

# Chapter 3. Patient Safety

## Importance

### Mortality

Number of Americans who die each year from medical errors (1999 est.) .....44,000-98,000<sup>1</sup>

### Prevalence

Rate of adverse events for hospitalized patients (annual estimates) .....2.9%-3.7%<sup>1</sup>

Rate of adverse drug reactions during hospital admissions (annual estimates).....2.0%-6.7%<sup>2-4</sup>

Rate of adverse drug events among Medicare beneficiaries  
in ambulatory settings .....50 per 1,000 person-years<sup>5</sup>

### Cost

Cost attributable to medical errors (2008 est.).....\$19.5 billion<sup>6</sup>

Total cost per error (2008 est.) .....\$13,000<sup>6</sup>

Annual cost attributable to surgical errors (2008 est.).....\$1.5 billion<sup>7</sup>

## Measures

The Institute of Medicine (IOM) defines patient safety as “freedom from accidental injury due to medical care or medical errors.”<sup>1</sup> In 1999, the IOM published *To Err Is Human: Building a Safer Health System*, which called for a national effort to reduce medical errors and improve patient safety.<sup>1</sup> In response to the IOM’s report, President George W. Bush signed the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).<sup>1</sup> The act was designed to spur the development of voluntary, provider-driven initiatives to improve the quality, safety, and outcomes of patient care. The Patient Safety Act addresses many of the current barriers to improving patient care.

Central to this effort is the ability to measure and track adverse events. Measuring patient safety is complicated by difficulties in assessing and ensuring the systematic reporting of medical errors and adverse events. All too often, adverse event reporting systems are laborious and cumbersome. Health care providers may also fear that if they participate in the analysis of medical errors or patient care processes, the findings may be used against them in court or harm their professional reputations. Many factors limit the ability to aggregate data in sufficient numbers to rapidly identify prevalent risks and hazards in the delivery of patient care, their underlying causes, and practices that are most effective in mitigating them. These include difficulties aggregating and sharing data confidentially across facilities or State lines.

In addition, although *To Err Is Human* does not mention race or ethnicity when discussing the problem of patient safety, such data are limited. Any differences that suggest patient race and/or ethnicity might influence

<sup>1</sup> Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to 299b-26.

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the risk of experiencing a patient safety event must be investigated to better understand the underlying reasons for any differences before the differences can be eliminated.

Despite these limitations, a better picture of patient safety is emerging. Progress has been made in recent years in raising awareness, developing reporting systems, and establishing national data collection standards. Examining patient safety using a combination of administrative data, medical record abstraction, spontaneous adverse event reports, and patient surveys allows a more robust understanding of what is improving and what is not. Still, data remain incomplete for a comprehensive national assessment of patient safety.<sup>8</sup>

The National Priorities Partnership (NPP) identified safety in health care as one of six national priorities. The goal is a health care system that is:

...relentless in continually reducing the risks of injury from care, aiming for “zero” harm wherever and whenever possible—a system that can promise absolutely reliable care, guaranteeing that every patient, every time, receives the benefits of care based solidly on science.<sup>9</sup>

The key goals include: (1) health care organizations and staff ensuring a culture of safety to reduce healthcare-associated infections (HAIs) and serious adverse events (SAEs), (2) hospitals reducing preventable and premature hospital-level mortality rates, and (3) hospitals improving their 30-day mortality rates for selected conditions (e.g., acute myocardial infarction, pneumonia).

The National Healthcare Disparities Report (NHDR) has tracked a growing number of patient safety measures. Organized around the NPP priority of Safety, the 2010 NHDR presents the following measures:

- Reduction of HAIs:
  - Appropriate timing of antibiotics (core measure).
  - Postoperative sepsis.
- Reduction of SAEs:
  - Ambulatory care visits due to adverse effects of medical care.
  - Mechanical adverse events.
  - Postoperative respiratory failure.
- Preventable and premature mortality rates:
  - Deaths following complications of care (core measure).
- 30-day mortality rates:
  - Pneumonia mortality rates.

