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001. list	re: President's Advisory Commission on Consumer Protection and Quality in Health Care Commissioners (3 pages)	02/16/2000	P2, P6/b(6)
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THE CHALLENGE AND POTENTIAL FOR ASSURING QUALITY HEALTH CARE FOR THE 21ST CENTURY Executive Summary

In its landmark report to President Clinton, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry called for a "national commitment to the measurement, improvement, and maintenance of high quality care for all Americans." As part of that effort, the Commission called for the creation of a Forum for Health Care Quality Measurement and Reporting "to develop and implement effective, efficient, and coordinated strategies for ensuring the widespread public availability of valid and reliable information on quality."

This report documents some of the existing quality problems in the health care system and identifies current strategies that have proven effective at improving quality outcomes, increasing confidence, and often reducing health care costs. It also underscores why a national effort is needed to improve the quality of health care.

Confronting Quality Problems

There are several areas where the quality of American health care is falling short, including underuse, overuse, misuse, and variation in use of health care services.

Underuse of services: The failure to provide a needed service can lead to additional complications, higher costs, and premature deaths. For example, a study of heart attack patients found that nearly 80 percent did not receive life-saving beta-blocker treatment, leading to as many as 18,000 unnecessary deaths each year. A survey of managed care plans by the National Committee for Quality Assurance (NCQA) found that 60 percent of diabetics age 31 and older had not received a recommended eye exam in the previous year. The same survey reported that 30 percent of women age 52 to 69 had not had a mammogram in the previous 2 years, and 30 percent of women between 21 and 64 had not had a Pap smear in the previous 3 years, despite the fact that early screening reduces mortality.

Overuse of Services. Unnecessary services add costs and can lead to complications that undermine the health of patients. For example, half of all patients diagnosed with a common cold are incorrectly prescribed antibiotics. Overuse of antibiotics has been shown to lead to resistance and as much as \$7.5 billion a year in excess costs. Another study found that 16 percent of hysterectomies performed in the U.S. were unnecessary.

Misuse of Services: Errors in health care delivery lead to missed or delayed diagnoses, higher costs, and unnecessary injuries and deaths. A study of New York State hospitals found 1 in 25 patients were injured by the care they received and deaths occurred in 13.6

percent of those cases. Negligence was blamed for 27.6 percent of the injuries and 51.3 percent of the deaths. Based on this study, researchers estimated that preventable errors in hospital care led to 180,000 deaths per year. Researchers estimate that as many as 30 percent of Pap smear test results were incorrectly classified as normal.

Variation of Services: There are significant variations in the practice of medicine across the U.S., among regions, and even within communities. For example, hospital discharge rates are 49 percent higher in the Northeast than they are in the West. A person with diabetes is one-and-a-half times as likely to get a needed eye exam in New England than in a Southern state.

The Role of Quality Measurement in Improving Care

In the last decade, Federal and State governments, private employers, health insurers, health plans, health care professionals, labor unions, and consumer advocates have developed successful strategies to measure and improve the quality of health care. For example:

The New York State Department of Health releases data on the quality of heart bypass surgeries at all of the hospitals in that state. Use of these data has helped reduce mortality in bypass cases by 50 percent in 5 years.

A Michigan hospital has reduced complications due to drug reactions in their cardiac care unit by 80 percent. At the LDS Hospital in Salt Lake City, Utah, a quality improvement program decreased adverse drug reactions related to antibiotics by 75 percent.

An asthma program in Boston has led to an 86 percent reduction in hospital visits and 79 percent reduction in emergency room visits. In 1992, asthma led to 468,000 hospitalizations in the United States and an annual cost of \$6.2 billion.

The use of NIH guidelines has led to a 100 percent increase in the use of a drug to prevent death among premature babies.

Minnesota hospitals have increased the use of beta-blocker therapy to prevent second, often fatal, heart attacks in patients by 63 percent through provider education and performance feedback.

Private employers and health plans have also used quality measurement and reporting to improve care and inform consumers. For example:

General Motors provides its employees with report cards rating health plans' quality of care. The reports include quality measures, satisfaction ratings, accreditation reports, and reports from site visits.

The Pacific Business Group on Health requires health plans to set aside 2 percent of the premiums they receive and only allows high-performance plans to retain those funds.

The United Auto Workers requires all health plans serving its members to be accredited by the NCQA.

Kaiser Permanente of Southern California has launched its "Intervention for Employment Maintenance for Members with End Stage Renal Disease," to help patients cope with this life-threatening illness and continue to work during treatment. Workers in the Kaiser program were 2.8 times more likely to maintain employment.

The Need for a National Effort

While there have been successful efforts to improve health outcomes, increase confidence, and reduce costs, the President's Commission noted that current efforts "vary widely in their aims and scope and have been, at best, only informally coordinated." In some areas, such as chronic disease, very little is being done to measure quality. In other areas, health plans are being overwhelmed by conflicting and redundant requests. The Commission's call for the creation of a Quality Forum is designed to accomplish the following:

- Identify core sets of quality measures for standardized reporting by all sectors of the health care industry;
- Establish a framework and capacity for quality measurement and reporting;
- Support the focused development of quality measures that enhance and improve the ability to evaluate and improve care;
- Make recommendations regarding an agenda for research and development needed to advance quality measurement and reporting;
- Ensure that comparative information on health care quality is valid, reliable, comprehensible, and widely available in the public domain.

The Commission recommended that the Forum be broadly representative of key stakeholders in health care, including: public and private purchasers, consumers, health care providers, health plans, labor unions, and experts in quality measurement and reporting. The Forum will help eliminate duplicative and overlapping demands for information from health care providers and plans, and it will provide consumers and other purchasers with a common yardstick to make direct comparisons of health plans, hospitals, nursing homes, or physicians. Because purchasers will be speaking with a more unified and pragmatic voice on quality information needs, accreditors, plans, and providers will be able to be much more responsive. This progress will help assure that health plans will compete on the basis of quality, not just cost and benefits.

THE CHALLENGE AND POTENTIAL FOR ASSURING QUALITY HEALTH CARE FOR THE 21ST CENTURY

I. Introduction

Millions of Americans receive high quality health care services. The United States has many of the world's finest health care professionals, academic health centers, and other research institutions. However, too often, the quality of care provided to patients is substandard. Too often, patients receive excessive services that undermine the quality of care and needlessly increase costs. At other times, they do not receive services that have proven to be effective at improving health outcomes and even reducing costs.

For example, one study found that only 20 percent of eligible patients received beta blockers following a heart attack, despite the fact that they have been proven to be an effective intervention, reducing mortality by 43 percent (Soumerai, et al., 1997). Another study found that antibiotics are frequently over-prescribed, contributing to microbial resistance to these drugs (Gonzales, et al., 1997). Such resistance could cost as much as \$7.5 billion a year for more expensive health care interventions (Phelps, 1989). Moreover, there is still an unacceptable rate of errors; one study estimates that preventable errors in hospital care lead to 180,000 needless deaths each year (Leape, 1994). There is also a wide variation of medical practices across the country. For example, hospital discharge rates were 49 percent higher in the Northeast than in the West (Graves and Gillum, 1997).

Poor quality care leads to sicker patients, more disabilities, higher costs, and lower confidence in the health care industry. As this report clearly documents, there is great potential to improve the quality of the nation's health care system, and there is widespread interest among representatives in the health care system to make these improvements.

Consumers want understandable and reliable information to help them make critical decisions about their health care. Most Americans consider it very important to know how well their health plan cares for members who are sick, catches health problems at an early stage, and keeps members as healthy as possible. In fact, 90 percent consider how well their health plan takes care of members who are sick very important, and 90 percent consider it very important to know how easy their health plan makes it for members to get the care they need (AHCPR-Kaiser, 1996). However, the vast majority of Americans did not see any information comparing the quality of health care plans, doctors or hospitals within the last year.

Private and public purchasers have also demonstrated that they want more information about the quality of the care they purchase for their employees, their dependents and beneficiaries as well as new strategies to improve it. As this report illustrates, many private purchasers are developing quality improvement programs, report cards and other measurement tools to help assure that they

can purchase health care based on quality, not just cost and benefits. For example, GTE provides its employees with report cards so they can choose a plan based on cost and quality, and the Pacific Business Group on Health requires HMOs to set aside 2 percent of the premium dollar and allows plans to keep that money only if they attain the performance standards set in customer service, quality, data collection, and other areas.

Other efforts have emerged to measure and report on health care quality that have begun to provide consumers and purchasers the information they need to purchase quality health care and to enable health professionals and others to develop targeted strategies to improve care. Businesses as well as government agencies are working with health care providers, health insurers, health plans, accreditation organizations, labor unions, and others to encourage the development of these efforts. This report shows that where these representatives have come together to make targeted efforts to improve the quality of care, they have been successful in improving health outcomes, increasing confidence, and often lowering costs.

Some successful strategies have been identified and implemented, but there is clearly a need for a national effort. In its Final Report, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry commends the investment in quality measurement and reporting made by some of the leading organizations in the field. But it notes that, "despite a growing number of efforts to measure and report on health care quality, useful information is neither uniformly nor widely available." Current efforts, the Commission added, "fall short of fully meeting users' needs and often are duplicative and unduly burdensome on health care providers, plans, and others." The Commission calls for "a national commitment to the measurement, improvement, and maintenance of high quality care for all citizens."

While there has been a patchwork of successful efforts to improve health care quality, the current system leaves many gaps, and in many other cases is redundant. Moreover, there is no mechanism to share best practices and successful strategies; many purchasers simply do not have the information they need to assure they can purchase health care on the basis of quality, and not just what it costs or what it covers.

To address these concerns, the President's Commission called for the creation of two complementary entities to advance efforts to measure and report on health care quality--a public sector Advisory Council on Health Care Quality and a private sector Forum for Health Care Quality Measurement and Reporting. President Clinton has called on Congress to create a Quality Council through legislation, which would establish national goals to improve health care quality and develop strategies to achieve them. He has asked Vice President Gore to help assure the development of the private Quality Forum that would bring together the public and private sectors to identify a core set of measures to be adopted by health plans across the country that would ensure that, for the first time, consumers have a consistent set of standards so they can choose health plans based on quality--not just on cost.

The Council and the Forum are part of the Quality Commission's overall recommendations to improve the quality of health care. In its first report to the President, the Quality Commission recommended a patients' bill of rights to assure that all Americans get the protections they need in a changing health care system. The Commission's recommendations build on the Administration's longstanding commitment to increase access to and improve the quality of health care. For example, last year the President enacted the largest investment in children's health care as well as unprecedented Medicare reforms that extended the life of the Medicare Trust Fund for a decade while improving plan choices and preventive benefits. However, access to health insurance is, of course, not sufficient to assure quality of health care.

As envisioned by the Commission, the Quality Forum will build the systemwide capacity to evaluate and report on health care quality. For the first time, representatives of private and public purchasers will work hand in hand with consumers, providers, and other interested parties to develop a comprehensive plan for implementing quality measurement, data collection, and reporting standards and ensure the widespread availability of this type of information to consumers, providers, purchasers and others.

The Forum will help eliminate duplicative and overlapping demands for information from health care providers and plans, and it will provide consumers and other purchasers with a common yardstick to make direct comparisons of health plans, hospitals, nursing homes, or physician. Because purchasers will be speaking with a more unified and pragmatic voice on quality information needs, accreditors, health plans, health professionals and providers will be able to be much more responsive. In so doing, it will help assure that health plans will compete on the basis of quality as well as cost and benefits.

II. Evidence of Quality Problems

While millions of Americans receive high quality health care services, there are a number of areas where the quality of care is falling short. This section documents some of these quality problems including underuse, overuse, misuse, and variation in use of health care services.

Underuse of Services. The failure to provide needed health care services often leads to unnecessary complications, higher costs, and premature mortality. There are numerous examples where services that have proven effective in improving care and often lowering costs are not being used. They include:

Diabetes Care. People living with diabetes require annual eye exams to avoid potential blindness (NIH, 1998). Yet, in its survey of managed care plans, the National Committee for Quality Assurance found that only 40 percent of diabetics age 31 years and older had received an eye exam during the previous year (NCQA, 1997).

Mammograms. Early detection of breast cancer through mammograms can prevent up to 30 percent of breast cancer deaths each year (CDC, 1998). However, NCQA found that 30 percent of women age 52 to 69 in surveyed managed care plans had not received a mammogram in the previous 2 years (NCQA, 1997).

Cervical cancer screening. As a result of early detection efforts, the incidence of invasive cervical cancer has decreased (CDC, 1998). Yet in 1996, nearly 30 percent of women between the ages of 21 and 64 had not received at least one Pap smear in the previous 3 years (NCQA, 1997). In 1998, an estimated 13,700 women will be diagnosed with cervical cancer and 4,900 women will die from the disease.

Heart Attacks. The use of beta blockers after heart attack has been shown to reduce mortality by 43 percent. Yet, in a sample of Medicare patients in New Jersey, only 21 percent of eligible patients received beta blockers (Soumerai, et al., 1997). Dr. Mark Chassin at the Mount Sinai School of Medicine has estimated that more consistent use of beta-blocker therapy could prevent an estimated 18,000 deaths each year (Chassin, 1997). The use of aspirin after heart attacks has also been shown to reduce mortality. But, in one study, a third of Medicare patients who survived a heart attack failed to receive aspirin within 2 days of hospitalization (Krumholz, et al., 1995).

