

Chapter 4. Patient Safety

Key Findings

This report documents progress and substantial gaps in patient safety, although they are difficult to track because of limited data. For example:

- Data collected on hospital-acquired infections from 1995-2002 show that some of the Healthy People 2010 targets for eliminating infections acquired in intensive care units (ICUs) have been met or nearly met.
- Data on adverse events due to medical care show that the rate of complications due to anesthesia is only 0.72 per 1,000 surgical discharges.
- Data on complications of care show that the rates for accidental laceration or puncture during a procedure rose from 2.4 to 3.4 per 1,000 discharges from 1994 to 2000.
- In terms of medication safety, 77.8% of people with a usual source of care in 1996 and 81.7% in 2000 said that their usual source of care asked them about other medication use in order to prevent drug interactions.

Background and Impact

Medical errors sometimes cause significant and deadly harm to patients. Researchers found that, in some hospitals in New York, Utah, and Colorado, injuries resulting from medical management occurred in about 2% of all hospitalizations with up to 14% of these injuries resulting in death and up to 7% resulting in permanent disabilities.^{1,2,3,4} Researchers also revealed that preventable adverse drug events occurred in about 2% of admissions in some Utah hospitals⁵ and Boston teaching hospitals.⁶ Based on such findings, a 1999 report estimated that 44,000 to 98,000 Americans die each year as a result of medical errors, making it the eighth leading cause of death, higher than the number of deaths from motor vehicle accidents.⁷ The report also estimated that medical errors cost as much as \$29 billion annually in lost income, disability, and health care costs.

Recently, medical mishaps have also gained a great deal of attention in the headline news. In one case, a heart transplantation in a highly acclaimed university hospital resulted in the death of an organ recipient because of mismatched blood type between the recipient and the donor.⁸ During this case, the medical practitioners failed to confirm the blood types, leading to the type O patient receiving a type A organ. In another case, an organ donor died 3 days after undergoing surgery to donate a portion of his liver to his ailing brother.⁹ The ensuing investigation identified no problems during the operation itself, but found a series of failures and errors in post-surgical care by an overburdened, junior staff.

Any practical approach to improving patient safety must start by documenting incidences of various types of errors and injuries.^{7,10} Reporting medical errors and injuries will raise awareness, facilitate understanding of risks and injury, aid in developing preventive strategies, and provide yardsticks to track progress.

How the NHQR Measures Patient Safety

The concept of patient safety as a quality measure is evolving. Patient safety is defined as freedom from accidental injury due to medical care,^{7,11} or absence of medical errors,^{12,13} or absence of misuse of services.^{14,15} These concepts cover a variety of injuries and errors occurring during any stage in the processes of care, including medical errors that are narrowly avoided (termed near misses) and errors that cause harm to patients. In addition to the lack of a single typology, documenting medical errors and injuries is further hampered by the lack of standards or an infrastructure for systematic data collection on errors.

This report documents incidences of medical errors and injuries with three sets of indicators. They reflect a narrow range of medical errors or injuries for which nationwide data are currently available.

AHRQ Patient Safety Indicators

The recently released AHRQ Patient Safety Indicators (PSIs) include 20 indicators focused on iatrogenic conditions and postoperative complications such as accidental laceration during a procedure, blood clots in the lungs following surgery, fracture following surgery, and birth-related injuries, using readily available hospital administrative data.^{16,17} Some of the 20 indicators, such as a foreign body left in the patient during a procedure, unequivocally reflect medical errors in hospitals. Others, such as postoperative hemorrhage and blood clots, may be due only in part to failure of planned treatment, and some cases may not be avoidable.