## Findings

### Healthcare-Associated Infections

Infections acquired during hospital care (nosocomial infections) are one of the most serious patient safety concerns. They are the most common complication of hospital care.<sup>10</sup> An estimated 1.7 million HAIs occur

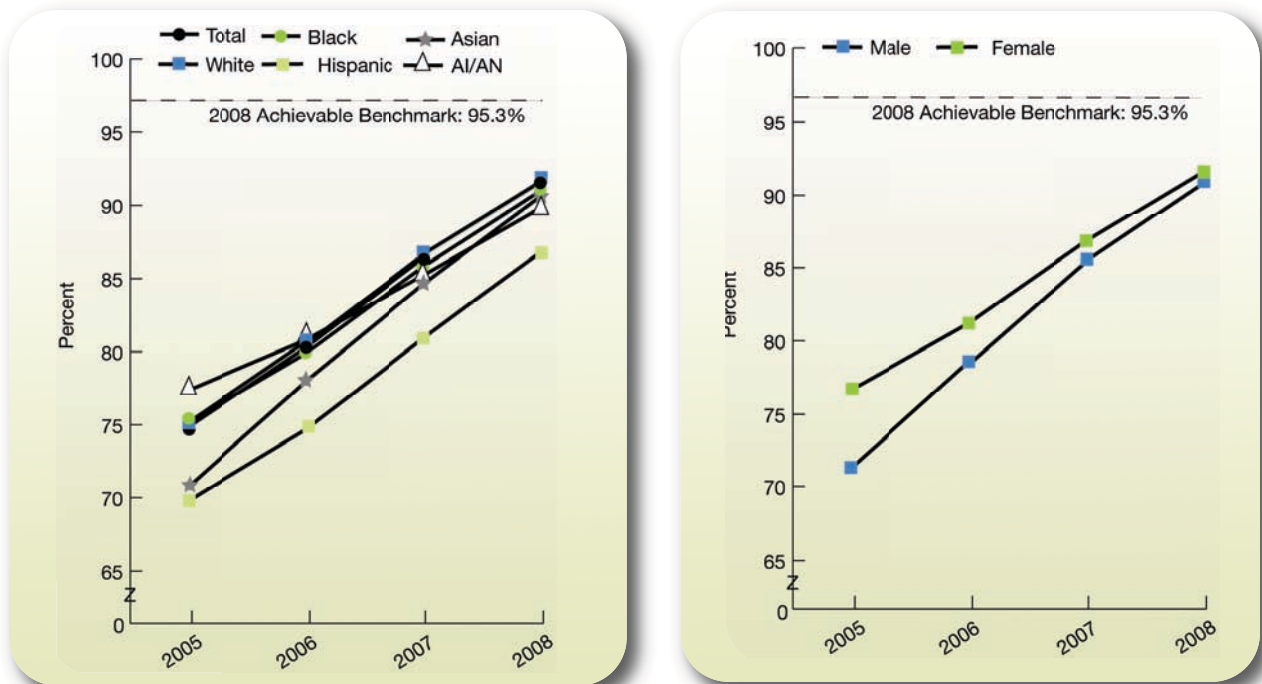
each year in hospitals, leading to about 100,000 deaths. The most common infections are urinary tract, surgical site, and bloodstream infections.<sup>11</sup>

A specific medical error cannot be identified in most cases of HAIs. However, better application of evidence-based preventive measures can reduce HAI rates within an institution. For example, one such measure includes the administration of prophylactic antibiotics at the right time prior to surgery.

## Prevention: Appropriate Timing of Antibiotics Among Surgical Patients

Wound infection following surgery is a common HAI. Hospitals can reduce the risk of surgical site infection by making sure patients get the right antibiotics at the right time on the day of their surgery. Surgery patients who get antibiotics within 1 hour before their operation are less likely to get wound infections than those who do not. Getting an antibiotic earlier or after surgery begins is not as effective. However, taking these antibiotics for more than 24 hours after routine surgery is usually not necessary and can increase the risk of side effects, such as antibiotic resistance and serious types of diarrhea. Among adult Medicare patients having surgery, the NHDR tracks receipt of antibiotics within 1 hour prior to surgical incision, discontinuation of antibiotics within 24 hours after end of surgery, and a composite of these two measures.

**Figure 3.1. Adult surgery patients who received appropriate timing of antibiotics: Overall composite, by race/ethnicity and gender, 2005-2008**



