ways, these hazards were the reason for the implementation of the blood-borne pathogen rule (29 CFR 1910.1030). With the occurrence of SARS, there has become a heightened awareness of the hazards of infectious diseases (Lange 2005; Lange and Mastrangelo 2006).

However, this is not the real concern; rather, the continuation of antibiotic resistance appears to be one of the top priorities. With the widespread use of antibiotics, both medically and agriculturally, there has been a rapid increase in resistance to various microbes. This is probably best illustrated by the occurrence of extensively drug-resistant tuberculosis. Today, there are some microbes that are resistant to basically all antibiotics, and treatment has become almost impossible. Thus, the risk of infection not only exists for patients but HCWs as well.

The overuse of antibiotics worldwide is feeding resistance. Once an organism becomes resistant, it is then able to transfer this protection to other microbes through various mechanisms (conjugation, transduction, and transfection). Some have suggested that microbes are even able to communicate such resistance among each other through quorum sensing. At one time, it was thought that microbes could be effectively controlled, but this is not true, and the lessons of natural selection were easily forgotten. Today, these lessons are being relearned and discovered.

What else has been forgotten that may be of even greater importance in the basic principles of infection control? The easiest answer is hand washing. This was taught to us by Ignaz Semmelweis many years ago. Basic infection control procedures, such as using chlorine, can be highly effective in reducing microbial loads and as such reduce resistance.

SHARPS

Needlesticks and related accidents are frequently reported in HCWs. In one study, needlestick injuries were reported to be at a rate of 488 per 1000 full-time positions (Clarke, Schubert, and Korner. 2007). These injuries can result in the transmission of blood-borne disease. Needlesticks are not the only sharp injuries that can occur. Cuts from the use of scalpels can also result in injuries.

INJURIES

Probably the most common problem reported for HCWs is injuries (musculoskeletal). HCWs are at high risk for sustaining various types of such injuries, including postural stress, back injuries, and strains. Awareness of ergonomic issues can be a staring point in trying to reduce these types of injuries. These injuries may become even more critical with an aging work force and the occurrence of obesity. As health-care costs increase and reimbursement decreases, workers are being asked to do more with less. This often equates to fewer HCWs available to assist and treat patients. This factor itself may be an important contributor for injury causation and gives rise to higher workmen's compensation claims.

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18 Perspectives of a Frontline Nurse

Maggie Flanagan

Hospital Performs a Wrong-sided Brain Surgery … for the Third Time in a Year

For the third time in the same year, doctors at Rhode Island Hospital have operated on the wrong side of a patient's head. The most recent incident occurred November 23, 2007. An 82-year-old woman required an operation to stop bleeding between her brain and her skull. A neurosurgeon at the hospital began a surgery by drilling the right side of the patient's head, even though a CT scan showed bleeding on the left side, according to local reports. The resident reportedly caught his mistake early, after which he closed the initial hole and proceeded on the left side of the patient's head. The patient was listed in fair condition on Sunday.

The case echoes a similar mistake made last February, in which a different doctor operated on the wrong side of a patient's head. And last August, an 86-year-old man died 3 weeks after a surgeon at Rhode Island Hospital accidentally operated on the wrong side of his head.

Frantically, the neonatologist's hands squeezed the resuscitation bag, forcing the newborn baby to breathe. Joining the fight against death, a team of nurses and respiratory therapists surrounded the baby's bed. The code cart's contents were pressed into the battle. A referring hospital had sent the baby, hours old and terribly sick. The mother had stayed behind where she had given birth. She had an infection, and now the baby was overwhelmed with the same infection. Within hours, our every effort failed, and an invisible enemy had claimed another innocent soul.

I cleaned the baby's body and prepared it for the morgue. While drawing the last sample of blood from the baby, the tip of the needle nicked my finger. While waiting in the ER to be evaluated for a blood-borne pathogen needlestick exposure, I held a tube of the baby's blood in my hands, still unclotted hours later. The blood should have clotted in minutes, thus a sickening reminder of how infected the baby had been. As a new nurse, I had never seen first-hand the microscopic enemy of infection win. I vowed to do everything I could to prevent disease transmission. I never wanted to be part of the reason someone lost his or her life or health to sepsis. For me, the battle line was now drawn!