Overuse of Services. Excessive and unnecessary health care services can increase health care costs without improving health and can place patients at greater risk for injuries and complications. Examples of overuse of services include:

Antibiotics. In 1992, half of all patients diagnosed with a cold and two-thirds of patients diagnosed with acute bronchitis received antibiotics (Gonzales, et al., 1997). Yet antibiotics offer little or no benefit for these conditions. In that year, twelve million antibiotic prescriptions were written during office visits for colds, upper respiratory tract infections and bronchitis. These prescriptions accounted for one out of every five antibiotic prescriptions to adults in that year. Overuse of antibiotics imposes unnecessary health care costs, places patients at risk for adverse drug reactions and contributes to the emergence of antibiotic-resistant pathogens. Such resistance could cost as much as \$7.5 billion a year in unnecessary costs (Phelps, 1989).

Hysterectomies. A study of the use of hysterectomies in seven managed care plans found that 16 percent were unnecessary (Bernstein, et al., 1993).

Tympanostomy tubes. From 1991 to 1992, 23 percent of tympanostomy tube insertions for children with ear infections were found to be inappropriate (Kleinman, et al., 1994).

Misuse of Services. Errors in health care services cause missed or delayed diagnoses, unnecessary injuries, premature death and often increased costs. Evidence of high rates of misuse of services include:

Hospital Injuries. In the landmark Harvard Medical Practice Study of hospitals in New York State, adverse events, where injuries result from medical management rather than underlying disease, occurred in 3.7 percent of all hospitalizations (Brennan, et al., 1991). Of these adverse events, nearly 14 resulted in death. Investigators attributed negligence as the cause of 27.6 percent of the adverse events and 51.3 percent of the deaths. Based on this study, Dr. Lucian Leape of Harvard School of Public Health has estimated that preventable errors in hospital care lead to 180,000 needless deaths each year (Leape, 1994).

Laboratory Tests. After rescreening, experts determined that anywhere from 10-to-30 percent of Pap smear test results were incorrectly classified as normal (Wilbur, 1997). These errors can result in missed or delayed diagnoses, sometimes meaning that patients have to go through more extensive and costly treatment.

Medication Errors. A study of two tertiary care hospitals found that among nonobstetrical patients that suffered an adverse reaction to a prescribed drug, an estimated 28 percent of these injuries were deemed preventable (Bates, et al., 1995). As a result, these patients spent more time in the hospital and health care costs increased. In fact, the authors of the study estimated that preventable adverse drug events would cost an additional \$2.8 million for a 700-bed teaching hospital (Bates, et al., 1997). If the costs in this study were representative of and extrapolated to the nation's acute care hospitals, these investigators estimated that the hospital costs of preventable adverse drug events would be \$2 billion annually.

Ear infections. One study demonstrates that the use of less expensive types of antibiotics for ear infections reduced the need for a second antibiotic course within 24 days of the initial therapy, was associated with a reduced rate of adverse drug reactions (ADRs), and led to similar or better outcomes than the more expensive alternatives (Berman, et al., 1997). Yet these more expensive alternatives are still commonly prescribed. If only half of the prescriptions for these antibiotics were written for the low-cost alternatives instead, the Colorado Medicaid program would have saved approximately 36 percent of its total costs for antibiotics for ear infections.

Variation in Services. There are significant geographic differences in practice that cannot be accounted for by differences in the health status of patients, available resources, patient preferences, or even clinical uncertainty. Such variation in services has contributed to disparities in mortality and morbidity.

Hospital services. Hospital discharge rates and lengths of stay in the Northeast were 49 percent and 40 percent higher, respectively, than those in Western states (Graves and Gillum, 1997).

Cesarean section rates. Cesarean section rates in Washington State hospitals ranged from 0 percent to 43 percent (McKenzie and Stephenson, 1993).

Diabetes care. Researchers found a twofold variation in routine care provided for diabetics (glycosylated hemoglobin measurement, eye exams, and total cholesterol measurement) across three states (Weiner, et al., 1995). The National Committee for Quality Assurance found a similar variation in the rate of eye exams routinely recommended for diabetics, with over 50 percent of diabetics receiving annual eye exams in New England managed care plans compared to 32.6 percent in plans in the South Central region of the country (NCQA, 1997).

III. From Quality Measures to Quality Care: Examples of Quality Improvement at Work

Federal and State governments, private purchasers, physicians, nurses, insurers, labor unions, health plans, hospitals, accreditation organizations, and others have begun to address some of the significant quality problems in the U.S. health care system. One approach they have taken is to improve the ability to measure and report on the quality of care being delivered. The reporting of quality measures prompts a closer look at provider or health plan practices both as feedback for clinicians or as publicly available scorecards for consumers and purchasers to evaluate. Several of these endeavors have led to improvements in the quality of care and in the health outcomes for consumers, while often saving costs. Among these are:

The Prevention of Heart Attacks with Beta-Blocker Treatment

Despite the clear medical evidence that the use of beta blockers can significantly reduce the odds that a heart attack patient will have a second, and often fatal, attack, researchers have shown that too often these patients are not prescribed this life-saving therapy. Faced with this problem, the Medicare Peer Review Organizations in Alabama, Connecticut, Iowa, and Wisconsin have launched a concerted campaign to increase use of beta blockers. They monitored beta-blocker use after heart attacks in Medicare patients and provided feedback to all practitioners in their states. As a result, beta-blocker use climbed from 31.8 percent of cases to 49.7 percent of cases (Marciniak, et al., 1998). Based on these promising findings, Medicare expanded this campaign nationwide among its PROs beginning in 1995.

With support from the Agency for Health Care Policy Research (AHCPR), the Minnesota Clinical Comparison and Assessment Program worked to generate consensus and commitment from providers to increase use of life-saving drugs like beta-blockers (Soumerai, et al., 1998). Using local medical opinion leaders at twenty hospitals, they focused on the evidence, identified barriers to change, and offered feedback of comparative performance. Their efforts yielded a 63 percent increase in the use of beta-blockers.

Using another life-saving treatment for heart attack patients, the Middletown Regional Hospital in Ohio reported decreased mortality rates by reducing the time from hospital admission to the administration of thrombolytic therapy. Mortality rates decreased from 10.9 percent to 6.5 percent in less than 1 year. For their efforts, this hospital received the Joint Commission on Accreditation of Healthcare Organization's 1997 Codman Award, recognizing excellence in the use of outcome measurement to improve quality.

The National Committee for Quality Assurance has begun requiring health plans to submit data on the use of beta blockers after a heart attack as part of its Health Plan Employer Data Information Set, version 3.0 (HEDIS 3.0), which is a standardized set of measures that assesses the performance of managed care organizations. This information assures that purchasers and consumers have comparative information about the use of beta blockers by the health professionals in a particular health plan. In 1998, the Health Care Financing Administration, the Federal agency that administers and oversees the Medicare and Medicaid programs, began requiring health plans participating in Medicare to submit HEDIS data, including information on beta blocker use.

Improving the Quality of Care for Heart Bypass Surgery

More than half a million Americans undergo coronary artery bypass surgery each year, but the quality of that surgery varies from hospital to hospital. To help consumers choose the best care, the State of New York and a consortium of hospitals have been using quality measurement and reporting techniques to flag problem areas and to improve the quality of care for bypass patients. For nearly a decade, the New York State Department of Health has collected and released hospital-specific data on coronary artery bypass surgery. Using these data, New York targets quality improvement efforts to those hospitals with quality problems, including site visits, comprehensive consultations, and probationary action taken against facilities until they agree to implement necessary changes. As a result of these efforts, between 1989 and 1992, the risk-adjusted mortality rate for bypass patients in New York State declined 41 percent (Hannan, et al., 1994). By 1993, the cardiac surgery mortality rate had declined by 52 percent (Longo, et al., 1997; Hannan, et al., 1994a).

The New England Cardiovascular Project, involving five hospitals in northern New England, was begun in 1990 to reduce mortality rates among coronary bypass patients. Similar to the New York program, this effort includes site visits, data reporting, and training for health care professionals. At the end of the project, researchers reported a 24 percent reduction in coronary artery bypass surgery mortality among the five hospitals (O'Connor, et al., 1996).

Other groups have undertaken quality measurement and reporting projects aimed at improving survival rates among heart bypass patients. General Motors, First Chicago NBD, and others initiated the Southeast Michigan Health Care Consortium, which is collecting outcomes data for

all health care centers in the region. They plan to publish data on angioplasty and coronary artery bypass surgery in the fall of 1998 (The Business Roundtable, 1997). Similarly, the California Office of Statewide Health Planning and Development and the Pacific Business Group on Health have developed the California Coronary Artery Bypass Graft Mortality Reporting Program, which collects and reports risk-adjusted, hospital-level mortality data for California hospitals that perform bypass surgery. Both of these groups hope to stimulate quality improvement by enabling comparisons among participating hospitals and health care providers (Meyer, et al., 1997).

Reducing Unnecessary Cesarean Deliveries

In 1995, nearly 4 million women entered hospitals to give birth, and 785,000 women underwent cesarean section. Research into the variations in the rates of cesarean section procedures has raised questions about whether cesarian sections are being used when they are not necessary. While clinically indicated for some deliveries, this surgical procedure carries risks as well as morbidity when used as an alternative to vaginal delivery. Studies show that women living in Southern states had the highest cesarean rates while women living in Western states had the lowest rates (Clarke and Taffel, 1996). Even within states, wide variations exist. For example, cesarean section rates in Washington State hospitals ranged from 0 percent to 43 percent (McKenzie and Stephenson, 1993).

The Greater Cleveland Health Quality Choice Coalition produces a biannual report card documenting patient outcomes in 27 local hospitals. In this report, the Coalition has tracked the number of cesarean section deliveries as a measure of performance in those hospitals. As a result, several Cleveland hospitals have developed and implemented practice guidelines and have fostered collaborative efforts with physicians to improve care. Over three successive reporting periods, the aggregate trend of total cesarean section rates in local hospitals has declined (Cleveland Health Quality Choice Program, 1997).

The Missouri Department of Health also developed a consumer report on obstetrical services. The *ShowMe Buyer's Guide: Obstetrical Services*, issued in 1993, covered all 90 Missouri hospitals (Longo, et al., 1997). The guide looked at the length of stay, number of births, level of perinatal care, availability of labor, delivery and recovery beds at each hospital. It reported the cesarean delivery rate, high-risk infant transfer rate, ultrasound rate, vaginal birth after cesarean, very low birth weight of each facility along with the rates of neonatal mortality, and patient satisfaction. Within 1 year of the report, approximately 50 percent of Missouri hospitals had taken action to address some of the issues raised by the guide: instituting or planning formal transfer agreements with tertiary care centers for referral of high-risk infants, developing car seat programs to improve safety, and training nurse educators for breast-feeding. On follow-up, hospitals previously performing a high level of cesarean deliveries also had reviewed their procedures and significantly lowered their rates for this procedure.

Various firms and group purchasers have embarked on similar efforts to improve obstetrical care. The Massachusetts Healthcare Purchaser Group, a coalition of 27 corporate and government health care purchasers, released a 1994 report card to coalition members on obstetric care and held a "best-practice forum" on cesarean sections (Jordan, et al., 1995). The Dallas-Ft. Worth Business Coalition has initiated a pilot study to develop best practices for pregnancy and childbirth through quality measurement and reporting. General Motors, Chrysler, and the United Auto Workers union have also joined together to develop best practices for cesarean section in Flint, Michigan (AFL-CIO, 1997).

Reducing Asthma-Related Deaths

Despite advances in treatment, mortality from asthma has risen 58 percent from 1979 to 1992 (NAEPP, 1998). Over the same period, both the incidence of asthma cases and hospitalizations related to it climbed. In 1993, asthma led to 468,000 hospitalizations, 100 million days of restricted activity annually, and a yearly cost of \$6.2 billion. However, there are a number of examples of quality improvement efforts that have been effective at improving health outcomes and reducing costs for people with asthma. These steps have resulted in fewer emergency room visits and hospital stays.

In 1989, the National Institutes of Health initiated the National Asthma Education and Prevention Program (NAEPP). One of its landmark accomplishments was the 1991 release of the *Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma*. In this guideline, the NIH recommends the use of anti-inflammatory therapy (e.g., corticosteroids) for long-term control of persistent asthma, along with patient/provider education and other measures (NAEPP, 1991). The NAEPP disseminated the report widely to health care professionals, medical schools, health care organizations, professional societies, and patients and updated the guidelines in 1997 (NAEPP, 1997). Prior to the guideline's release, only 21 percent of emergency physicians reported prescribing early corticosteroid administration in asthma. In 1994, 82 percent of physicians reported that they followed this practice recommended in the guideline (Lantner, et al., 1995).

Parkland Memorial Hospital in Dallas, TX, has implemented a plan of increased education for asthma patients and providers, coupled with more intensive treatment (NAEPP, 1996). The hospital recorded a 53 percent reduction in emergency department visits by asthma patients during the first 2 years. In an inner-city program in Boston, children with asthma experienced an 86 percent reduction in hospital admissions and a 79 percent decline in emergency department visits in response to interventions, including one-on-one consultations with an asthma outreach nurse, patient education in self-management, and regular monitoring of patient progress (Greineder, 1995).

The Mayo Clinic of Rochester, MN, reduced asthma-related emergency department and urgent care center visits by 22 percent (Weiss, 1997). Hospitalization rates for Family Medicine asthma patients under 65 also fell, by 47 percent for those patients between the ages of 45 and 64. Their approach involved improved monitoring of asthma severity through the use of peak flow meter readings and site visits to physician offices to promote prescribing of anti-inflammatory drugs for asthma. By creating slots in the Family Medicine scheduling system, the hospital ensured that asthmatics could make follow-up appointments before leaving the Center.

The National Committee for Quality Assurance has introduced a measure of appropriate medications for people with asthma in its HEDIS 3.0 testing set. The Office of Personnel Management and the Foundation for Accountability (FACCT) have also embarked on a collaborative effort to improve asthma disease management (AFL-CIO, 1997).