**Key:** AI/AN = American Indian or Alaska Native.

**Source:** Centers for Medicare & Medicaid Services, Medicare Quality Improvement Organization Program, 2005-2008.

**Denominator:** Hospitalized patients having surgery.

**Note:** Populations not specifically noted as Hispanic are non-Hispanic.

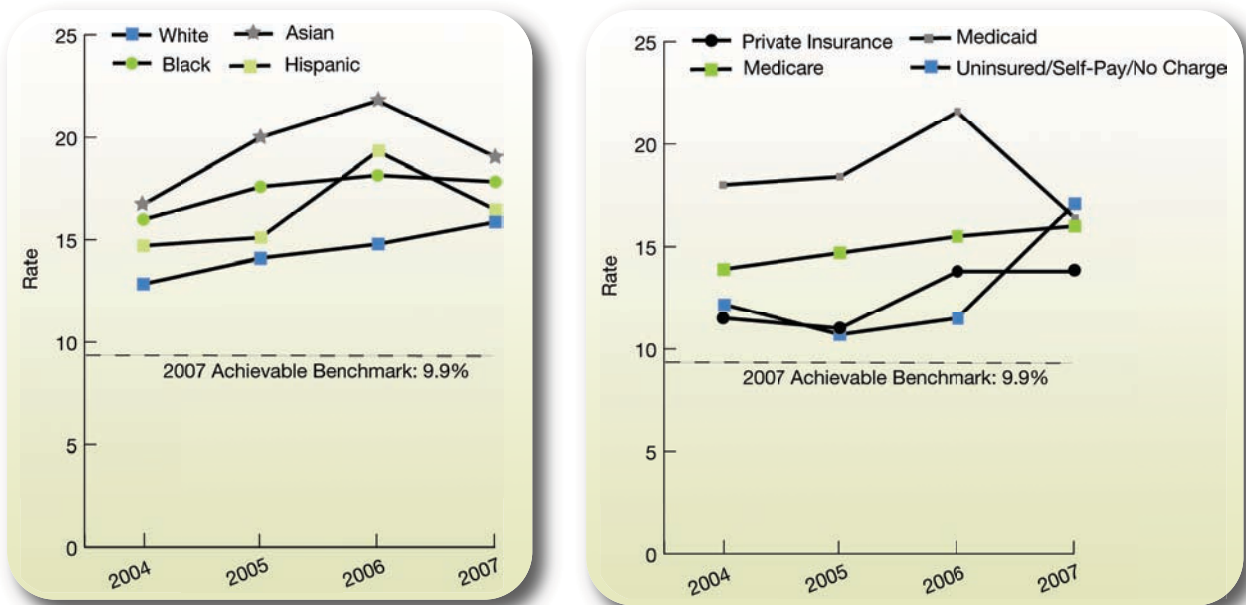
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- The percentage of adult surgery patients who received appropriate timing of antibiotics improved from 2005 to 2008 (from 74.9% to 91.4%; Figure 3.1). Significant improvement was also seen among all racial, ethnic, and gender groups during this period.
- There were no statistically significant differences between racial and ethnic minority groups and Whites in the percentage of adult surgery patients who received appropriate timing of antibiotics.
- The 2008 top 5 State achievable benchmark was 95.3%.<sup>ii</sup> At the current 5.6% annual rate of increase, this benchmark could be attained in about 1 year. Whites, Blacks, and Asians could attain the achievable benchmark within 1 year. American Indians and Alaska Natives and Hispanics could attain the benchmark within 2 years.

## Outcome: Postoperative Sepsis

Sepsis, a severe bloodstream infection, can occur after surgery. In a recent study, postoperative sepsis occurred in 4.5% of emergency surgery patients and 2.0% of elective surgery patients.<sup>12</sup> Regarding racial disparities, a recent study revealed that higher rates of infection as well as higher risk for acute organ dysfunction both contribute to higher sepsis rates among Blacks compared with Whites.<sup>13</sup> Rates can be reduced by giving patients appropriate prophylactic antibiotics 1 hour prior to surgical incision.

**Figure 3.2. Postoperative sepsis per 1,000 elective-surgery discharges with an operating room procedure, by race/ethnicity and insurance status, 2004-2007**



**Source:** Agency for Healthcare Research and Quality (AHRQ), Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, and AHRQ Quality Indicators, version 3.1, 2004-2007.

**Denominator:** All elective hospital surgical discharges, age 18 and over, with length of stay of 4 or more days, excluding patients admitted for infection, patients with cancer or immunocompromised states, patients with obstetric conditions, and admissions specifically for sepsis.

**Note:** White, Black, and Asian are non-Hispanic. Rates are adjusted by age, gender, age-gender interactions, comorbidities, and diagnosis-related group clusters.

<sup>ii</sup> The top 5 States that contributed to the achievable benchmark are Hawaii, Maine, New Hampshire, South Dakota, and Vermont.