This report documents national incidence rates for 1994, 1997, and 2000 and for some subpopulations using hospital discharge records from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample, a nationally stratified sample of U.S. hospitals (nearly 1,000 hospitals) selected from 28 States (in 2000). The incidences are identified from standard *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes used by hospitals to record diagnoses and procedures in hospital discharge records or administrative data for each patient treated. Many benefits are associated with the use of administrative data, including ease of access and low cost. However, there are some limitations, primarily coding across organizations and completeness in coding (some relevant diagnoses and procedures may be unrecorded). Furthermore, the ICD-9-CM system was not developed to report medical errors or injuries, and as such, it is not as clinically precise or complete as would be desired for this purpose.^{16,18,19,20,21,22}

CDC's National Nosocomial Infections Surveillance

National Nosocomial Infections Surveillance (NNIS) is a voluntary, hospital-based reporting system started in 1970 to monitor hospital-acquired infections and to guide the prevention efforts of infection control practitioners.^{23,24} This system uses uniform case definitions and data collection methods to collect data from about 300 hospitals and establishes risk-adjusted benchmarks for hospital-acquired infection rates.

NNIS data from 1998-2002 are used to report respiratory tract, urinary tract, and bloodstream infections in ICUs and in low birthweight infants. NNIS is not nationally representative. Due to the nature of voluntary reporting, NNIS may underestimate incidence rates to some extent.²⁵

MEPS Data on Medication Use

The Medical Expenditure Panel Survey, a nationally representative survey of households, reports data on health care expenditures and services, including medication use. This report tracks two measures from MEPS. The first measure reports the percentage of people with a usual source of care who reported that their usual source of care usually asked about prescriptions from other providers to avoid potentially harmful drug interactions. The second measure reports incidence rates (1996 and 1998) of 33 medications that should be used in limited circumstances in the elderly. The 33 medications are further separated into three categories: 1) 11 medications that according to a recent study should always be avoided in the elderly; 2) 8 medications that are appropriate in rare circumstances, and 3) 14 medications that may sometimes be indicated but are often misused.²⁶ When interpreting the results for these measures, it is important to note that there are differing opinions about what are or are not inappropriate medications for the elderly. Conflicting opinions occur even in guidelines and physicians' references for medication use.²⁷

How the Nation Is Doingⁱ

Healthy People 2010 sets targets for six measures of infections acquired in ICUs. Except for these six measures, there are no national objectives against which to compare incidence rates reported here to determine how the Nation is doing in patient safety. Nevertheless, the available reported measures suggest targets for improvement.