Employers like AT&T, First Chicago NBD, and Deere and Company have also made efforts to improve the care of employees with asthma and reduce costs for such care (The Business Roundtable, 1997). In the first year of its program, Deere and Company, an Illinois-based manufacturer of farm equipment, recorded a 12 percent reduction in asthma-related treatment costs (Strickland, 1996). The company has achieved this by inviting workers and dependents with asthma to participate in an asthma education program, and facilitating the development of personal action plans with their physicians to guide employees' self-management of this chronic condition.

Health plans have also recorded success with disease management programs in asthma. The Family Health Plan Cooperative of Milwaukee, Wisconsin, has developed an Asthma Treatment Plan based on the NIH guidelines. They have identified the population at high risk, developed an education plan for asthmatics focusing on self-management, and encouraged physicians to work with their patients to create effective, customized asthma management plans. From 1993 to 1994, the Family Health Plan Cooperative reported a 22 percent reduction in asthma hospital admissions for patients between the ages of 2 and 19 (GHAA, 1995).

Increasing Influenza Vaccination Among Adults

Influenza and pneumonia is the sixth leading cause of death in the United States (NCHS, 1997). For the elderly, influenza and its complications are particularly problematic, with 95 percent of the resulting deaths occurring in Americans over the age of 60 (Govaert, et al., 1994). Studies of influenza vaccine demonstrate saved lives and lower costs. In one clinical trial, influenza vaccination halved the incidence of the flu among patients over the age of 60 (Govaert, et al., 1994). Yet only 52 percent of people aged 65 and over received the vaccine in 1993 (CDC, 1995).

The National Committee for Quality Assurance now requires health plans to report on the number of older adults in the plans who receive flu shots each year. The Department of Veterans Affairs has encouraged local VA hospitals to immunize 100 percent of its patients against the flu (Department of Veterans Affairs, 1996). Under a 4-year program, the Centers for Disease Control and Prevention (CDC) and the Health Care Financing Administration (HCFA) have implemented the Medicare Influenza Vaccine Demonstration project to promote use of this preventive measure (CDC, 1992). HCFA distributed letters to Medicare beneficiaries, provided physician reminders, trained nurses to recognize high-risk patients, and piggybacked vaccination messages on telephone company mailers. Over a 3-year period, overall flu vaccination rates climbed from 26 percent to 48 percent. In a few of the intervention sites, vaccination rates surpassed 60 percent.

Building on the success of this demonstration project, influenza vaccine became a covered benefit under the Medicare program, and HCFA has undertaken a national effort to increase the use of the influenza vaccine. HCFA is working with its Peer Review Organizations (PROs), the Centers for Disease Control and Prevention, and the National Coalition for Adult Immunization to determine how best to improve immunization rates. It is also working with states, community-based organizations, and senior advocacy groups to promote this practice. The overall goal of the HCFA effort is to achieve a 60 percent influenza immunization rate among Medicare beneficiaries age 65 and older by the year 2000.

Reducing the Incidence of Pressure Ulcers

For the hospitalized and home care patient, pressure ulcers, or bed sores, can be a serious and chronic problem. While bedbound or immobile, unrelieved pressure on the skin can lead to its breakdown and damage to the underlying tissue. Patients in critical care, with hip fractures or with spinal injuries are at particular risk. Studies have found that as many as one in four nursing home patients experience pressure ulcers and the cost of treating them is more than \$1.3 billion annually (Bergstrom, et al., 1994).

The Agency for Health Care Policy and Research has published two clinical practice guidelines addressing the prediction, prevention, and treatment of pressure ulcers (Bergstrom, 1992; Bergstrom, 1994). Various groups have implemented quality improvement programs to prevent and treat pressure ulcers based on these guidelines (Suntken, et al., 1996).

In its 140 long term care facilities, the Department of Veterans Affairs has undertaken a major quality improvement program to reduce the rate of pressure ulcers. In 1991, the VA Office of Quality Management began a program of calculating facility-specific incidence rates of pressure ulcers and disseminating the results to all long term care facilities in the VA system (Berlowitz, 1997). The VA viewed pressure ulcer development as an ideal indicator because they are common, required the coordinated efforts and attention of multiple health care providers, and

could serve as a sentinel for more systemic problems in a facility. A VA facility in Memphis, TN, employed a team-based approach to monitor patients and provide skin care. The rate of pressure ulcer development dropped from 11.5 percent to zero. Overall, the VA has experienced a decline in the incidence of pressure ulcers from 4.9 percent in 1990 to 3.1 percent in 1993. This offers another example where the feedback of quality measures prompts improvements in the quality of care.

Reducing Low-Birthweight Births

Though infant mortality rates in the United States have declined, the incidence of low birthweight babies has not. This trend is troubling since seventy percent of infant mortality traces to low birthweight newborns (Goldenberg, et al., 1998). Also, low birthweight babies often require extensive and costly treatments. An AHCPR-sponsored Patient Outcome Research Team (PORT) studied the use of drugs called corticosteroids as one treatment to reduce morbidity and mortality in these newborns. For these premature newborns, the PORT found that corticosteroids prevented many of the complications associated with prematurity—respiratory distress syndrome, brain hemorrhage and death.

Based on the PORT's work and other findings, an NIH consensus panel issued a guideline recommending corticosteroid treatment of women at risk of very pre-term deliveries (NIH, 1994). The NIH disseminated this guideline to Federal health agencies, health care organizations, continuing medical education directors at hospitals, deans of medical schools, and directors of state and county medical societies. The media and major medical journals also covered the release of the guideline. Prior to the release of the guideline, only 30 percent of women who delivered prematurely received corticosteroids. By 1996, this had risen to 70 percent (Goldenberg et al., 1998). Another study found that nearly 87 percent of obstetricians surveyed after the release of the NIH consensus statement believed that corticosteroids could reduce infant mortality. Consistent with the NIH guidelines, 91 percent of obstetricians reported that they would prescribe this drug therapy to prevent the complications of pre-term deliveries (Wright, 1996). An NIH-commissioned study concludes that if corticosteroids were used in 60 percent of cases threatening preterm delivery, \$157 million could be saved annually (NIH, 1994).

Preventing Adverse Drug Reactions

Preventable adverse drug events cause significant mortality each year (Leape, 1994). Responding to this problem, providers have led efforts to make significant improvements in the rate of adverse drug events.

LDS Hospital in Salt Lake City, Utah, has taken steps to improve its rate of adverse drug events. From 1990 to 1993, they discovered that 2.43 percent of hospital patients experienced an adverse drug event (Classen, 1997). The hospital projected that if 50 percent of these reactions were

prevented, cost savings would total \$500,000, and hospitalization would be reduced by 450 days annually. The hospital took a multi-pronged approach that involved providing timely feedback to physicians to prevent severe problems; more effective tracking of patient drug allergies; a program that monitors kidney function while patients receive certain antibiotics with toxic effects on the kidneys; and a computerized disease management program for antibiotic use that integrates all of these components. These efforts led to a 75 percent decline in adverse drug reactions related to antibiotics.

Through the Institute for Healthcare Improvement's Breakthrough series, Michigan's Pontiac Osteopathic Hospital Medical Center achieved an 80 percent reduction in adverse drug events in its cardiac monitoring unit in 1 year (Leape, 1998). The program included standardization of physician order forms, especially for common conditions covered by standardized treatment regimens; thorough notation of patient drug allergies through computerized systems and wristbands; education on and easy access to drug incompatibility information; increased availability of needed medications; and routine monitoring of drug distribution. In total, 43 health care organizations participated in the Breakthrough series, setting a goal of reducing adverse drug reactions by 30 percent or more. After 1 year, one-third of the organizations had exceeded those targets.

The American Medical Association recently launched a National Patient Safety Foundation with broad support from accreditation organizations, academic institutions, health plans, and other partners. Its mission is to "enhance the safety of the US health care system" by (1) promoting research on human and organizational error and its prevention; (2) increasing awareness and communication in patient safety and errors; and (3) encouraging the application of knowledge in this field (National Patient Safety Foundation, 1998).

The Joint Commission on the Accreditation of Healthcare Organizations has established a Sentinel Event Policy, which encourages accredited health care organizations to voluntarily report unexpected events or errors that lead to death, serious physical or psychological injury (JCAHO, 1998). If an organization does not conduct an acceptable analysis of the root cause of the error, the JCAHO will place that hospital on Accreditation Watch, a fact that may be publicly disclosed as part of the organization's existing accreditation status. This designation signifies that the organization is under close monitoring by the Joint Commission.

The Department of Veterans Affairs has also designed an error reduction system in health care for use throughout its delivery system. This VA effort has taken lessons from the Aviation Safety Reporting System. Under this system, the Federal Aviation Administration has increased the reporting of errors in aviation and improved safety with steps ranging from better air traffic control procedures to a recognition of problems with pilot fatigue (President's Advisory Commission, 1998).

IV. Private Sector Efforts in Value-Based Purchasing and Quality Improvement

Employers, labor unions, and other private group purchasers have increasingly demanded higher quality care for the dollars they spend on health coverage. One official at GTE stated, "We think that improved quality inherently costs less. Improve the quality of health care and, in turn, improve the quality of life" (The Business Roundtable, 1997). GTE found that in 1995, its high performance managed care plans had hospital costs that were 11.5 percent below the national average. Risk-adjusted mortality rates were 8 percent lower than previously expected. On the other hand, low performance managed care plans had costs that were 3.6 percent above the national average and risk-adjusted mortality rates that were only 2 percent lower than expected (Sheffler, 1996). Many private purchasers are developing quality improvement programs, developing report cards and other measurement tools to help assure that they can purchase health care based on quality, not just cost and benefits. By measuring and rewarding quality, all of these purchasers have invested their resources in an effort to improve care, increase satisfaction, and reduce costs. For example:

- ◆ GTE provides its employees and their families with financial incentives to enroll in "exceptional quality" plans (those with high ratings on quality measures and satisfaction surveys). Employees receive report cards on plans so that they can choose a plan based on cost and quality. Initial analysis of this approach showed that employees who considered making a health plan change were most sensitive to cost. However, they also relied significantly on specific quality information, with 30 percent considering GTE's designation of "exceptional quality," and 45 percent considering the quality scores based on HEDIS and participant satisfaction measures (Sheffler, 1996).
- ◆ General Motors blends several measures of health care quality into one amalgamated quality measure and draws from direct indicators of quality from HEDIS, employee satisfaction measures, accreditation status, and impressions gained from site visits. GM also works with its plans to develop quality improvement strategies and facilitate the sharing of best practices (Meyer, et al., 1997).
- ◆ Digital Equipment Corporation emphasizes value (which it defines as the sum of quality of care and consumer satisfaction, divided by costs) in its health care purchasing decisions. Using information yielded from its performance reporting requirements, Digital identifies the best plan in each region as the "benchmark" plan and bases its contribution to the cost of health coverage on the premium charged by that plan (Meyer, et al., 1997).
- ◆ The Pacific Business Group on Health requires HMOs to set aside 2 percent of the premium dollar and allows plans to keep that money only if they attain the performance

standards set in customer service, quality, data collection, and other areas (Bodenheimer, et al., 1998).

- ◆ Seven leading business and employer organizations have recently announced a new initiative, the Employer Quality Partnership (EQP), to "accelerate the growing emphasis on quality in private health plans." EQP's has released informational guides and launched a Web site as part of their efforts to educate the public about the role of employers as health care purchasers.
- ◆ The United Auto Workers labor union requires quality accreditation for all health plans offered to its members, and it is working on a strategy to provide information, including NCQA accreditation status and some quality assessment based on HEDIS measures (AFL-CIO, 1997).

Recognizing that quality health care can also lead to increased worker productivity, health plans are developing quality improvement programs that improve productivity and reduce costs. For example, the Southern California Region of Kaiser Permanente developed an "Intervention for Employment Maintenance for Members with End Stage Renal Disease." This program involves a pre-dialysis orientation for patients. Six months before beginning dialysis, patients and their families are referred to a clinical social worker and nurse educator for evaluation and education. This collaborative team effort continues throughout the periods prior to and during dialysis, and routine monitoring and education is available for the patient. As a result of this program, blue-collar workers in the Kaiser program were 2.8 times more likely to maintain employment than a control group, with these individuals working an average of 35 hours per week. According to Kaiser, " 'working patients had increased quality of life, self-esteem, better health, and a more positive attitude toward work and life than nonworkers' " (Kaiser Permanente, 1996).

V. Why We Need a National Effort to Improve Quality

Some effective strategies have been developed to improve the quality of health care delivered to patients every day. The promising developments described in this report, along with other efforts by private industry, labor unions, States, and the Federal government, are reason for optimism. However, it is also clear that a patchwork of efforts will not lead to significant, continuous nationwide improvements in health care quality.

As the President's Commission noted, "Incentives to improve quality have been diluted by measurement efforts that vary widely in their aims and scope, and that have been, at best, only informally coordinated" (Final Report, 1998). There are many areas that have been left unaddressed by the current system. For example, there are few quality measures or quality improvement programs on chronic conditions, and little data about quality care in institutional

settings, such as nursing homes or home health agencies. Moreover, there are millions of consumers and public and private purchasers that do not have access to any of this type of information.

Also, the current system is often burdensome and redundant. For example, health plans and providers often have to collect excessive data to satisfy the variety of different reporting requirements and information needs of purchasers and consumers. Testifying before the President's Advisory Commission, Dr. Steven Udvarhelyi of Independence Blue Cross of Pennsylvania characterized the development and application of performance measures as essential to improving quality. However, he also noted that to report separate versions of HEDIS 3.0 required for commercial, Medicaid and Medicare populations and for each of three states, Independence Blue Cross had to file nine different reports with a total of 675 indicators. State-by-state mandates for ad hoc performance measures add to the quality measurement burdens facing his organization.