Hospital-acquired infections are serious medical errors. Infection is the number one reason why hospitalized infants die. This is also true with many other groups of hospitalized patients. Modern medicine has depended upon antibiotics to fight

infections, but now many types of infections are becoming resistant to common antibiotics. While treated in a health-care facility, patients can become infected in many ways. Some patients are colonized with harmful organisms before entering the health-care setting, and as their health becomes compromised, the infection takes over. Family members and other visitors can be a source of infection. However, of increasing concern are patients that are infected while being treated. Health-care acquired infections are a serious, growing problem. The U.S. Department of Public Health estimates 1.7 million Americans become infected in health-care facilities each year, with 99,000 dying from those infections. What is required is a systemic approach to eliminating the sources of infection in contamination in health care.

Effective hand washing is the top strategy to reduce disease transmission in health care. However, hand washing alone cannot keep patients from being infected if the health-care environment is not kept clean. I have worked as a registered nurse (RN) in 10 hospitals for close to 30 years and have seen that proper hand washing can be challenging to accomplish in many situations. One of the major reasons is poor staffing in health-care facilities where the staff is struggling to keep up with the patients' needs. Then, hand washing becomes hurried, if not forgotten. Fifteen to thirty seconds of hand washing between patients or after hands become contaminated may not accomplished. Another problem is when adequate facilities for hand washing are not provided. Sinks may be few. I have seen instances where warm water was not available. The best hand washing takes place where there is no touching of the sink, soap dispenser, or towel dispenser. Foot pedals have been available to dispense water and soap for years but are frequently not employed. Electronic faucets and towel dispensers are now starting to be used in health care. Sinks may be found in patient rooms but not always in the hallways of inpatient settings. When these patients become isolation patients, it is difficult to wash outside of the patients' room when removing isolation gear because there are frequently no sinks to be found. Try finding a sink for hand washing in a hospital cafeteria. This brings us to the next strategy for hand hygiene: alcohol hand gel.

Alcohol hand gels are now beginning to appear in health-care cafeterias, as well as throughout health-care facilities. They are beneficial when hand-washing facilities are not available and are only to be used when hands are not visibly soiled. However, these gels vary in their effectiveness due to differences in the amounts of alcohol they contain. A serious concern is that they do not kill harmful pathogens that are in spore form, like the most common cause of diarrhea in health-care facilities, the dreaded "C. diff," which is the nickname for *Clostridium difficle*. "C. diff" is very hardy, with its protective spores, and can live on surfaces for months. In fact, "C. diff" infections are becoming increasingly common in health care. Alcohol hand gel can kill the healthy organisms on the skin that help keep the pathogenic organisms under control. So with repeated use, will hands be more likely to harbor harmful bacteria or even fungus? Time will tell. Fungal bloodstream infections have been on the rise and can be lethal.

Gloves have been helpful in preventing the spread of health-care infections. However, gloves can vary in quality, and some types of gloves have better protective integrity than others, supposedly offering greater protection against transmittal of the smallest infectious agents, such as viruses.

Antimicrobial wipes are increasingly being used to clean surfaces and equipment in the health-care environment. To be effective, surfaces that are to be cleaned need to be cleared of visible soil and then saturated with the fluid from these cleaning wipes for a certain amount of time, usually several minutes. When health-care workers are in a hurry, the recommended surface saturation time may not be achieved, allowing for stronger, more resistant organisms to survive on the surface cleaned. Health-care workers' clothes can also be a source for infection. That is why protective gowns are frequently used when a patient becomes isolated. Industrial laundering of clothing and other linens used by health-care facilities have been successful in eliminating sources of disease transmission. The use of chemical sterilization by drastic pH shifts and extreme high heat in the drying cycles are the standard linen-cleaning practices employed by hospitals. These conditions are not duplicated in the health-care workers' home laundry. Disease transmission to the health-care workers' homes is now a risk when work clothes are laundered at home. Disease transmission can also occur when clothes that are not clean are worn back to work.

Poor isolation practices can be a source of disease transmission in health care. "One-size-fits-all" isolation gowns may not fit larger body types, exposing wrists and backs. Equipment used on an isolation patient may not be always truly dedicated to that patient and may be wiped with antimicrobial wipes between patients instead of terminally cleaned with stronger cleaning chemicals, which should occur at the end of the patient's stay. At one hospital where I worked, used food trays from isolation patients were placed on tray collectors and then returned to the kitchen, where they were used to bring up the next batch of food trays. It was only after nurses brought up the infection control issues repeatedly at the monthly hospital safety committee that the tray collectors now get washed before the next food trays are placed inside.