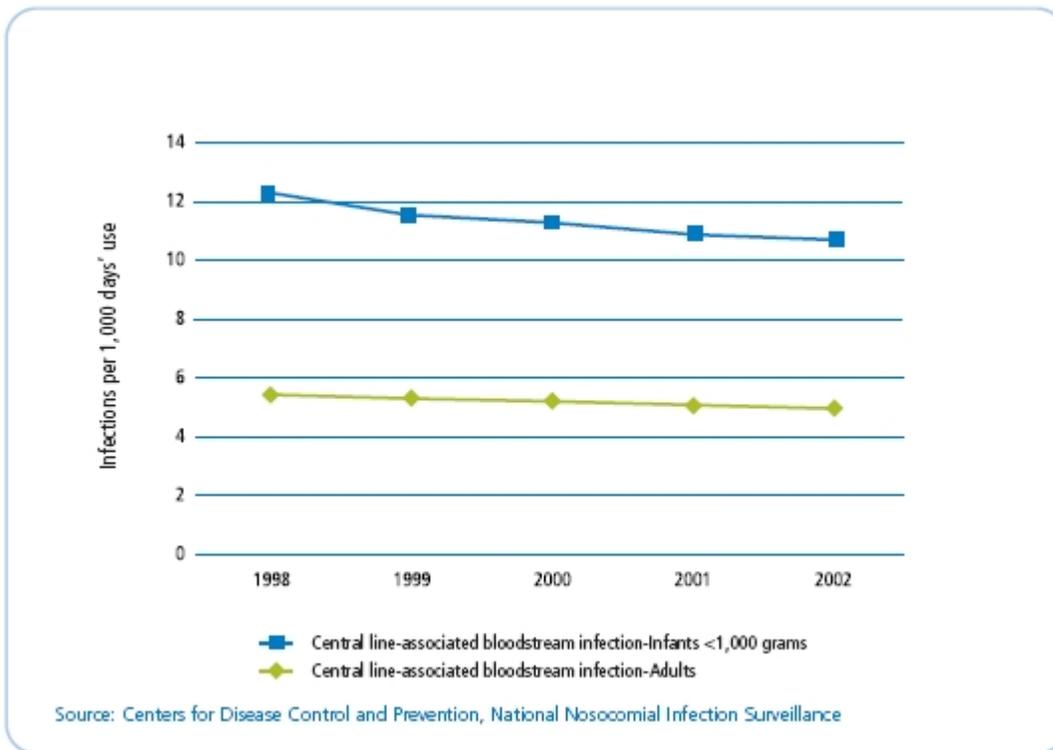
Hospital-Acquired Infections

Infections acquired in hospitals and ICUs are common, with about 2 million patients infected each year; one-fourth of the infections occur in ICUs.^{28,29} Nearly 90,000 patients die of nosocomial infections each year, and the infections have an annual cost of approximately \$4.5 billion.³⁰

ⁱ Adjusting for known contributing factors, such as gender, age, and insurance status (multivariate analysis), would allow for more detailed exploration of the data, but this generally was not feasible for this report. Any adjustments that were done are noted in the detailed tables. The data presented in this report do not imply causation.

NNIS data show that hospital-acquired infections in some types of ICUs have gradually declined from 1998 to 2002 (see Figure 1). By the year 2002, the targets set for Healthy People 2010 for central line-associated bloodstream infections (5.0 per 1,000 days' use) in adults and for infants weighing 1,000 grams or less at birth in ICUs (11.0 per 1,000 days' use) had been met.

Figure 1. Nosocomial infections in intensive care



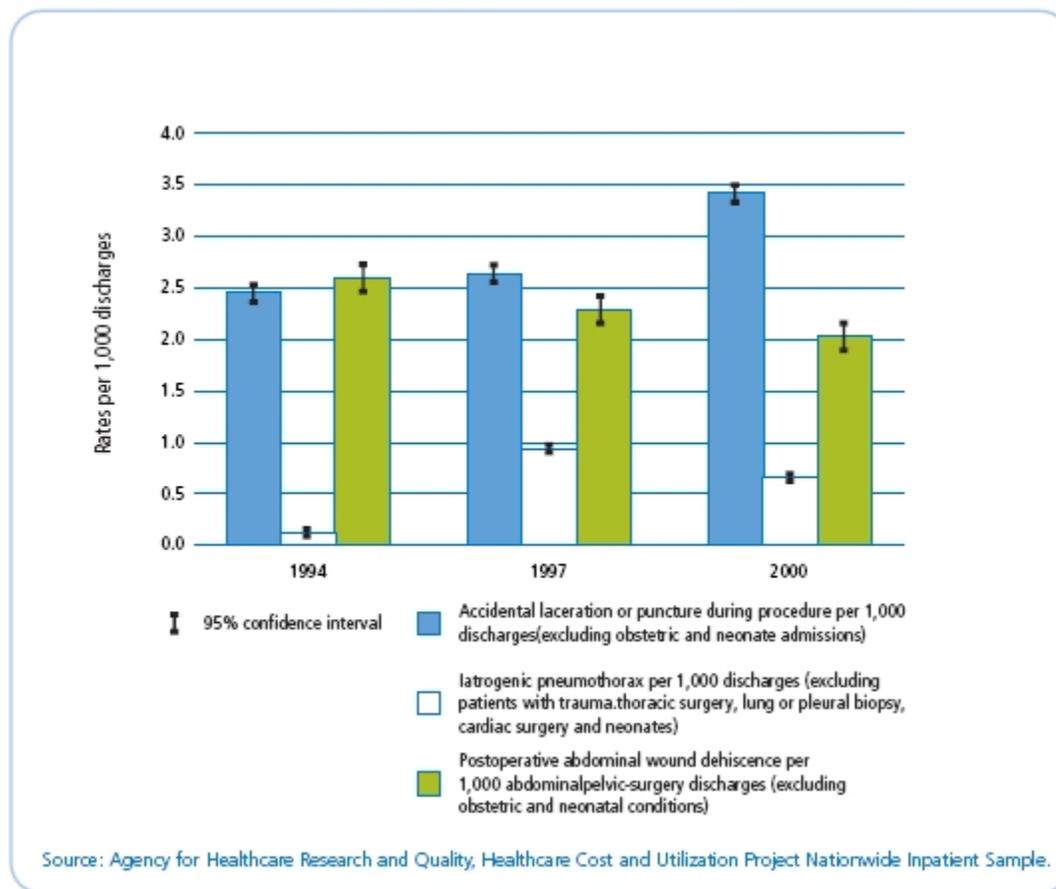
AHRQ PSIs and HCUP data show that, from 1994 to 2000, hospital-acquired infections after infusion, injection, transfusion, and vaccination increased from 1.37 to 2.01 per 1,000 hospital discharges. Postoperative sepsis also increased from 0.69 to 11.26 per 1,000 elective-surgery discharges with length of stay longer than 3 days.