Moreover, at present, employers, labor unions and other group purchasers do not have a central repository for learning about best purchasing practices, nor do they have affordable access to the technical assistance that would permit replication of the practices of pioneers (Meyer, et al., 1997). Therefore, a program that has proven effective in lowering mortality following cardiac surgery in New York hospitals or a model asthma program that has improved health outcomes and saved purchasers money may never be borrowed by others interested in implementing similar initiatives.

VI. Proposing a Forum for Health Care Quality Measurement and Reporting

It is clear that directing attention to measurement gaps, reducing the burden of multiple reporting requirements, and encouraging the sharing of best practices will require much greater coordination across sectors of the health care industry.

In its Final Report to the President, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry recommended a Forum for Health Care Quality Measurement and Reporting that would:

- Develop a comprehensive plan for implementing quality measurement, data collection, and reporting standards to ensure the widespread public availability of comparative information on the quality of care furnished by all sectors of the health care industry;
- Establish measurement priorities that address the national aims for improvement and that meet the common information needs of consumers, purchasers, Federal and State policymakers, public health officials, and other stakeholders;

- Periodically endorse core sets of quality measures and standardized methods for measurement and reporting;
- Make recommendations regarding an agenda for research and development needed to advance quality measurement and reporting, and sponsor research and development activities if resources are available;
- Develop and foster implementation of an effective public education, communication and dissemination plan to make quality measures and comparative information on quality most useful to consumers and other interested parties; and
- Encourage the development of health information systems and technology to support quality measurement, reporting, and improvement needs.

To be effective as a private sector entity, the Commission noted that the Forum must be broadly representative of key stakeholders in health care. Such participation will draw upon public and private group purchasers; individuals and organizations focused on representation of consumers and patients; health care providers; labor unions; experts in quality assurance, improvement and measurement; quality oversight organizations; health care researchers; and public health experts. This broad participation will enable the Forum to be attuned to the changing needs of the health care system, and as a private sector entity, afford it greater flexibility to respond. Substantial representation of purchasers and consumers in its governance will also position the Forum to marshal market forces needed to drive this initiative forward. By coming together, this wide range of private and public purchasing power would be able to use their combined market power to assure they receive the information they need.

At the same time this effort would reduce the burdens on providers and health plans who would be able to collect a consistent set of data, reducing the duplication and burdens in the current system. Health care providers would also be able to use this information to develop targeted ways to improve their own performance. Moreover, by collecting and making this information publicly available, consumers, employers, and other purchasers would be able to make meaningful comparisons on the quality among plans and providers. For the first time, health plans and providers would compete on the quality of services not just costs and benefits.

Developing and disseminating these consistent measures of quality would also enable individuals to track the health care industry's progress in achieving national quality improvement aims and to guide public planning and policy making.

As the examples in this report demonstrate, collaboration does occur among providers, health plans, consumers, employers and other health care purchasers, but these examples are far too few and often too isolated. It is no longer fair or sufficient to depend on these leaders to carry the full weight of this effort. There is a clear need to coordinate and build upon these leading edge efforts, so that many more Americans can benefit from this critical work to advance the quality of health care.

VII. Planning for a Forum

To launch a Forum for Health Care Quality Measurement and Reporting, the Quality Commission recognized the need to resolve important issues of governance, organizational structure, and financial support under the auspices of a neutral convener. The first stage of this process will be a six-month period where a planning committee will work to lay the groundwork for the operations of the Forum, recruit stable funding, and ensure broad representation of stakeholders. Private and public purchasers, consumer groups, health plans, and healthcare accrediting organizations have welcomed the efforts to create this private sector entity and affirm the need for collaborative and coordinated efforts.

Building on the work of the Advisory Commission, this report highlights some of the best examples of what the public and private sectors can do to improve health care quality. Their leading edge efforts tell us that we can do better. By moving from a patchwork of public and private efforts to systemwide changes, we can bridge the gap between actual practice and best practice. Creating a Forum for Health Care Quality Measurement and Reporting is a critical step in this direction.

References

- AFL-CIO. *Union Guide to Quality Managed Care*, 1997.
- Agency for Health Care Policy and Research and Kaiser Family Foundation. *Americans as Health Care Consumers: The Role of Quality Information*. 1996 October.
- Bates D, Cullen D, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *Journal of the American Medical Association* 1995; 274: 29-34.
- Bates D, Spell N, Cullen D, et al. The costs of adverse drug events in hospitalized patients. *Journal of the American Medical Association* 1997; 277: 307-311.
- Bergstrom N, Allman R, Carlson C, et al. *Pressure Ulcers in Adults: Prediction and Prevention*. Agency for Health Care Policy and Research Clinical Practice Guideline , Number 3. AHCPR Publication No. 9209947. May 1992.
- Bergstrom N, Allman R, Alvarez O, et al. *Treatment of Pressure Ulcers*. Agency for Health Care Policy and Research Clinical Practice Guideline, Number 15. AHCPR Publication No. 95-0652. December 1994.
- Berlowitz D and Halpern J. Evaluating and Improving Pressure Ulcer Care: The VA Experience with Administrative Data. *Joint Commission Journal on Quality Improvement*. 1997 August; 23(8): 424-433.
- Berman S, Byrns P, Bondy J, et al. Otitis media-related antibiotic prescribing patterns, outcomes, and expenditures in a pediatric medicaid population. *Pediatrics*. 1997 Oct; 100(4): 585-592.
- Bernstein SJ, McGlynn EA, Siu AL, et al. The appropriateness of hysterectomy. A comparison of care in seven health plans. Health Maintenance Organization Quality of Care Consortium. *Journal of the American Medical Association*. 1993; 269(18): 2398-2402.
- Brennan T, Leape L, Laird N, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *New England Journal of Medicine* 1991; 324(6): 370-376.
- Bodenheimer T, Sullivan K. How large employers are shaping the health care marketplace? *New England Journal of Medicine* 1998; 338(14): 1003-1007.

The Business Roundtable. *Quality Health Care is Good Business: A Survey of Health Care Quality Initiatives by Members of the Business Roundtable*, September 1997.

Centers for Disease Control. Medicare influenza vaccine demonstration—selected states, 1988-1992. *Morbidity and Mortality Weekly Report* 1992; 41(9): 152-155.

Centers for Disease Control. Influenza and pneumococcal vaccination coverage levels among persons aged >65 years—United States, 1973-1993. *Morbidity and Mortality Weekly Reports* 1995; 44: 506-515.

Centers for Disease Control. National Breast and Cervical Cancer Early Detection Program Fact Sheet. <http://www.cdc.gov/nccdphp/dcpc/nbccedp/about.htm>. 1998.

Chassin MR. Assessing strategies for quality improvement. *Health Affairs* 1997; 16(3): 151-161

Clarke SC and Taffel SM. State variation in rates of cesarean and VBAC delivery: 1989 and 1993. *Statistical Bulletin/Metropolitan Insurance Companies* 1996 Jan; 77(1): 28-36.

Classen D, Pestonik S, Evans S, et al. Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality. *Journal of the American Medical Association* 1997; 277: 301-306.

Cleveland Health Quality Choice Program. The Greater Cleveland Consumer Report on Hospital Performance: A Summary of Information from The Cleveland-Area Hospital Quality Outcomes Measurements and Patient Satisfaction Report, November 11, 1997, <http://clevnet.cpl.org/CHQC>.

Department of Veterans Affairs Health Services Research and Development Service, Management Decision and Research Center. *Practice Matters*. 1996; 1(1).

Goldenberg R, et al. *Low Birthweight PORT Final Report: Patient Outcomes Research Team on Low Birthweight in Minority and High-Risk Women*. Agency for Health Care Policy and Research. 1998. Unpublished.

Gonzales R, Steiner J, Sande M. Antibiotic prescribing for adults with colds, upper respiratory tract infections, and bronchitis by ambulatory care physicians. *Journal of the American Medical Association* 1997; 278: 901-904.

Govaert M, Thijs C, Masurel N, et al. The efficacy of influenza vaccination in elderly individuals. *Journal of the American Medical Association* 1994; 272(21): 1661-1665.

Graves E and Gillum B. National hospital discharge survey: annual summary, 1994. *Vital and Health Statistics* 1997; 13: 1-146.

Greineder DK, Loane KC, Parks P. Reduction in resource utilization by an asthma outreach program. *Archives of Pediatrics and Adolescent Medicine* 1995; 149(4): 415-420.

Group Health Association of America. *Innovative Answers for America's Health Care: Best Practices in HMOs*. 1995.

Hannan EL, Kilburn H, Racz M, Shields E, Chassin MR. *Journal of the American Medical Association* 1994; 271: 761-766.

Hannan E, Kumar D, Racz M, et al. New York State's Cardiac Surgery Reporting System: four years later. *Annals of Thoracic Surgery* 1994; 58: 1852-1857.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO). *Sentinel Event Policy Reference Manual*. Chicago: JCAHO. 1998.

Jordan H, Staus J, and Bailit M. Reporting and using health plan performance information in Massachusetts. *Joint Commission Journal on Quality Improvement* 1995; 21: 167-177).

Kaiser Permanente. Quality Notes. May/June 1996.

Kleinman L, Kosecoff J, Dubois R, et al. The medical appropriateness of tympanostomy tubes proposed for children younger than 16 years in the United States. *Journal of the American Medical Association* 1994; 271: 1250-1255.

Krumholz H, Radford M, Ellerbeck E, et al. Aspirin in the Treatment of Acute Myocardial Infarction in Elderly Medicare Beneficiaries: Patterns of Use and Outcomes. *Circulation* 1995; 92(10): 2841-2847.

Lantner R, Ros S. Emergency management of asthma in children: impact of NIH guidelines. *Annals of Allergy, Asthma and Immunology* 1995; 74: 188-191.

Leape L. Error in medicine. *Journal of the American Medical Association* 1994; 272: 1851-1857.

Leape L, Kabacoff A, Berwick D, and Roessner J. *Breakthrough Series Guide: Reducing Adverse Drug Events*. Boston: Institute for Healthcare Improvement. 1998.

Longo DR, Garland L, Schramm W, Fraas J, Hoskins B, Howell V. Consumer reports in health care: do they make a difference in patient care? *Journal of the American Medical Association* 1997; 278: 1579-1584.

Marciniak T, Ellerbeck E, Radford M, et al. Improving the quality of care for Medicare patients with acute myocardial infarction: Results from the Cooperative Cardiovascular Project. *Journal of the American Medical Association* 1998; 279: 1351-1357.

McKenzie L, et al. Variation in cesarean section rates among hospitals in Washington State. *American Journal of Public Health*. 1993 Aug; 83(8): 1109-1112.

Meyer J, Rybowski L, Eichler R. *Theory and Reality of Value-based Purchasing: Lessons from Pioneers*. AHCPR Publication No. 98-0004, November 1997.

National Asthma Education and Prevention Program (NAEPP). *Guidelines for the Diagnosis and Management of Asthma*. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health. NIH Publication No. 91-3042, 1991.

National Asthma Education and Prevention Program (NAEPP). AsthmaMemo. http://www.nhlbi.nih.gov/nhlbi/lung/asthma/prof/asth_mem.htm. 1996.

National Asthma Education and Prevention Program (NAEPP). *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma*. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health. NIH Publication No. 97-4051, 1997.

National Asthma Education and Prevention Program (NAEPP). *Practical Guide for the Diagnosis and Management of Asthma*. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health. NIH Publication No. 97-4053, 1997.

National Asthma Education Program (NAEPP). Program Description. http://www.nhlbi.nih.gov/nhlbi/othcomp/opec/naepp/naep_pd.htm. 1998.

National Center for Health Statistics. Births, Marriages, Divorces, and Deaths for 1996. 45(12.20): 97-1120, 1997.

National Committee for Quality Assurance. *The State of Managed Care Quality*. 1997. <http://www.ncqa.org>.

National Committee for Quality Assurance. <http://www.ncqa.org>. 1998

National Institutes of Health. National Diabetes Education Program.

<http://www.niddk.nih.gov/health/diabetes/diabetes.htm>. 1998

National Institutes of Health Consensus Development Conference on the Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes. The effect of antenatal steroids for fetal maturation on perinatal outcomes. NIH Consensus Statement, 1994 Feb 28-Mar 2; 12(2).

National Patient Safety Foundation. <http://www.ama-assn.org/med-sci/npsf/main.htm>. 1998.

O'Connor G, Plume SK, Olmstead EM, et al. A regional intervention to improve the hospital mortality associated with coronary artery bypass graft surgery. *Journal of the American Medical Association* 1996; 275(11): 841-846.

Phelps C. Bug/drug resistance: sometimes less is more. *Medical Care*. 1989; 27: 194-203.

President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. *Quality First: Better Health Care for All Americans – Final Report to the President of the United States*. 1998 March.

Sheffler S. What do we know about the information that people need or use? Lessons from employed populations? Presentation before the Henry J. Kaiser Family Foundation/Agency for Health Care Policy and Research Conference – Value and Choice: Providing Consumers with Information on the Quality of Health Care. Arlington, VA. October 29-30, 1996.

Soumerai SB, McLaughlin TJ, Spiegelman D, et al. Adverse outcomes of underuse of β -blockers in elderly survivors of acute myocardial infarction. *Journal of the American Medical Association* 1997; 277(2): 115-121.