Poor staffing is often a reason why isolation practices in health care fail. This is not only due to health-care professionals being too rushed to comply, but also due to insufficient infection control personnel and housekeepers. Health-care facilities now have to make due with less, and housekeeping staff reductions are often seen as a way to save money in the budget. Housekeepers in health care are commonly underrespected, undertrained, and underpaid. Housekeepers may not speak English as their first language, and training may not be in their native tongue. All the hand washing in the world cannot protect a patient from a dirty health-care environment. A surgeon can save your life one day, and a dirty piece of equipment can infect you the next day. Hence, the importance of the cleaning crew! (Next time you see dedicated parking for the MDs, ask where the dedicated parking is for the housekeepers!) The sterile processing department is another important, behind-the-scenes unit that can save your life. Many times, this department staff is treated like the housekeepers. They can be overworked, undertrained, and underpaid, further putting the vulnerable health-care patient at risk with improperly cleaned instruments and equipment. One hospital I worked at was using sterilizers improperly for years before it was discovered by the new infection control nurse. Some hospitals may stretch their budgets by having personnel take on dual roles, like kitchen staff who then work as housekeepers.

Good stewardship in health care is important, but saving on supplies should not become more important than protecting patients from infection. What I found at one hospital was a lack of specialized equipment for certain procedures and surgeries. So, instead of sterilizing the equipment, the pieces were chemically cleaned, which should only be done in an emergency, such as when an essential piece of equipment becomes contaminated during the procedure and is needed immediately. This should never be done routinely!

When to isolate patients has become a debate in health care. Patients who are colonized with methicillin-resistant *Staphylococcus aureus* are always isolated in some hospitals, even if the risk of disease transmission is low. These patients may have a positive nasal swab culture but no draining wounds, cough, or impaired skin. In the same setting, patients who have actively draining wounds and are fighting for their lives with a very virulent organism are not in isolation because the organism is resistant to common antibiotics. Hospital sick policies may encourage health-care workers to work while sick, thus placing their patients' health at risk.

Years ago, an immigrant RN who worked with me was having night fevers but was afraid to call in sick because she had used her allotted sick days for the year. She was afraid of not only being fired but also of being deported, and did not complain of any illness. She unknowingly exposed an entire neonatal ICU to TB. Medically fragile infants had to take heavy-duty, anti-tuberculin medications for months.

Fabric is a poor choice for use in health-care furnishings. It is difficult to clean and often is not cleaned routinely as needed, yet it is found in health-care facilities, including curtains that are pulled between patients' beds. Refrigerators have been a problem in health-care facilities when not properly cleaned, and also when the correct temperatures are not maintained and monitored. At one hospital I worked at, the refrigerator containing temperature-sensitive vaccines was found unplugged and the temperature had been not monitored for days. That hospital was found by the state to have many medication refrigerators out of temperature range and unmonitored and was cited by the state. At another hospital, pharmacy technicians commonly would not place antibiotics in the refrigerator when delivering them to the neonatal intensive care unit, allowing the temperature-sensitive medications to warm to room temperature for an unknown amount of time, possibly compromising the strength of the medications.

The following are needed in a health-care culture where safety is paramount:

- Hand-washing facilities that are adequate and convenient
- Time enough to adequately hand wash, clean the health-care environment, and also bathe patients
- Effective equipment such as quality gloves, gowns that fit, and soap and paper towels that do not impair skin
- Integrity
- Enough equipment to use for isolation patients
- Employer-provided pens, stethoscopes, clothing, and shoe covers

- Adequate staffing in all departments, including infection control, housekeeping, sterile processing, and direct-care staff
- Effective cleaning of chemicals that are easy to use the correct way
- Effective isolation practices
- Furnishings in health care that are easy to clean
- Sick policies that are not punitive and enable sick workers to stay home

19 Medical Error
A Personal Story

Daniel Gilmore

A $200,000 Testicle

In yet another case of a wrongful operation, surgeons mistakenly removed the healthy right testicle of 47-year-old Air Force veteran Benjamin Houghton. The patient had been complaining of pain and shrinkage of his left testicle, so doctors decided to schedule surgery to remove it due to cancer fears. However, the veteran's medical records suggest a series of missteps—from an error on the consent form to a failure on the part of medical personnel to mark the proper surgical site before the procedure. The error, which took place at the West Los Angeles VA Medical Center, spurred a $200,000 lawsuit from Houghton and his wife.