Injuries or Adverse Events Due to Medical Care

AHRQ Patient Safety Indicators flag some events that are more likely to be the result of technical expertise or human errors rather than system-level errors. Foreign objects left in the patient during procedures (usually sponges or surgical instruments) is one such measure, and guidelines and procedures exist to prevent such events.^{31,32} Iatrogenic pneumothorax (lung puncture) may occur during insertion of a central line, thoracic surgery, thoracentesis, or pleural or transbronchial biopsy.³³ Some of the ruptures of surgical wounds may be avoided by thorough cleaning, control of bleeding, and proper suture technique.³⁴ Transfusion reactions may be due to unrecognized clerical errors.³⁵

For 1994, 1997, and 2000, incidences of iatrogenic pneumothorax (excluding complicated cases such as trauma and thoracic surgery and adjusting for patient risk) ranged from 0.16-0.96 per 1,000 discharges, with the highest rate occurring in 1997. The rates for accidental laceration or puncture during a procedure (again controlling for risk) were 2.44 to 3.40 per 1,000 discharges rising over the period. For wound dehiscence (rupture of surgical wounds) following abdominopelvic surgery, controlling for risk, the rates declined over the period from 2.58 to 2.06 per 1,000 such surgical discharges(see Figure 2). Foreign body left in during procedure and transfusion reactions were less frequent, at about 0.09 per 1,000 discharges for foreign bodies left in each year and at less than 0.01 per 1,000 discharges for transfusion reactions each year.

Figure 2. Adverse events due to medical care



Complications of Care

Complications of care vary in nature and seriousness. Some complications are affected significantly by patient severity of illness, comorbid conditions, and complexity of treatment and may not be preventable.^{36,37,38} However, adequate care or care provided according to current knowledge or evidence may prevent some of these complications.³⁹ For example, complications of anesthesia have been substantially reduced by adherence to process guidelines.⁴⁰

A substantial number of complications were identified using AHRQ PSIs and HCUP data. Over the period studied (1994-2000), the numbers of postoperative incidents occurring per 1,000 surgical discharges for the following complications were:

- Hemorrhage or hematoma—about 2 per 1,000 surgical discharges.
- Pulmonary embolism or deep vein thrombosis—about 8 per 1,000 surgical discharges.
- Respiratory failure for elective surgical patients without respiratory disease— about 4 per 1,000 surgical discharges.
- Physiologic and metabolic derangements for elective surgical patients— about 1 per 1,000 discharges.
- Complications of anesthesia— less than 1 (about 0.7) per 1,000 surgical discharges.
- Hip fractures after surgery for patients 18 and older who were not susceptible to falling— less than 1 (about 0.8) per 1,000 surgical discharges.