Soumerai SB, McLaughlin TJ, Gurwitz JH, et al. Effect of local medical opinion leaders on quality of care for acute myocardial infarction: a randomized controlled trial. *Journal of the American Medical Association* 1998; 279(17): 1358-1363.

Strickland D. Asthma--a prominent target for disease management programs. *1997 Disease State Management Sourcebook: A Resource Guide to Chronic Care Programs*. Faulkner & Gray. 1996.

Suntken G, Starr B, Ermer Seltun J, et al. Implementation of a comprehensive skin care program across care settings using the AHCPR pressure ulcer prevention and treatment guidelines. *Ostomy/Wound Management*. 1996 Mar; 42(2): 20-22.

Weiss K, Mendoza G, Schall M, et al. *Breakthrough Series Guide: Improving Asthma Care in Children and Adults*. Boston: Institute for Healthcare Improvement, 1997.

Wiener J, Parente S, Garnick D, et al. Variation in office-based quality: a claims-based profile of care provided to Medicare patients with diabetes. *Journal of the American Medical Association* 1995. 273: 1503-1508.

Wilbur D. False negatives in focused rescreening of papincolaou smears: how frequently are 'abnormal' cells detected in retrospective review of smears preceding cancer or high-grade intraepithelial neoplasia. *Archives of Pathology and Laboratory Medicine* 1997; 121(3): 273-276.

Wright L, Merenstein G, and Goldenberg R, et al. The NIH Consensus Development Conference on corticosteroids for fetal maturation: change in obstetric attitudes. Paper presented to the Society of Perinatal Obstetricians. Spring 1996.

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Errors in Health Care: A Leading Cause of Death and Injury

Health care is not as safe as it should be. A substantial body of evidence points to medical errors as a leading cause of death and injury.

- *Sizable numbers of Americans are harmed as a result of medical errors.* Two studies of large samples of hospital admissions, one in New York using 1984 data and another in Colorado and Utah using 1992 data, found that the proportion of hospital admissions experiencing an adverse event, defined as injuries caused by medical management, were 2.9 and 3.7 percent,¹ respectively. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent in New York, and 53 percent in Colorado and Utah.²

- Preventable adverse events are a leading cause of death in the United States. When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors.³ Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th leading cause of death.⁴ Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).⁵

- Total national costs (lost income, lost household production, disability, health care costs) are estimated to be between \$37.6 billion and \$50 billion for adverse events and between \$17 billion and \$29 billion for preventable adverse events.⁶ Health care costs account for over one-half of the total costs. Even when using the lower estimates, the total national costs associated with adverse events and preventable adverse events represent approximately 4 percent and 2 percent, respectively, of national health expenditures in 1996.⁷ In 1992, the direct and

indirect costs of adverse events were slightly higher than the direct and indirect costs of caring for people with HIV and AIDS.⁸

- In terms of lives lost, patient safety is as important an issue as worker safety. Although more than 6,000 Americans die from workplace injuries every year,^{9,10} in 1993 medication errors are estimated to have accounted for about 7,000 deaths.¹¹ Medication errors account for one out of 131 outpatient deaths and one out of 854 inpatient deaths.

- Medication-related errors occur frequently in hospitals; not all result in actual harm, but those that do are costly. One recent study conducted at two prestigious teaching hospitals found that almost two percent of admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of \$4,700 per admission or about \$2.8 million annually for a 700-bed teaching hospital.¹² If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about \$2 billion for the nation as a whole.

- Hospital patients represent only a fraction of the total population at risk of experiencing a medication-related error. In 1998, nearly 2.5 billion prescriptions were dispensed by U.S. pharmacies at a cost of about \$92 billion.¹³ Numerous studies document errors in prescribing medications,^{14,15} dispensing by pharmacists,¹⁶ and unintentional nonadherence on the part of the patient.¹⁷ Medication errors have the potential to increase as a major contributor to avoidable morbidity and mortality as new medications are introduced for a wider range of indications.

This chapter provides a summary of findings in the literature on the frequency and cost of health care errors and the factors that contribute to their occurrence.

INTRODUCTION

Although the literature pertaining to errors in health care has grown steadily over the last decade and some notable studies are particularly strong methodologically, we do not yet have a complete picture of the epidemiology of errors. Many studies focus on patients experiencing injury and provide valuable insight into the magnitude of harm resulting from errors. Other studies, more limited in number, focus on the occurrence of errors, both those that result in harm and those that do not (sometimes called “near misses”). More is known about errors that occur in hospitals than in other health care delivery settings.

Synthesizing and interpreting the findings in the literature pertaining to errors in health care is complicated due to the absence of standardized nomenclature. For purposes of this report, the terms error and adverse event are defined as follows:

An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).¹⁸

An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event."¹⁹ Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).²⁰

When a study in the literature has used a definition that deviates from the above definitions, it is noted below.

Medication-related error has been studied extensively for several reasons: it is one of the most common types of error, substantial numbers of individuals are affected, and it accounts for a sizable increase in health care costs.^{21, 22, 23} There are also methodologic issues: (1) prescription drugs are widely used, so it is easy to identify an adequate sample of patients who experience adverse drug events; (2) the drug prescribing process provides good documentation of medical decisions, and much of this documentation resides in automated, easily accessible databases; and (3) deaths attributable to medication errors are recorded on death certificates. There are probably other areas of health care delivery that have been studied to a lesser degree but may offer equal or greater opportunity for improvement in safety.

Efforts to assess the importance of various types of errors are currently hampered by the lack of a standardized taxonomy for reporting adverse events, errors, and risk factors.^{24,25} A limited number of studies focus directly on the causes of adverse events, but attempts to classify adverse events according to "root causes" are complicated by the fact that several interlocking factors often contribute to an error or series of errors that in turn result in an adverse event.^{26,27} In recent years, some progress toward a more standardized nomenclature and taxonomy has been made in the medication area, but much work remains to be done.²⁸

The following discussion of the literature addresses four questions:

1. How frequently do errors occur?
2. What factors contribute to errors?
3. What are the costs of errors?
4. Are public perceptions of safety in health care consistent with the evidence?

HOW FREQUENTLY DO ERRORS OCCUR?

For the most part, studies that provide insight into the incidence and prevalence of errors fall into two categories:

1. *General studies of patients experiencing adverse events.* These are studies of adverse events in general, not studies limited to medication-related events. These studies are limited in number, but some represent large-scale, multi-institutional analyses. Virtually all studies in this category focus on hospitalized patients. With the exception of medication-related events discussed in the second category, little if any research has focused on errors or adverse events occurring outside of hospital settings, for example, in ambulatory care clinics, surgicenters, office practices, home health, or care administered by patients, their family, and friends at home.

2. *Studies of patients experiencing medication-related errors.* There is an abundance of studies that fall into this category. Although many focus on errors and adverse events associated with ordering and administering medication to hospitalized patients, some studies focus on patients in ambulatory settings.

Adverse Events

An adverse event is defined as an injury caused by medical management rather than by the underlying disease or condition of the patient.²⁹ Not all, but a sizable proportion of adverse events are the result of errors. Numerous studies have looked at the proportion of adverse events attributable to medical error. Due to methodologic challenges, far fewer studies focus on the full range of error—namely, those that result in injury *and* those that expose the patient to risk but do not result in injury.

The most extensive study of adverse events is the Harvard Medical Practice Study, a study of more than 30,000 randomly selected discharges from 51 randomly selected hospitals in New York State in 1984.³⁰ Adverse events, manifest by prolonged hospitalization or disability at the time of discharge or both, occurred in 3.7 percent of the hospitalizations. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent and the proportion of adverse events due to negligence was 27.6 percent. Although most of these adverse events gave rise to disability lasting less than six months, 13.6 percent resulted in death and 2.6 percent caused permanently disabling injuries. Drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent).^{31,32}

The findings of the Harvard Medical Practice Study in New York have recently been corroborated by a study of adverse events in Colorado and Utah occurring in 1992.³³ This study included the review of medical records pertaining to a random sample of 15,000 discharges from a representative sample of hospitals in the two states. Adverse events occurred in 2.9 percent of hospitalizations in each state. Over four out of five of these adverse events occurred in the hospital, the remaining occurred prior to admission in physicians' offices, patients' homes or other non-hospital settings. The proportion of adverse events due to negligence was 29.2 percent, and the proportion of adverse events that

were preventable was 53 percent.³⁴ As was the case in the New York study, over 50 percent of adverse events were minor, temporary injuries. But the study in New York found that 13.6 percent of adverse events led to death, as compared with 8.8 percent in Colorado and Utah. In New York, about one in four negligent adverse events led to death, while in Colorado and Utah, death resulted in about 1 out of every 11 negligent adverse events. Factors that might explain the differences between the two studies include: temporal changes in health care, and differences in the states' patient populations and health care systems.³⁵

Both the study in New York and the study in Colorado and Utah identified a subset of preventable adverse events that also satisfied criteria applied by the legal system in determining negligence. It is important to note that although some of these cases may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.

Extrapolation of the results of the Colorado and Utah study to the over 33.6 million admissions to hospitals in the United States in 1997, implies that at least 44,000 Americans die in hospitals each year as a result of preventable medical errors.³⁶ Based on the results of the New York study, the number of deaths due to medical error may be as high as 98,000.³⁷ By way of comparison, the lower estimate is greater than the number of deaths attributable to the 8th leading cause of death.³⁸

Some maintain these extrapolations likely underestimate the occurrence of preventable adverse events because these studies: (1) considered only those patients whose injuries resulted in a specified level of harm; (2) imposed a high threshold to determine whether an adverse event was preventable or negligent (concurrence of two reviewers); and (3) included only errors that are documented in patient records.³⁹

Two studies that relied on both medical record abstraction and other information sources, such as provider reports, have found higher rates of adverse events occurring in hospitals. In a study of 815 consecutive patients on a general medical service of a university hospital, it was found that 36 percent had an iatrogenic illness, defined as any illness that resulted from a diagnostic procedure, from any form of therapy, or from a harmful occurrence that was not a natural consequence of the patient's disease.⁴⁰ Of the 815 patients, nine percent had an iatrogenic illness that threatened life or produced considerable disability, and for another two percent, iatrogenic illness was believed to contribute to the death of the patient.

In a study of 1,047 patients admitted to two intensive care units and one surgical unit at a large teaching hospital, 480 (45.8 percent) were identified as having had an adverse event, where adverse event was defined as "situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen".⁴¹ For 185 patients (17.7 percent), the adverse event was serious, producing disability or death. The likelihood of experiencing an adverse event increased about six percent for each day of hospital stay.

Some information on errors can also be gleaned from studies that focus on inpatients who died or experienced a myocardial infarction or postsurgical complication. In a study of 182 deaths in 12 hospitals from three conditions (cerebrovascular accident, pneumonia, or myocardial infarction), it was found that at least 14 percent and possibly as many as 27 percent of the deaths might have been prevented.⁴² A 1991 analysis of 203 incidents of cardiac arrest at a teaching hospital,⁴³ found that 14 percent followed an iatrogenic complication and that more than half of these might have been prevented. In a study of 44,603 patients who underwent surgery between 1977 and 1990 at a large medical center, 2,428 patients (5.4 percent) suffered complications and nearly one-half of these complications were attributable to error.⁴⁴ Another 749 died during the same hospitalization; 7.5 percent of these deaths were attributed to error.

Patients who died during surgery requiring general anesthesia have been the focus of many studies over the last few decades. Anesthesia is an area in which very impressive improvements in safety have been made. As more and more attention has been focused on understanding the factors that contribute to error and on the design of safer systems, preventable mishaps have declined.^{45,46,47,48} Studies, some conducted in Australia, the United Kingdom and other countries, indicate that, today, anesthesia mortality rates are about one death per 200,000–300,000 anesthetics administered, compared with two deaths per 10,000 anesthetics in the early 1980s.⁴⁹ The gains in anesthesia are very impressive and were accomplished through a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines, and other systematic approaches to reducing errors.⁵⁰

Lastly, some studies have relied on incident reporting systems to identify and analyze errors. For example, in Australia, 324 general practitioners participating voluntarily in an incident reporting system reported a total of 805 incidents during October 1993 through June 1995, of which 76 percent were preventable and 27 percent had the potential for severe harm.⁵¹ These studies provide information on the types of errors that occur but are not useful for estimating the incidence of errors, because the population at risk (i.e., the denominator) is generally unknown.

Medication-Related Errors

Even though medication errors that result in death or serious injury occur infrequently, sizable and increasing numbers of people are affected because of the extensive use of drugs in both out-of-hospital and in-hospital settings. In 1998, nearly 2.5 billion prescriptions were dispensed in U.S. pharmacies at an estimated cost of about \$92 billion.⁵² An estimated 3.75 billion drug administrations were made to patients in hospitals.⁵³

In a review of U.S. death certificates between 1983 and 1993, it was found that 7,391 people died in 1993 from medication errors (accidental poisoning by drugs, medicaments, and biologicals that resulted from acknowledged errors by

patients or medical personnel), compared with 2,876 people in 1983, representing a 2.57-fold increase.⁵⁴ Outpatient deaths due to medication errors rose 8.48-fold during the 10-year period, compared with a 2.37-fold increase in inpatient deaths.

Medication Errors in Hospitals

Medication errors occur frequently in hospitals. Numerous studies have assessed the incidence of adverse drug events (ADEs), defined as an injury resulting from medical intervention related to a drug.⁵⁵ Not all ADEs are attributable to errors. For example, a patient with no history of allergic reactions to drugs, who experiences an allergic reaction to an antibiotic, has suffered an ADE, but this ADE would not be attributable to error. However, an error would have occurred if an antibiotic was prescribed to a patient with a history of documented allergic reactions, because the medical record was unavailable or not consulted. We discuss only those studies of ADEs that identified the subset of ADEs determined to be preventable (i.e., attributable to errors).