Six of us (four emergency medical technicians [EMTs] and two firefighters) had entered the elevator in response to a medical emergency on the third floor of the assisted living complex. My partner pushed the "4" button, and we began to make small talk as the elevator began its ascent. It went up for several seconds, shook for a second, and suddenly stopped. The elevator car shuddered, and there was a momentary feeling of weightlessness.

Then, the elevator crashed violently into the building's basement—a drop of approximately 28–30 feet! The noise was deafening, tiles cascaded from the ceiling, and I remember feeling a stabbing pain in my back and numbness and burning in my legs. I began to hear the groans and exclamations of shock from my fellow rescuers.

Fast forward to a misty, dreary morning several months later. It was November, and it seemed like something was making me feel quite a bit more nervous than I had been feeling, but I decided it must have been the weather. I remember trying really hard to *act* calm and fearless, but it was not working. I wanted my wife to feel comfortable about the surgery, but I was having a hard time not showing my fear. Finally, I just blurted out that I had a really bad feeling about this and that I was having second thoughts. In the end, we decided that I was just feeling some normal pre-surgery jitters and that I would continue on as planned.

At the time of the accident I was looking forward to attending nursing school after a hiatus related to another work-related injury. Following the accident, I was forced to go onto workers' compensation, which turned out to be an agonizing, humiliating, and drawn-out experience. This was compounded by the severe pain and nerve damage that I was experiencing, making each and every day difficult.

It had taken 8 months to get the major back surgery approved by the insurance company. The procedure was scheduled to be a three level diskectomy. Theoretically, this would remove the disk material that was seriously affecting my lower back and legs, and I was hoping that it would eliminate the constant pain. I had seen three different neurosurgeons, and each one had come to the same conclusion. I needed the diskectomy to be performed right away and possibly would need a back fusion surgery as well.

We had arrived at the hospital very early, as I was among the first of that day's surgical cases. I was escorted to the surgical floor, where I said goodbye to my wife and was encouraged to use the bathroom. I was then put in a cubicle in the surgical holding area and I was told to change into a surgical gown. I did that and sat upright on the stretcher with my legs straight out on the bed.

A few minutes later a surgical tech came in and put an automatic blood pressure cuff on my arm and a pulse oxygen sensor on my finger. He also placed me on a cardiac monitor. When he placed the leads for the monitor on my chest, he commented that I was a little bit sweaty, and asked if I was okay. I told him that I was a bit nervous but that I thought I would be okay. He told me that someone would be in soon to give me some medication that would help me relax. Next, the neurosurgeon came in and told me about what they planned to do during the surgery and how I would likely feel after I woke up.

After some time, a man came to my bedside and introduced himself as a resident anesthesiologist. He was very calm and reassuring, which put me more at ease—but he also looked extremely tired and commented that he had just worked 48 hours straight with no sleep. We also talked about my very recent marriage, and I told him about my baby daughter while he placed an IV in my hand and hung a bag of fluid. He asked if I had ever experienced heartburn and began preparing a syringe to inject some medication into the IV line. I asked him at that time what he was giving me. He apparently said "Pepcid," but for some reason I only heard the last part of the word. For that reason, I thought that he was giving me Versed, which is a strong sedative commonly used to prepare patients for surgery and to help them feel calm. He slowly injected the entire contents of the syringe into the IV and then turned to arrange some things on the metal table beside my bed. A few seconds later I began to feel very strange and uncomfortable. Again, I had expected some level of sedation, but this drug was not really making me feel calm at all. My body began to feel extraordinarily weak. This was unlike any feeling I had ever experienced. I wanted to tell the doctor that I was feeling very strange, but I decided it must be a normal effect of the sedative and that I should try to be brave and deal with it.