Pressure sores (measured for patients who were hospitalized for more than 4 days who were not paralyzed or admitted from long-term care facilities) were more frequent, about 20 per 1,000 discharges, rising from 17 to 22 over the period 1994-2000. These rates are generally lower than those reported in studies that focused on these specific conditions in single institutions using medical record review.^{41,42,43}

Birth-Related Trauma

Birth trauma refers primarily to injuries to the neonate's head and neck as a result of labor and delivery. These traumas are often associated with abnormal fetal presentations, abnormal fetal descent, and large infants that require the application of forceps or vacuum extraction. Birth trauma occurred in about 7-15 per 1,000 live births between 1994 and 1997 and fell to about 7 per 1,000 in 2000, consistent with previous reports.⁴⁴ Obstetric trauma, mostly injuries to genital tract and the anal sphincter, occurred in about 8% of women delivering without instrument assistance, 23% of women with instrument-assisted vaginal deliveries, and 0.6% of cesarean section deliveries from 1994-2000. These rates are lower than, but close to, previously published reports.⁴⁵

Potentially Avoidable Death

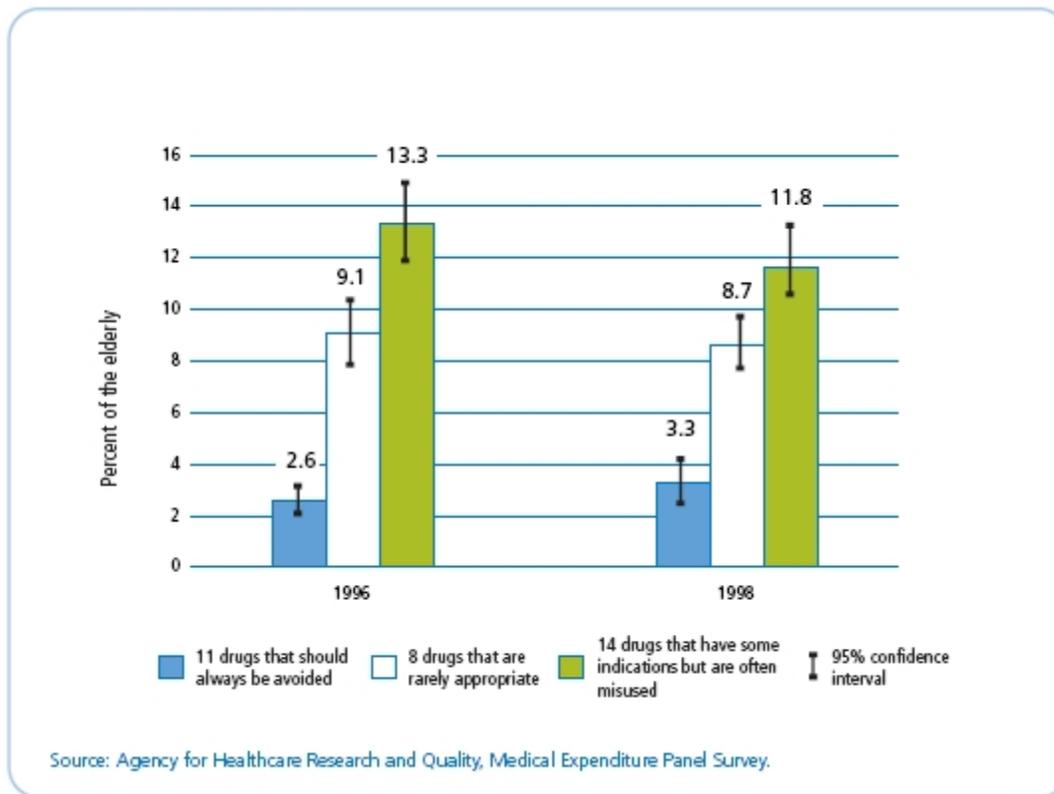
Mortality rates, whether risk-adjusted or condition-specific, are not considered definitive measures of quality of care in hospitals. Death rates may increase with increasing severity of illness. Moreover, a full accounting and adjustment for severity of illness is difficult to achieve.^{46,47} Nevertheless, high mortality rates among patients in diagnosis-related groups (DRGs) that normally have low mortality rates (less than 5%), raise concerns.⁴⁸ The mortality rates for patients in low mortality DRGs are significantly higher for the elderly and men.

Medication Safety

Prescribing medications that are not appropriate or with potentially harmful drug-drug interactions poses a threat to patient safety.^{49,50,51,52} One strategy is to ask patients what medications they currently are taking before prescribing additional medications. Data from MEPS show that, of people with a usual source of care, 77.8% of the respondents in 1996 and 81.7% in 2000 said that their usual source of care asked them about other medication use.