In an analysis of 289,411 medication orders written during one year in a tertiary-care teaching hospital, the overall error rate was estimated to be 3.13 errors for each 1,000 orders written and the rate of significant errors to be 1.81 per 1,000 orders.⁵⁶ In a review of 4,031 adult admissions to 11 medical and surgical units at two tertiary care hospitals, Bates et al. identified 247 ADEs for an extrapolated event rate of 6.5 ADEs per 100 nonobstetrical admissions, and a mean number per hospital per year of approximately 1,900 ADEs.⁵⁷ Twenty-eight percent were judged preventable.

In a study of patients admitted to coronary intensive care, medical, surgical, and obstetric units in an urban tertiary care hospital over a 37-day period, the rate of drug-related incidents was 73 in 2,967 patient-days: 27 incidents were judged ADEs; 34, potential ADEs; and 12, problems orders.⁵⁸ Of the 27 ADEs, five were life threatening, nine were serious, and 13 were significant. Of the 27 ADEs, 15(56 percent) were judged definitely or probably preventable. In a study of prescribing errors detected and averted by pharmacists in a 631-bed tertiary care teaching hospital between July 1994 and June 1995, the estimated overall rate of errors was 3.99 per 1,000 medication orders.⁵⁹

Children are at particular risk of medication errors, and as discussed below, this is attributable primarily to incorrect dosages.^{60,61} In a study of 101,022 medication orders at two children's teaching hospitals, a total of 479 errant medication orders were identified, of which 27 represented potentially lethal prescribing errors.⁶² The frequency of errors was similar at the two institutions, 4.9 and 4.5 errors per 1,000 medication orders. The error rate per 100 patient-days was greater in the pediatric intensive care units (PICUs) than in the pediatric ward or neonatal intensive care units, and the authors attribute this to the greater heterogeneity of patients cared for in PICUs and the broad range of drugs and dosages used. In a four-year prospective quality assurance study, 315

medication errors resulting in injury were reported among the 2,147 neonatal and pediatric intensive care admissions, an error rate of one per 6.8 admissions.⁶³ The frequency of iatrogenic injury of any sort due to a medication error was 3.1 percent—one injury for each 33 intensive care admissions.

Not surprisingly, the potential for medication-related error increases as the average number of drugs administered increases. In a prospective cohort study of 4,031 adult admissions to 11 medical and surgical units in two tertiary care hospitals (including two medical and three surgical ICUs), the rate of preventable ADEs and preventable potential ADEs in ICUs was 19 events per 1,000 patient-days, nearly twice the rate of non-ICUs.⁶⁴ When adjusted for the number of drugs used in the previous 24 hours or ordered since admission, there were no differences in error rates between ICUs and non-ICUs.

Current estimates of the incidence of medication errors are undoubtedly low because many errors go undocumented and unreported.^{65,66,67,68} For example, in a study of patients admitted to five patient care units at a tertiary care hospital during a six month period in 1993, it was found that incident reports were filed with the hospital's quality assurance program or called into the pharmacy hotline for only three of the 54 people experiencing an adverse drug event.⁶⁹

Some errors are also difficult to detect in the absence of computerized surveillance systems. In a study of 36,653 hospitalized patients, Classen et al. identified 731 ADEs in 648 patients, but only 92 of these were reported by physicians, pharmacists, and nurses.⁷⁰ The remaining 631 were detected from automated signals, the most common of which were diphenhydramine hydrochloride and naloxone hydrochloride use, high serum drug levels, leukopenia, and the use of pyronadione and antidiarrheals.

Medication Errors in Ambulatory Settings

There is evidence indicating that ADEs account for a sizable number of admissions to inpatient facilities, but we do not know what proportion of these ADE-related admissions are attributable to errors. One study found that between three and 11 percent of hospital admissions were attributable to ADEs.⁷¹ A review of 14 Australian studies published between 1988 and 1996 reported that 2.4 to 3.6 percent of all hospital admissions were drug related, and between 32 and 69 percent were definitely or possibly preventable. Drug groups most commonly involved were cytotoxics, cardiovascular agents, antihypertensives, anticoagulants, and nonsteroidal anti-inflammatory drugs.⁷²

ADEs also result in increased visits to physician offices and emergency departments. In an analysis of 1,000 patients drawn from a community, office-based medical practice who were observed for adverse drug reactions, adverse effects were recorded in 42 (4.2 percent), of which 23 were judged to be unnecessary and potentially avoidable.⁷³ In an analysis of 62,216 visits to an emergency department by patients enrolled in a health maintenance organization

(HMO), it was found that 1,074 (1.7 percent) were related to medication non-compliance or inappropriate prescribing.⁷⁴

There is a sizable body of literature to document the incidence of patient noncompliance with medication regimens, but less is known about the proportion of noncompliance attributable to medical error (defined as accidental or unintentional nonadherence to a therapeutic program) as opposed to intentional noncompliance. In a meta-analysis of seven studies, Sullivan et al. estimate that 5.5 percent of admissions can be attributed to drug therapy noncompliance, amounting to 1.94 million admissions and \$8.5 billion in hospital expenditures in 1986.⁷⁵ Similar results were obtained by Einarson in a meta-analysis of 37 studies published between 1966 and 1989, which found that hospital admissions caused by ADEs, resulting from noncompliance or unintentionally inappropriate drug use, ranged from 0.2 to 21.7 percent with a median of 4.9 percent and a mean of 5.5 percent.⁷⁶ Patient noncompliance is clearly an important quality issue, but it should be emphasized that we do not know the extent to which non-compliance is related to errors.

FACTORS THAT CONTRIBUTE TO ERRORS

Studies of Adverse Events

Patient safety problems of many kinds occur during the course of providing health care. They include transfusion errors and adverse drug events; wrong-site surgery and surgical injuries; preventable suicides; restraint-related injuries or death; hospital-acquired or other treatment-related infections; and falls, burns, pressure ulcers, and mistaken identity. Leape et al. have characterized the kinds of errors that resulted in medical injury in the Medical Practice Study as diagnostic, treatment, preventive, or other errors (see Box 2.1).

More than two-thirds (70 percent) of the adverse events found in this study were thought to be preventable, with the most common types of preventable errors being technical errors (44 percent), diagnosis (17 percent), failure to prevent injury (12 percent) and errors in the use of a drug (10 percent). The contributions of complexity and technology to such error rates is highlighted by the higher rates of events that occur in the highly technical surgical specialties of vascular surgery, cardiac surgery, and neurosurgery. In hospitals, high error rates with serious consequences are most likely in intensive care units, operating rooms and emergency departments.

Thomas et al., in their study of admissions to hospitals in Colorado and Utah experiencing adverse events found that about 30 percent were attributable to negligence.⁷⁷ The hospital location with the highest proportion of negligent adverse events (52.6 percent) was the emergency department. The authors note the complexity inherent in emergency medical care and point to the need to improve teamwork and standardize work procedures.

Other studies have made similar attempts to classify errors. Dubois and Brook studied 49 preventable deaths from 12 hospitals, and found that for those who died of a myocardial infarction, preventable deaths reflected errors in management; for cerebrovascular accident, most deaths reflected errors in diagnosis; and for pneumonia, some deaths reflected errors in management and some reflected errors in diagnosis⁷⁸. In an analysis of 203 cardiac arrests at a teaching hospital, Bedell et al., found that of the half that might have been prevented, the most common causes of potentially preventable arrest were medication errors and toxic effects, and suboptimal response by physicians to clinical signs and symptoms⁷⁹.

Studies of Medication Errors

Ensuring appropriate medication use is a complex process involving multiple organizations and professionals from various disciplines; knowledge of drugs; timely access to accurate and complete patient information; and a series of interrelated decisions over a period of time. As shown in Box 2.2, errors can creep into this process at various points. Some errors are errors of commission (e.g., administration of improper drug), while others are errors of omission (e.g., failure to administer a drug that was prescribed).

BOX 2.1 Types of Errors

Diagnostic

- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment

- Error in the performance of an operation, procedure, or test
- Error in administering the treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate (not indicated) care

Preventive

- Failure to provide prophylactic treatment
- Inadequate monitoring or follow-up of treatment

Other

- Failure of communication
- Equipment failure
- Other system failure

SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. *Qual Rev Bull* 19(5):144-149 1993

BOX 2.2 Medication Use Processes**Prescribing**

- Assessing the need for and selecting the correct drug
- Individualizing the therapeutic regimen
- Designating the desired therapeutic response

Dispensing

- Reviewing the order
- Processing the order
- Compounding and preparing the drug
- Dispensing the drug in a timely manner

Administering

- Administering the right medication to the right patient
- Administering medication when indicated
- Informing the patient about the medication
- Including the patient in administration

Monitoring

- Monitoring and documenting patient's response
- Identify and report adverse drug events
- Reevaluate drug selection, regimen, frequency and duration

Systems and Management Control

- Collaborating and communicating amongst caregivers
- Review and manage patient's complete therapeutic drug regimen

SOURCE: Nadzam, Deborah M., Development of medication-use indicators by the Joint Commission on Accreditation of Health Care Organizations. *AJHP*. 48:1925-1930, 1991.

Medication errors are often preventable, although reducing the error rate significantly will require multiple interventions. In the study of prescribing errors conducted by Lesar et al.⁸⁰, the most common factors associated with errors were decline in renal or hepatic function requiring alteration of drug therapy (13.9 percent); patient history of allergy to the same medication class (12.1 percent); using the wrong drug name, dosage form, or abbreviation (11.4 percent for both brand name and generic name orders); incorrect dosage calculations (11.1 percent); and atypical or unusual and critical dosage frequency considerations (10.8 percent). The most common groups of factors associated with errors were those related to knowledge and the application of knowledge regarding drug therapy (30 percent); knowledge and use of knowledge regarding patient factors that affect drug therapy (29.2 percent); use of calculations, decimal points, or unit and rate expression factors (17.5 percent); and nomenclature—for example incorrect drug name, dosage form, or abbreviations (13.4 percent).

Many studies have identified inappropriate prescribing as a particularly important factor in accounting for medication errors. In an analysis of 1987 Na-

tional Medical Expenditure Survey data, it was found that physicians prescribe potentially inappropriate medications for nearly a quarter of all older people living in the community.⁸¹ In a study of 366 consecutive patients admitted to a department of cardiology, “definite” or “probable” drug events (i.e., adverse drug reactions and dose-related therapeutic failures) accounted for 15 admissions, of which five were judged to be due to error in prescription and another five judged to have been avoidable had appropriate measures been taken by prescribing physicians.⁸² In an analysis of 682 children admitted to a Congenital Heart Disease Center at a teaching hospital in the United Kingdom, 441 medication errors were reported by nurses, doctors, and pharmacists, of which prescribing errors accounted for 68 percent, followed by administration errors (25 percent) and supply errors (seven percent).⁸³ In Burnum’s⁸⁴ analysis of 1,000 patients drawn from a community office-based medical practice who experienced adverse drug reactions, 23 patients were judged to have experienced an “unnecessary and potentially avoidable” event, 10 of which were due to physician error (i.e., six due to administration of a drug not indicated and four to improper drug administration).

Physicians do not routinely screen for potential drug interactions, even when medication history information is readily available. In an analysis of 424 randomly selected visits to a hospital emergency department, 47 percent led to added medication, and in 10 percent of the visits in which at least one medication was added, the new medication added a potential adverse interaction.⁸⁵ In all cases, a medication history was recorded on the patients and available to the physicians.

Errors can occur in the dispensing of drugs by pharmacists. In a recent investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in Massachusetts.⁸⁶ Eighty-eight percent of the errors involved giving patients the wrong drug or the wrong strength.

Errors in the ordering and administration of medications are common in hospitals. Bates et al.⁸⁷, in an analysis of more than 4,000 admissions to two tertiary care hospitals, found that about 28 percent of 247 adverse drug events were preventable and most of these resulted from errors that occurred at the stages of ordering and administration. Davis and Cohen⁸⁸ in their review of the literature and other evidence on errors report an error rate of 12 percent to be common in the preparation and administration of medications in hospitals. In a study of medication orders at two children’s teaching hospitals, Folli et al.⁸⁹ found that errors occurred in almost five out of every 1,000 orders and that the most prevalent error was overdose.

Patients make errors too. With greater emphasis on community-based long-term care, increased ambulatory surgery, shorter hospital lengths of stay, and greater reliance on complex drug therapy, patients play an increasingly important role in the administration of drugs. Greenberg et al.⁹⁰ found that 4.3 percent of the elderly enrolled in Medicare social HMOs required assistance with the administration of medications. The inability to manage complex drug therapies

explains why some elderly are in institutional rather than community-based long-term-care settings.⁹¹

Automated information and decision support systems are effective in reducing many types of errors. In an analysis of admissions to 11 medical and surgical units at two tertiary care hospitals, Leape et al.⁹² identified 334 errors as the causes of 264 preventable ADEs and potential ADEs. About three out of four errors were caused by one of seven types of systems failures (drug knowledge dissemination, dose and identity checking, patient information availability, order transcription, allergy defense, medication order tracking, and interservice communication), and all could have been improved by better information systems that disseminate knowledge about drugs and make drug and patient information readily accessible at the time it is needed.