At this point the resident told me that he needed to get something outside the room and would be back in a few minutes. As he closed the curtains I tried to look at the clock on the wall across the room. My eyes would not focus, and my face began to feel extremely numb. My eyes suddenly fell into a crossed position, and I found myself looking at my nose, without being able to move my eyes! This was an extremely disconcerting and uncomfortable feeling, and I began to feel frightened. My entire body was becoming progressively weaker and getting totally numb. I tried to reach up to take my glasses off to see if I could focus my eyes, but I realized that I could not move my arms at all. It was right then that I realized something had gone

badly wrong, and I started to feel real panic. I tried to cry out for the doctor, but I could not even speak!

Suddenly, it seemed like every muscle in my body just let go and I collapsed forward onto myself. I began to realize that every single muscle in my body, including all the muscles in my face, my throat, and all my extremities were *totally* paralyzed. My bowels and bladder completely let go, and suddenly I knew that I was in very serious trouble. I began to try to scream, as loudly as I possibly could for my life, but nothing came out; just a weak gurgle from my paralyzed throat. I remember feeling the deepest, darkest, most raw terror that I have ever known. I was continuously screaming for help with all of my body and soul, but absolutely nothing was coming out. It was then that I came to the horrifying realization that I was *not breathing. My diaphragm and accessory breathing muscles were now completely paralyzed!* My body repeatedly tried to suck air without success, like a fish out of water. I quickly came to the horrifying conclusion that there was nothing I was going to be able to do about this awful situation, and my entire life flashed before my eyes. I was going to die, right there in this hospital's surgical holding area! At that time, I remember having one of the most incongruous thoughts I had ever had—here I was fighting for my life like I had never before fought for *anything* and there were *normal conversations* going on all around me, just outside my cubicle. I was forced to silently beg God for my life and pray that I would live to see my family and my baby daughter just one more time.

After 3 or 4 minutes of this unimaginable horror—minutes that seemed more like a lifetime—the resident finally answered the alarm on the pulse oxygen sensor, which had begun sounding because the percentage of oxygen in my bloodstream was getting low. It had gone below 65%, which is dangerously low. The doctor entered the cubicle to find me completely cyanotic, in full respiratory arrest and covered in urine and feces. I heard him gasp in surprise, and he tried to sit me up and began yelling for help, calling "code blue, code blue!" Others came in to help, and they were able to lift me up and lower the head of the stretcher to get me into a recumbent position to try to open my airway. I heard the familiar and unmistakable sounds of professional alarm all around me and could hear the overhead speakers repeatedly announcing the code blue. They tried to insert a breathing tube but were unable to do so in the first few minutes. The problem was that whoever tilted my head back and lifted my chin to open my airway did not realize that my paralyzed tongue had fallen outside my mouth and was hanging between my teeth.

I could still hear and feel everything going on around me, and I distinctly remember hearing a crunching sound and feeling horrible, searing pain as I bit my own tongue almost in half while my airway was being opened. My mouth immediately filled with blood, which made it almost impossible for the doctors to insert the breathing tube. They were finally able to place an oropharyngeal airway and began to breathe for me with an ambu bag. I remember feeling profoundly grateful that I was *finally* receiving some oxygen although I still felt very much like I was going to die. After at least 4 minutes of being in complete respiratory arrest, the team was finally able to suction my airway of blood, remove the oropharyngeal airway, and place a breathing tube.

Something that is very revealing regarding the human psyche began to happen at this moment, and I have since read accounts of near death experiences that sound very similar to what I felt right then. I had begun to believe that if I continued to fight like I had been to stay alive, I would not end up in a better place. In other words, it seemed as if I kept trying to scream and continued to feel so immensely sad and regretful I might spend eternity in an awful place where those kinds of terrifying feelings would *never* go away. I knew that I was going through the process of dying, and in a manner of speaking, I just gave up. I let go of life itself and let myself slip into the darkness beyond, peacefully and without prejudice, panic, or negative feelings. I did not see or hear anything else beyond that point; I just felt this powerful and overwhelming feeling of understanding and acceptance.

The next thing I remember is violently waking up with a tube in my throat, completely restrained and being mechanically ventilated. To say that I was shocked to be alive is putting it mildly. I began to gag uncontrollably and tried to pull the tube out, which I could not do because I was tied down so tightly. I remember trying to scream over and over, but nothing came out, this time because the cuffed endotracheal tube was occluding my airway.