Another line of defense is to avoid a contraindicated drug. The same survey shows that, in 1996 and 1998, about 1 in 5 elderly Americans was prescribed at least 1 of the 33 drugs considered potentially inappropriate for the elderly. About 3 in 100 elderly had 1 of 11 drugs according to this study that should always be avoided by the elderly (see Figure 3).^{26,50} These rates are consistent with results from previous studies.^{26,53,54,55,56,57,58,59,60,61,62}

Figure 3. Inappropriate drug prescription for community-dwelling elderly Americans



What We Don't Know

Today, health care is much safer than at the time Florence Nightingale published her *Notes on Hospitals* in 1863, when she attributed many deaths in English hospitals to unsanitary conditions⁶³ or, in modern terms, nosocomial or hospital-acquired infections. However, medical

care has become increasingly complex and more concerns have been raised about safety. Despite recognition of medical errors and injuries as a cause of death and patient safety as an area for improvement,⁷ the overall approach to patient safety (e.g., focusing on medical errors or on medical injuries)^{11,13} and definitional issues (e.g., what is considered preventable)⁶⁴ continue to be debated. Currently, few data exist to provide a national picture of patient safety. Consequently, little is known about the prevalence of medical errors and injuries in the United States.

This report presents incidence rates only for selected types of medical errors and injuries associated with the delivery of care. Not all such incidences that are reported are preventable. Data currently available and used in this report generally are limited in what they can show and, therefore, are not sufficient to identify progress. In fact, the reported (but not actual) incidence rates may go up for some time as reporting systems become more accurate and complete.

Nonetheless, the identified incidences of medical errors and injuries associated with the delivery of care indicate room for improvement.

What Can Be Done

Some health professionals have made strides in improving patient safety. For example, anesthesiologists have managed to improve anesthesia-related mortality dramatically in the last 40 years, changing anesthesia from a hazardous undertaking to one with an exemplary safety record.^{65,66} Hospital-acquired infections have also been substantially reduced over several decades.²³ The last decade witnessed sustained efforts at Federal and State levels, in collaboration with the private sector, to make health care safe. The President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry published its report in 1998, which put reducing misuses of health care at the top of the agenda for quality improvement. In November 1999, the IOM released *To Err Is Human: Building a Safer Health System*, further putting the long-existing problem into the spotlight.⁷ In February 2002, HHS, under the leadership of its Quality Interagency Coordination Task Force, developed a series of programs in response to the IOM's report.¹⁰

In recent years, AHRQ and other Federal agencies have sponsored extensive research on patient safety, much of which has been aimed at developing systems to accurately report medical errors and injuries associated with the delivery of care. In partnership with other Federal agencies, AHRQ has developed and funded a portfolio of research projects that: 1) identify risks and hazards that lead to medical errors and the causes of patient injury associated with the delivery of health care, 2) identify and design practices that eliminate medical errors and test them to determine their effectiveness, 3) disseminate information on and educate health professionals, students, and practitioners about proven patient safety practices that reduce or prevent patient injury associated with the delivery of health care, and 4) monitor and evaluate threats to patient safety. AHRQ has sought to improve patient safety by promoting best practices, training new researchers, linking safety professionals and communication through Web-based tools, and

promoting international collaboration. AHRQ has also compiled and released various safety tips for patients and health care professionals based on available evidence.

In addition, other agencies developed strategies tailored to their constituencies. The Centers for Medicare & Medicaid Services started, among many programs aimed at safety, a Medicare Patient Safety Monitoring System (MPSMS). It is a retrospective chart review system to describe the size and nature of the iatrogenic injuries associated with hospital care among Medicare beneficiaries. The Department of Veterans Affairs has implemented several programs addressing safety including the Patient Safety Improvement Awards Program, which offers positive reinforcement for those already following best practices. The VA has established four Patient Safety Centers of Inquiry, which conduct research and design reporting systems to broadcast their findings.ⁱⁱ In collaboration with the American College of Surgeons, the VA has developed a National Surgical Quality Improvement Project focusing on reducing surgical complications.