Computerized drug order entry systems have much potential to reduce errors. In a study of 379 consecutive admissions to three medical units at an urban tertiary care hospital, 10,070 medication orders were written and 530 medication errors were identified (5.3 errors per 100 orders). More than half of the medication errors involved at least one missing dose of a medication.⁹³ Of the 530 medication errors, five (0.9 percent) resulted in adverse drug events that were judged preventable, and another 35 represented potential adverse drug events (i.e., medication errors with the potential for injury but in which no injury occurred). Physician computer order entry could have prevented 84 percent missing dose medication errors, 86 percent of potential adverse drug events, and 60 percent of preventable adverse drug events. However, more sophisticated technology is not the only option; involving pharmacists in reviewing drug orders significantly reduced the potential harm resulting from errant medication orders.^{94,95}

THE COST OF ERRORS

In addition to the unfortunate health consequences suffered by many as a result of medical error, there are direct and indirect costs borne by society as a whole as a result of medical errors. Direct costs refer to higher health care expenditures, while indirect costs include factors such as lost productivity, disability costs, and personal costs of care.

Based on analysis of 459 adverse events identified by reviewing the medical records of 14,732 randomly selected 1992 discharges from 28 hospitals in Colorado and Utah, Thomas et al., estimated the total costs (lost income, lost household production, disability and health care costs) to be nearly \$662 million of which health care costs totaled \$348 million.⁹⁶ The total costs associated with the 265 of the 459 adverse events that were found to be preventable were \$308 million, of which \$159 million represented health care costs. Based on extrapolation to all hospital admissions in the United States, the authors estimate the national costs of adverse events to be \$37.6 billion and of preventable adverse events to be \$17 billion. The total national costs associated with adverse events was approximately 4 percent of national health expenditures in 1996. In 1992,

the direct and indirect costs of adverse events were slightly higher than the direct and indirect costs of caring for people with HIV and AIDS.

It has been estimated that for every dollar spent on ambulatory medications, another dollar is spent to treat new health problems caused by the medication.⁹⁷ Studies of the direct costs of medication-related errors fall into three categories; (1) population-based studies of patients in a community or health plan; (2) studies of medication-related errors that occur in hospitals; and (3) studies of medication-related errors that occur in nursing homes.

One estimate places the annual national health care cost of drug-related morbidity and mortality in the ambulatory setting as high as \$76.6 billion in 1994.⁹⁸ Not all drug-related morbidity and mortality is preventable, but numerous studies document errors in prescribing,^{99,100} dispensing by pharmacists,¹⁰¹ and unintentional nonadherence on the part of the patient.¹⁰²

Medication-related errors occur frequently, most do not result in actual harm, but those that do are costly. One recent study conducted at two prestigious teaching hospitals found that almost two percent of admissions experienced a preventable ADE, resulting in an average increased length of stay of 4.6 days and an average increased hospital cost of nearly \$4,700 per admission.¹⁰³ This amounts to about \$2.8 million annually for a 700-bed teaching hospital, and if these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about \$2 billion for the nation as a whole.

In a matched case-control study of all patients admitted to a large teaching hospital from January 1990 through December 1993, it was found that adverse drug events complicated 2.43 admissions per 100.¹⁰⁴ Controls were matched to cases on primary discharge diagnosis related group (DRG), age, sex, acuity, and year of admission. The occurrence of an ADE was associated with an increased length of stay of 1.91 days and an increased cost of \$2,262. The increased risk of death among patients experiencing an adverse drug event was 1.88.

Other studies corroborate the high cost of medication-related errors. One study conducted in a university-affiliated medical center hospital estimated that the annual costs of treating the 1,911 medication-related problems identified through the hospital's voluntary reporting system in 1994 totaled slightly less than \$1.5 million.¹⁰⁵ Bloom has estimated that \$3.9 billion was spent in 1983 to manage the preventable gastrointestinal adverse effects of nonsteroidal anti-inflammatory drugs.¹⁰⁶

Medication-related errors also occur in nursing homes. For every dollar spent on drugs in nursing facilities, \$1.33 is consumed in the treatment of drug-related morbidity and mortality, amounting to \$7.6 billion for the nation as a whole, of which \$3.6 billion has been estimated to be avoidable.¹⁰⁷

PUBLIC PERCEPTIONS OF SAFETY

Although the risk of dying as a result of a medical error far surpasses the risk of dying in an airline accident, a good deal more public attention has been

focused on improving safety in the airline industry than in the health care industry. The likelihood of dying per domestic jet flight is estimated to be one in eight million.¹⁰⁸ Statistically, an average passenger would have to fly around the clock for more than 438 years before being involved in a fatal crash. This compares very favorably with a death risk per domestic flight of one in two million during the decade 1967–1976. Some believe that public concern about airline safety, in response to the impact of news stories, has played an important role in the dramatic improvement in safety in the airline industry.

The American public is aware that health care is less safe than some other environments, but to date, it has made few demands on the health care industry to demonstrate improvement. In a public opinion poll conducted by Louis Harris & Associates for the National Patient Safety Foundation, the health care environment was perceived as “moderately safe” (rated 4.9 on a scale of one through seven where one is not safe at all and seven is very safe).¹⁰⁹ Respondents viewed the health care environment as much safer than nuclear power or food handling, but somewhat less safe than airline travel or the work environment.

Americans have a very limited understanding of health care safety issues. When asked, What comes to mind when you think about patient safety issues in the health care environment? 28 percent of respondents did not mention anything, 20 percent mentioned exposure to infection, 13 percent cited the general level of care patients receive, and 11 percent cited qualifications of health professionals.¹¹⁰ When asked about the main cause of medical mistakes, respondents most frequently cited carelessness or negligence (29 percent) of health care professionals, who are overworked, worried, or stressed (27 percent).

Most people learn about medical mistakes through anecdotes. More than four out of five respondents have heard about a situation in which a medical mistake was made.¹¹¹ When asked how they heard about the most recent medical mistake, 42 percent cited a friend or relative; 39 percent, television, newspaper, or radio; and 12 percent, personal experience.

Most people view medical mistakes as an “individual provider issue” rather than a failure in the process of delivering care in a complex delivery system. When asked about possible solutions to prevent medical mistakes, actions rated very effective by respondents were “keeping health care professionals with bad track records from providing care” (75 percent) and “better training of health care professionals” (69 percent).¹¹²

There are numerous factors that might contribute to the “disconnect” between public perceptions and actual health care error rates. The various accreditation and licensure programs for health care organizations and providers have been promoted as “Good Housekeeping Seals of Approval,” yet they fail to provide adequate assurance of a safe environment. Reducing medical errors and improving patient safety are not an explicit focus of these processes. Even licensed and accredited organizations may have implemented only rudimentary systems and processes to ensure patient safety.

For the most part, media coverage has been limited to occasional reporting of anecdotal cases. The impact of anecdotal information on safety may also be

less effective in health care than in the nuclear waste or airline industries, where an individual event often impacts dozens or hundreds of people at a time.

Patient safety is also hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal proceedings encourages silence about errors committed or observed. Most errors and safety issues go undetected and unreported, both externally and within health care organizations.

REFERENCES

1. Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *N Engl J Med.* 324:370-376, 1991. See also; Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *N Engl J Med.* 324(6):377-384, 1991. Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. *Med Care* forthcoming Spring 2000.
2. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255-264, 1999. See also; Leape, et al., 1991. Brennan, et al., 1991.
3. American Hospital Association. Hospital Statistics. Chicago, IL. 1999.
4. Centers for Disease Control and Prevention (National Center for Health Statistics). Deaths: Final Data for 1997. *National Vital Statistics Reports.* 47(19):27, 1999.
5. Centers for Disease Control and Prevention (National Center for Health Statistics). Births and Deaths: Preliminary Data for 1998. *National Vital Statistics Reports.* 47(25):6, 1999.
6. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255-264, 1999.
7. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255-264, 1999.
8. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255-264, 1999.
9. Occupational Safety and Health Administration. The New OSHA: Reinventing Worker Safety and Health [Web Page]. Dec 16 1998. Available at: www.osha.gov/oshinfo/reinvent.html.
10. Bureau of Labor Statistics. National Census of Fatal Occupational Injuries. 1998. U.S. Department of Labor: Washington, D.C. August, 1999.
11. Phillips, David P., Christenfeld, Nicholas, Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. *Lancet.* 351:643-644, 1998.
12. Bates, David W.; Spell, Nathan; Cullen David J.; et al. The Costs of Adverse Drug Events in Hospitalized Patients. *JAMA.* 277:307-311, 1997.
13. National Wholesale Druggists' Association. *Industry Profile and Healthcare Factbook.* Reston, VA: 1998.

14. Hallas, Jesper; Haghfelt, Torben; Gram, Lars F., et al. Drug Related Admissions to a Cardiology Department: Frequency and Avoidability. *J Intern Med.* 228:379-384, 1990.
15. Willcox, Sharon M.; Himmelstein, David U.; Woolhandler, Steffie. Inappropriate Drug Prescribing for the Community Dwelling Elderly. *JAMA.* 272:292, 1994.
16. Knox, Richard. Prescription Errors Tied to Lack of Advice: Pharmacists Skirting Law, Massachusetts Study Finds. *Boston Globe.* February 10, 1999:(Metro):B1.
17. Einarson, Thomas R. Drug-Related Hospital Admissions. *Ann Pharmacother.* 27:832-840, 1993.
18. Reason, James T. Human Error. Cambridge, MA: Cambridge University Press: 1990.
19. Brennan, et al., 1991.
20. Leape, et al., 1991. See also; Brennan, et al., 1991.
21. Leape, et al., 1991.
22. Manasse, Henri R. Jr. Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy, part 1. *Am J Hosp Pharm.* 46:929-944, 1989.
23. Johnson, Jeffrey A., and Bootman, J. Lyle. Drug-Related Morbidity and Mortality: A Cost-of-Illness Model. *Arch Intern Med* 155(18):1949-1956, 1995.
24. Victoroff, Michael S. The Right Intentions: Errors and Accountability. *J Fam Pract* 45:38-39, 1997.
25. Andrews, Lori B.; Stocking, Carol; Krizek, Thomas; et al. An Alternative Strategy for Studying Adverse Events in Medical Care. *Lancet.* 349:309-313, 1997.
26. Vincent, Charles; Taylor-Adams, Sally and Stanhope, Nicole. Framework for Analysing Risk and Safety in Clinical Medicine. *BMJ* 316(11):1154-1157, 1998.
27. Cook, Richard and Woods, David. Operating at the Sharp End: the Complexity of Human Error. Bogner, Marilyn Sue, Ed. Human Errors in Medicine. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994; pp. 255-310.
28. Nadzam, Deborah M. Development of Medication-Use Indicators by the Joint Commission on Accreditation of Health Care Organizations. *AJHP.* 48:1925-1930, 1991.
29. Brennan, et al., 1991.
30. Brennan, et al., 1991.
31. Leape, et al., 1991.
32. Brennan, et al., 1991.
33. Thomas, et al., 2000.
34. Thomas, et al., 1999.
35. Thomas, et al., 2000.
36. American Hospital Association. Hospital Statistics. Chicago, IL. 1999. See also; Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. *Med Care* forthcoming March 2000.³⁶ See also; Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255-264, 1999.
37. American Hospital Association. Hospital Statistics. Chicago, IL. 1999. See also; Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *N Engl J Med.* 324:370-376, 1991. See also; Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *N Engl J Med.* 324(6):377-384, 1991.
38. Centers for Disease Control and Prevention (National Center for Health Statistics). Deaths: Final Data for 1997. *National Vital Statistics Reports* 47(19):27, 1999. See also: Centers for Disease Control and Prevention (National Center for Health Statistics).

Births and Deaths: Preliminary Data for 1998. *National Vital Statistics Reports*. 47(25):6, 1999.

39. Andrews, et al., 1997.
40. Steel, Knight; Gertman, Paul M.; Crescenzi, Caroline, et al. Iatrogenic Illness on a General Medical Service at a University Hospital. *N Eng J Med*. 304:638–642, 1981.
41. Andrews, et al., 1997.
42. Dubois, Robert W. and Brook, Robert H. Preventable Deaths: Who, How Often, and Why? *Ann Intern Med*. 109:582–589, 1988.
43. Bedell, Susanne E.; Deitz, David C.; Leeman, David, et al. Incidence and Characteristics of Preventable Iatrogenic Cardiac Arrests. *JAMA*. 265(21):2815–2820, 1995.
44. McGuire, Hunter H.; Horsley, J. Shelton; Salter, David R., et al. Measuring and Managing Quality of Surgery: Statistical vs Incidental Approaches. *Arch Surg*. 127:733–737, 1992.
45. Cooper, Jeffrey B.; Newbower, Ronald S.; Long, Charlene D., et al. Preventable Anesthesia Mishaps: A Study of Human Factors. *Anesthesiology*. 49:399–406, 1978.
46. Gaba, David M. Human Error in Anesthetic Mishaps. *Int Anesthesiol Clin*. 27(3):137–147, 1989.
47. Duncan, Peter G. and Cohen, Michael. Postoperative Complications: Factors of Significance to Anaesthetic Practice. *Can J Anaesth*. 34:2–8, 1987.
48. Cohen, Michael R.; Duncan, Peter G.; Pope, William D. B., et al. A Survey of 112,000 Anaesthetics at One Teaching Hospital (1975–1983). *Can Anaesth Soc J*. 33:22–31, 1986.
49. Sentinel Events: Approaches to Error Reduction and Prevention. *Jt Comm J Qual Improv*. 24(4):175–186, 1998.
50. Chassin, Mark R. Is Health Care Ready for Six Sigma Quality? *Milbank Q*. 764:565–591, 1998.
51. Bhasale, Alice L.; Miller, Graeme C.; Reid, Sharon E., et al. Analysing Potential Harm in Australian General Practice: an Incident-Monitoring Study. *MJA*. 169:73–76, 1998.
52. National Wholesale Druggists' Association. *Industry Profile and Healthcare Factbook*, *op cit*.
53. Manasse, 1989.
54. Phillips, et al., 1998.
55. Bates, David W.; Boyle, Deborah L.; Vander Vilet, Martha, et al. Relationship between Medication Errors and Adverse Drug Events. *J Gen Intern Med*. 10:199–205, 1995.
56. Lesar, Timothy S.; Briceland, Laurie, and Stein, Daniel S. Factors Related to Errors in Medication Prescribing. *JAMA*. 277(4):312–317, 1997.
57. Bates, David W.; Cullen, David J.; Laird, Nan M.; et al. Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. *JAMA*. 274:29–34, 1995.
58. Bates, David W.; Leape, Lucian L., and Petrycki, Stanley. Incidence and Preventability of Adverse Drug Events in Hospitalized Adults. *J Gen Intern Med*. 8:289–294, 1993.
59. Lesar, Briceland, and Stein, 1997.
60. Koren, Gideon and Haslam, Robert H. Pediatric Medication Errors: Predicting and Preventing Tenfold Disasters. *J Clin Pharmacol*. 34:1043–1045., 1994.
61. Perlstein, Paul H.; Callison, Cornelia; White, Mary., et al. Errors in Drug Computations During Newborn Intensive Care. *Am J Dis Child*. 33:376–379, 1979.