Thankfully, after a few minutes, a very perceptive and compassionate ICU nurse came to the bedside and gently told me something had happened in the presurgical holding area but that the doctors thought my prognosis was good. I was profoundly grateful to hear this news and repeatedly thanked God for my life.

After being in the ICU for the better part of a day, the breathing tube was removed and I finally was able to sit up a little bit. My family came in to visit me. I distinctly remember not caring how or why the entire incident happened; I was just profoundly grateful to be alive.

After a short time, a group of physicians, some of whom had been in attendance for my "code," came in to visit me. They told me that I had had a grand mal seizure and had stopped breathing. They then said that there were two possible reasons this might have happened. The first might have been that I had experienced a catastrophic reaction to the medication I had been given. The second was that I could potentially have a brain tumor or some other kind of inherent defect, which reacted with the medication and caused me to have the purported seizure. At that point, I informed the team that I had not lost consciousness at all during the first 5–7 minutes of the incident and that I had heard everything each of them had said while they were treating me. I recounted my symptoms and some of the procedures that had occurred during the incident while they looked on, absolutely astonished. I asked if it was possible that I had been given the wrong medication. It did not seem like anyone wanted to consider that possibility, so we did not push it too much at that time.

Later that day, with only my family present, the chief of anesthesiology, whom we had met earlier, mentioned that the symptoms I described did match closely with the effects of a drug called Pavulon, also known as pancuronium bromide (a paralytic drug that is just like curare, albeit 10 times stronger), but also that the team that had been present in the holding area still strongly believed I had some type of reaction to the Pepcid that the resident had reported giving me. Upon that news, my mother, who is an experienced registered nurse, requested that they take samples of my blood, urine, and so on, and freeze them for testing later.

In the following days and weeks, I was subjected to dozens of tests and scans, including 2 days of around-the-clock observation in the hospital, all of which resulted in absolutely nothing found, which of course caused more confusion about what happened that day. My family and I began to ask more persistent questions in the days and weeks after the incident. We were repeatedly told that I most likely had a serious allergy to the Pepcid and that I should abstain from that entire class of drugs. Honestly, by this time I had come to my own conclusion that this was simply not the case, and it seemed more and more probable that my brush with death had been caused by a medication mistake.

After more than a year of badgering the hospital and pleading with the chief of anesthesiology to be honest with us, it was finally admitted that the resident anesthesiologist who was treating me *had in fact made a horrific medication error.* He had accidentally given me a massive dose of Pavulon. This was confirmed by a test that was done by an outside third party hospital after they tested a sample of blood that was taken from me that morning.

Pavulon is one of the most terrifying poisons known to humankind. It causes massive, widespread paralysis almost immediately following administration, and complete respiratory arrest shortly thereafter. It is used on human beings only in measured doses and *only when they are heavily sedated or unconscious*, to keep them completely manageable so that they can be appropriately treated. In fact, it is so dangerous that most facilities keep the drug in a locked refrigerator at all times, and often two experienced providers must sign it out for use. The reason people must be sedated before receiving this class of drugs is that being chemically paralyzed, *even for a few seconds* (especially without prior knowledge), is one of the most terrifying situations that can happen to a human being. Pancuronium bromide is the second of a trio of drugs used in lethal injection executions in the United States. The first is always sodium pentothal, an extremely powerful sedative that renders the prisoner unconscious very quickly, and then Pavulon is injected to paralyze and stop the prisoner's breathing. Pavulon is administered only after it has been confirmed that the condemned is in fact completely unconscious and unaware. The reason for this practice is that if Pavulon were the first drug given, the ensuing paralysis would be the *ultimate* form of cruel and unusual punishment. Incidentally, the third drug that is administered in lethal injections is potassium chloride, which almost immediately stops the heart, which then of course kills the person.

Of course, it did not end there for me or my family. Shortly after the medication error, I began to have terrible nightmares, flashbacks, and moderate panic attacks, which I had certainly never experienced before the error. If I happened to see, hear, or read anything that even remotely resembled a breathing problem like choking, strangling, or drowning, I would have panic attacks and recurring nightmares for days after. After several visits to the local ER for a variety of issues, such as chest pain, shortness of breath, and tremors, I was finally diagnosed with moderate to severe posttraumatic stress disorder and finally began to get treatment, which did not occur until almost 2 years after the medication error.