The Food and Drug Administration is developing bar-coding and databases aimed at reducing medication errors and adverse drug events. Many States have developed voluntary reporting systems and some have mandated reporting of medical injuries.⁶⁷ In the private sector, the Joint Commission on Accreditation of Healthcare Organizations has instituted Web-based data collection of sentinel events and developed standards for root cause analysis. An IOM committee is developing standards and data systems for reporting patient safety data. Hospitals, health plans, and employers are also developing programs and information infrastructures for improving safety. More recently there have been legislative efforts to create a voluntary reporting system, which explicitly promised confidentiality to hospitals and doctors and that the collected data would not be discovered through the legal system for use in malpractice suits.⁶⁸ Medical malpractice reform is also gaining momentum to ensure that malpractice litigation safeguards patient safety and is not a barrier to accurate reporting of medical errors.

These developments will help standardize definitions, terminology, measurement, and databases in patient safety. In the meantime, benchmarks and performance objectives will be formulated to assess patient safety and best practices to prevent medical errors and injuries. Future editions of this annual report may be able to take advantage of progress on these multiple fronts to provide a more accurate assessment of the safety of the U.S. health care system.

ⁱⁱ For more information, go to www.va.gov/OCA/testimony/27jy00PS_usa.htm.

List of Measures

Patient Safety

<i>Measure Title</i>	<i>National</i>	<i>State</i>
Complications of care:		
Birth trauma	Table 2.1(00)	—
Death in low mortality DRGs	Table 2.2(00)	—
Failure to rescue	—	—
Transfusion reaction and Transfusion reaction (area)	Table 2.3a (00-PSI16) Table 2.3b (00-PSI26)	—
Foreign body left in body during procedure and Foreign body left in body during procedure (area)	Table 2.4a (00-PSI5) Table 2.4b (00-PSI21)	—
Central line-associated bloodstream infections in intensive care unit patients	Table 2.5	—
Central line-associated bloodstream infections in infants weighing <1,000 grams at birth in intensive care	Table 2.6a	—
Complications of anesthesia	Table 2.7 (00)	—
Decubitus ulcer	Table 2.8 (00)	—
Iatrogenic pneumothorax and Iatrogenic pneumothorax (area)	Table 2.9a (00-PSI6) Table 2.9b (00-PSI22)	—
Infection due to intravenous lines or catheters and infection due to intravenous lines or catheters (area)	Table 2.10a (00-PSI7) Table 2.10b (00-PSI23)	—
Postoperative hip fracture	Table 2.11 (00)	—
Postoperative hemorrhage or hematoma	Table 2.12 (00)	—
Postoperative physiologic and metabolic derangements	Table 2.13 (00)	—
Postoperative respiratory failure	Table 2.14 (00)	—
Postoperative pulmonary embolism or deep vein thrombosis	Table 2.15 (00)	—
Postoperative septicemia	Table 2.16 (00)	—

Patient Safety

<i>Measure Title</i>	<i>National</i>	<i>State</i>
Complications of care (cont.)		
Technical difficulty with procedure and technical difficulty with procedure (area)	Table 2.17a (00-PSI15) Table 2.17b (00-PSI25)	—
Postoperative wound dehiscence and postoperative wound dehiscence (area)	Table 2.18a (00-PSI14)	—
Obstetric trauma - vaginal with instrument	Table 2.18b (00-PSI24) Table 2.19 (00)	— —
Obstetric trauma - vaginal without instrument	Table 2.20 (00)	—
Obstetric trauma - cesarean delivery	Table 2.21 (00)	—
Prescribing medications:		
% of community dwelling elderly who had at least one prescription of the 33 medications that are potentially inappropriate for the elderly.	Table 2.22a (98) Table 2.22b (96)	—
% of adults who report that usual source of care asks about prescription medications and treatments from other providers	Table 2.23a (00) Table 2.23b (96)	—

Note: See Tables Appendix for tables listed above.

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