62. Folli, Hugo L.; Poole, Robert L.; Benitz, William E., et al. Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals. *Pediatrics*. 79:718-722, 1987.
63. Raju, Tonse N. K.; Kecskes, Susan; Thornton, John P., et al. Medication Errors in Neonatal and Paediatric Intensive-Care Units. *Lancet*. 374-376, 1989.
64. Cullen, David J.; Sweitzer, Bobbie Jean; Bates, David W.; et al. Preventable Adverse Drug Events in Hospitalized Patients: A Comparative Study of Intensive Care and General Care Units. *Crit Care Med*. 25(8):1289-1297, 1997.
65. Manasse, 1989.
66. Davies, D.M., ed. Textbook on Adverse Drug Reactions. 3rd. ed. Oxford: Oxford University Press; 1985.
67. Griffin, JP and Weber, JCP. Voluntary Systems of Adverse Reaction Reporting—Part I. *Adverse Drug React Acute Poisoning Rev*. 4:213-230, 1985.
68. Griffin, JP and Weber, JCP. Voluntary Systems of Adverse Reaction Reporting—Part II. *Adverse Drug React Acute Poisoning Rev*. 5:23-25, 1986.
69. Cullen, David J.; Bates, David W.; Small, Stephen D.; et al. The Incident Reporting System Does Not Detect Adverse Drug Events. *Jt Comm J Qual Improv*. 21(10):541-548, 1995.
70. Classen, David C.; Pestonik, Stanley, L.; Evans, Scott; Burke, John P. et al. Computerized Surveillance of Adverse Drug Events in Hospital Patients. *JAMA*. 266(20):2847-2851.
71. Beard, Keith. Adverse Reactions as a Cause of Hospital Admissions in the Aged. *Drug Aging*. 2:356-61, 1992.
72. Roughead, Elizabeth E.; Gilbert, Andrew L.; Primrose, J. G., et al. Drug-Related Hospital Admissions: A Review of Australian Studies Published 1998-1996. *Med J. Aust*. 168:405-408, 1998.
73. Burnum, John F. Preventability of Adverse Drug Reactions. *Ann Intern Med*. 85:80, 1976.
74. Schneitman-McIntire, Orinda.; Farnen, Tracy A.; Gordon, Nancy, et al. Medication Misadventures Resulting in Emergency Department Visits at an HMO Medical Center. *Am J Health Syst Pharm*. 3:1416-1422, 1996.
75. Sullivan, Sean D.; Kreling, David H.; Hazlet, Thomas K. et al. Noncompliance with Medication Regimens and Subsequent Hospitalizations: A Literature Analysis and Cost of Hospitalization Estimate. *J Research in Pharmaceutical Economics*. 2(2):19-33, 1990.
76. Einarson, 1993.
77. Thomas, et al., 2000.
78. Dubois, Robert W. and Brook, Robert H. Preventable Deaths: Who, How Often, and Why? *Annals of Internal Medicine* 109:582-589, 1988.
79. Bedell, Susanna E.; Deitz, David C.; Leeman, David; Delbanco, Thomas, L. Incidence and Characteristics of Preventable Iatrogenic Cardiac Arrests. *JAMA*. 265:2815-2820, 1991.
80. Lesar, Briceland, and Stein, 1997.
81. Willcox, Sharon M.; Himmelstein, David U.; Woolhandler, Steffie, et al. Inappropriate Drug Prescribing for the Community Dwelling Elderly, *op cit*.
82. Hallas, et al., 1997.
83. Wilson, Dirk G.; McCartney, R. G.; Newcombe, Robert G., et al. Medication Errors in Paediatric Practice: Insights from a Continuous Quality Improvement Approach. *Eur J Pediatr*. 157:769-774, 1998.
84. Burnum, 1976.

85. Beers, Mark H.; Storrie, Michele, and Lee, Genell. Potential Adverse Drug Interactions in the Emergency Room. *Ann Intern Med.* 112:61–64, 1990.
86. Knox, 1999.
87. Bates, et al., 1995.
88. Davis, Neil M. and Cohen, Michael R. Medication Errors: Causes and Prevention. Philadelphia, PA: George F. Stickley, Co., 1981.
89. Folli, et al., 1987.
90. Greenberg, Jay; Leutz, Walter; Greenlick, Merwyn, et al. The Social HMO Demonstration: Early Experience. *Health Affairs.* 7:66, 1988.
91. Strandberg, Lee R. Drugs as a Reason for Nursing Home Admissions. *Am Health Care Assoc J.* 10:20–23, 1984.
92. Leape, Lucian L.; Bates, David W., and Cullen, David J. Systems Analysis of Adverse Drug Events. *JAMA.* 274:35–43, 1995.
93. Bates, et al., 1995.
94. Folli, et al., 1987.
95. Blum, Keith V.; Abel, S.R.; Urbanski, Chris J., et al. Medication Error Prevention by Pharmacists. *Am J Hosp Pharm.* 45:1902–1903, 1988
96. Thomas, et al., 1999.
97. Alliance for Aging Research. When Medicine Hurts Instead of Helps. Washington, DC: The Alliance for Aging Research; 1998.
98. Johnson, et al., 1995.
99. Hallas, et al., 1997.
100. Willcox, et al., 1994.
101. Knox, 1999.
102. Einarson, 1993.
103. Bates, David W., et al. The Costs of Adverse Drug Events in Hospitalized Patients, *op cit*, 1995.
104. Classen, David C.; Pestotnik, Stanley L.; Evans, R. Scott, et al. Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality. *JAMA.* 277:301–306, 1997.
105. Schneider, Philip J.; Gift, Maja G.; Lee, Yu-Ping, et al. Cost of Medication-Related Problems at a University Hospital. *Am J Health-Syst Pharm.* 52:2415–2418, 1995.
106. Bloom, Bernard S. Cost of Treating Arthritis and NSAID-Related Gastrointestinal Side-Effects. *Aliment. Pharmacol. Ther.* 1(Suppl 2):131–8, 1998.
107. Bootman, J. Lyle; Harrison, LTC Donald L., and Cox, Emily. The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities. *Arch Intern Med.* 157(18):2089–2096, 1997.
108. Federal Aviation Administration, Office of System Safety. Aviation Safety Reporting System (ASRS) Database [Web Page]. 1999. Available at: http://nasdac.faa.gov/safety_data.
109. National Patient Safety Foundation. Diverse Groups Come Together to Improve Health Care Safety Through the National Patient Safety Foundation [Web Page]. 1997 Aug 29. Available at: <http://www.ama-assn.org/med-sci/npsf/pr897.htm>. Note: press release.
110. National Patient Safety Foundation, 1997.
111. National Patient Safety Foundation, 1997.
112. National Patient Safety Foundation, 1997.

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002. list	re: Roll Out Plan for Medical Errors Announcement (partial) (4 pages)	02/20	P6/b(6)

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Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

FOLDER TITLE:

Errors [Folder 7]

2012-0463-S

rc750

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P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
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Bam Robert

DRAFT 2/20: ROLL OUT PLAN FOR MEDICAL ERRORS ANNOUNCEMENT

HHS / VA / DOD CONTACT NUMBERS

John Eisenberg
Tom Garthwaite
Sue Bailey

P6/(b)(6)
P6/(b)(6)

CJ called
CJ called
CJ called

ATA

Robert

[002]

Rich
cell

P6/(b)(6)

SUNDAY, FEBRUARY 20

Evening:

Individual Calls to Policy Validators

Lewin

Molly Joel-Kaye

(Janet Corrigan to call)

JCAHO

Dennis O'Leary

(work: 630 792 5650 / home:)

Quality Forum

Gail Warden

Ken Kizer

Jim Tallon

313 876 9243
(work: 313 876 8715 / home:)

(home:)

(work: 212 494 0777 / home:)

Researchers

Lucien Leape

Don Berwick

(NAMD to call / home:)

(work: 617 754 4852 /)

CJ called

Janet Corrigan

(work: 617 754 4852 /)

CJ called

Hospitals

Tom Scully

Dan Cisto

(work: 202 624 1527 / home:)

(work: 518 431 7800 / home:)

CJ called

Ron Hollander

Rick Pollack

Duane Donner

(pager:)

(pager:)

cddauner@calhealth.org send press paper

Hill

Ned McCulloch

Peter Reineke

(home:)

(work: 224 7303)

direct line

Carl Eckhardt

P6/(b)(6)

Imcquillan-
@usatoday.
com

Embassy
Suites
SC
Columbia

Tom
Nichols

P6/(b)(6)

press paper

home:

P6/(b)(6)

7:00 pm

Conference Call with Quality Commission Members 757 2104 code 26775

Betty Bednarczyk
Christine Cassel
Robert Geogine
Val Halmandaris
Sandra Hernandez
Nan Hunter
Sylvia Drew Ivies
Risa Lavizzo-Mourey
Sheila Leatherman
Ben Lytle
Randall MacDonald
Beverly Malone
Gerald McEntee

Paul Montrone
Phil Nudelman
Herbert Pardes
Ron Pollack
Chris Queram
Tom Reardon
Kathleen Sebelius
Steve Sharfstein
Peter Thomas
Mary Wakefield
Gail Warden
Alan Weil
Richard Sorian

[002]

P6/(b)(6)

MONDAY, FEBRUARY 21

~~9:00 am~~

Call to AMA
Rich Deem

(work: 312 464 4758 / home: P6/(b)(6))
page P6/(b)(6) fax 312
464 5322) send press paper and exec
summary tomorrow

Morning:

Call to ANA
Mary Foley

(work: 202 651 7018 / home: P6/(b)(6))
send press paper

Call to NGA
Ray Sheppach

(work: 202 624 5320 / home: P6/(b)(6))
CJ called

Call to CHA
Reverend Michael Place
Jack Bresch

(home: P6/(b)(6))
(work: 296 3993 / home: P6/(b)(6))

Call to AHA
Dick Davidson

(work: 638 1100 / until Sunday:

P6/(b)(6)

1245

P6/(b)(6)

12 noon:

Call with Business Groups 456 2561 code 2291

Bruce Bradley

(work: 313 556 1166

Chris Quorum

(home:

Pat Powers

(home:

Susan del Banco

(cell phone:

Chuck Buck

(home:

Jim Cubbin

(home:

Afternoon:

Calls to Print Reporters

Larry McQuillan (USA)

(work: 703 907 7101 / home:

Robert Pear (NYT)

(work: 202 862 0344 / home:

Laurie McGinley (WSJ)

(work: 202 862 9224 / home:

Rick Weiss (WP)

(work: 202 334 5514 / home:

Alissa Rubin (LAT)

(work: 202 861 9298 / home:

Kevin Galvin (AP)

(work: 202 776 9494 / home:

Paul Heldman (BNA)

(work: 624 1842)

Andrea Gurlin (Philadelphia Inq)

(work: 215 854 4374)

Mr. Gorman
Marc Kauffman (WP)

4:30 pm:

Conference call with Democrats 1888 422 7105 code 967204

Daschle

Kerrey

Gephardt

Graham

Dingell

Moynihan

Stark

Dodd

Kennedy

Brown

Harkin

Hoyer

Lieberman

Akaka

5:30 pm:

Conference call with Committee Staff 1888 422 7105 code 894736

Bliley

Rockefeller

Bilirakis

Moynihan

Thomas

Scarborough

Stearns

Cummings

Gutierrez

Stump

Porter

Evans

Obey

Goodling

Jeffords

Clay

Frist

Boehner

Roth

Andrews

Specter

** Eileen O'Connor*

Arshad

Mohammad

Staff Level Calls

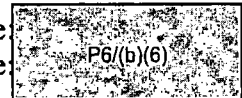
Nickles
Inouye
Johnson
Snowe
Upton

Grassley
McCrery
McDermott
Smith
Morella

Calls to Insurance Groups

Karen Ignani
Chip Kahn

(work: 202 778 3203 / home:
(work: 202 824 1858 / home:

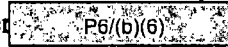
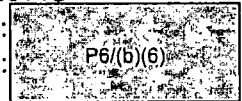


7:00 pm

Conference call with Consumer Groups call in 757 2104 code 26775

Brian Limburgh
Art Levin
Becky Cherney
Gerry Shea
John Rother

(work: 202 789 3606 / home:
(work: 212 674 7105 / home:
(work: 407 425 9559)
(pager:
(work: 434 3704 / home:

**TUESDAY, FEBRUARY 22**

12 noon

POTUS briefing
Oval

12:15 pm

Event Room 450