Although the hospital did finally admit that the medication error had in fact occurred, they refused to take any responsibility for my reaction to it. In fact, they minimized the event and openly criticized me for not being able to get over it. In fact, I received a

letter from the chief of anesthesiology that essentially said I had nothing to complain about at all in regard to this error, because in actuality they had saved my life! No steps were taken, as far as I know, to study this medication mistake in depth or to take action against the doctor who made it. I was actually billed $30,000 for everything that happened that day and all of the subsequent tests, although the hospital did finally rescind the bill, upon threat of a lawsuit. Today, in 2011, this type of error would almost certainly be classified by the Joint Commission as a "sentinel event." Theoretically, this would automatically trigger a major investigation and follow-up study of what might have been done by the hospital to prevent that particular type of error. The investigation would almost certainly not be punitive in nature but would seek to understand what caused this disturbing error in the first place, and it would ultimately take steps to try to prevent it from happening again.

The fact that administration at the facility (a level I trauma center) and several physicians apparently attempted to cover this up for so long is one of the more disturbing parts of the entire affair. It was almost certain that they knew what had happened that day or shortly after the error occurred because there were two empty vials found in the "sharps" box in my cubicle, which had been emptied the night before. According to one of the doctors that was present, one of the vials was Pepcid and the other was Pavulon—and there was only one syringe. This type of thing should be an unacceptable occurrence in modern medicine, and it is my strong belief that medication errors should always be openly admitted and discussed. I definitely would have felt much better about the entire incident if something was learned by the hospital or by the resident who accidentally administered the medication. Perhaps he did learn something that day, but I will never know because I was never part of any investigation.

Those 5 minutes affected my life more than any one incident that has happened in my life before or since. I am not quite sure what about the incident changed me so much—whether it was simply the sheer horror of the situation, my coming so close to death, or just the fact that I was completely and absolutely helpless for that 5 minutes, but it definitely did change me. I became fearful and anxious about almost everything and always felt like I was ill or that something was awry regarding my health. It took me almost 10 years to recover to the point where I am now 100% percent anxiety free. I learned to control the feelings of panic, and I do not find myself thinking about the incident much at all anymore. Of course, I do feel like there is a significant chunk of my life missing because of the incident, and in my opinion every single health-care provider should remember how profoundly medication errors can affect the lives of human beings—or even more horrifying, that medication mistakes can and often do take people's lives. As a nursing student and an experienced EMT, I had that concept repeatedly drilled into me, but nothing reinforces book learning better than real life experience.

ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY

Epidemic of Medical Errors and Hospital-Acquired Infections

Systemic and Social

Medical Errors Leading Cause of Death in the U.S. (and possibly Canada)

Medical error as defined in the book encompasses many categories including, but not limited to, medical error, hospital-acquired infections, medication errors, deaths from misdiagnosis, deaths from infectious diarrhea in nursing homes, surgical and post-operative complications, lethal blood clots in veins, and excessive radiation from CT scans. When the deaths from the above categories are counted they become the leading cause of fatality to Americans, outpacing cancer and heart disease. Add the numbers of fatalities (mortality) to the millions each year who are injured (morbidity) and whose quality of life is forever affected, and an epidemic of harm is defined.

Epidemic of Medical Errors and Hospital-Acquired Infections: Systemic and Social Causes describes the systemic and social causes of medical error and iatrogenic events, all of which are cited in the peer review science, that have a direct effect on the epidemic of patient injury, but are rarely or never considered. These systemic causes include factory medicine (for-profit medicine), staffing ratios both in clinical and nonclinical departments, shift work, healthcare working conditions, lack of accountability, legal issues that conflict with patient safety issues, bullying and hierarchical relationships, training of healthcare workers that never rises to the level of the risk, injury to healthcare workers. The premise of the book is that if the above systemic or social causes are not considered or changed then medical error will continue to be an epidemic and no substantial impact on the numbers will be realized.

An expert with 30 years of experience as a health and safety officer in healthcare and as an activist for community health and safety issues, editor and author William Charney explores the issues surrounding medical errors and examines the science behind possible solutions. He presents an efficient dialogue that produces a more systemic exploration and targeting of the causes of medical error and drives an exacting message: we are dealing with an epidemic of harm and unless systemic issues are solved, little will change to subdue the epidemic.

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