- From 2004 to 2007, the overall rate of postoperative sepsis increased from 13.2 per 1,000 discharges to 15 (data not shown).
- During the same period, a significant increase was also seen among all racial, ethnic, and insurance groups, except for the Medicaid group, which did not change significantly (Figure 3.2).
- In 2007, Blacks and Asians had a significantly higher rate of postoperative sepsis than non-Hispanic Whites (17.8 and 19.0 per 1,000 hospital discharges compared with 15.9).
- People with Medicare, Medicaid, and no insurance had significantly higher postoperative sepsis rates than people with private insurance (16, 16.4, and 17.1 per 1,000 hospital discharges, respectively, compared with 13.8).
- The 2007 top 4 State achievable benchmark was 9.9 per 1,000 hospital discharges.<sup>iii</sup> The overall rate of postoperative sepsis, as well as the rates among all racial, ethnic, and insurance groups were increasing (moving away from the benchmark).

## Adverse Events

Adverse effects of medical care can arise from medical and surgical procedures as well as from adverse drug reactions. Although patient safety initiatives are predominantly focused on inpatient hospital events, adverse effects of medical care are much more commonly treated at visits to outpatient settings with more than <sup>12</sup> million such visits occurring annually. Providers treating adverse events in outpatient settings may include office-based physicians, hospital outpatient departments, and hospital emergency departments. Events treated in ambulatory settings may be less severe than those occurring in inpatient settings. Some adverse events, such as known side effects of appropriately prescribed medications, may be unavoidable, while others may be considered medical errors. Although the following measure does not distinguish between the two types of events, it provides an overall sense of the burden these events place on the population.

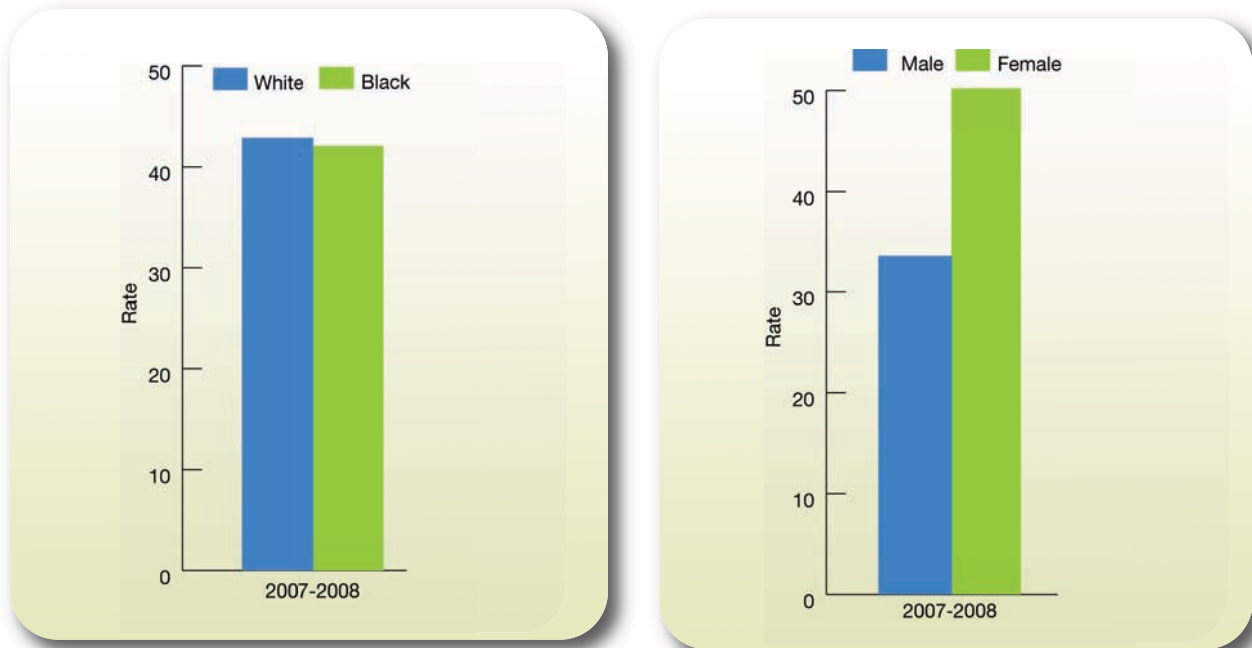
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<sup>iii</sup> The top 4 States that contributed to the achievable benchmark are Arkansas, Massachusetts, Nebraska, and Rhode Island.

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## Outcome: Ambulatory Care Visits Due to Adverse Effects of Medical Care

Figure 3.3. Ambulatory medical care visits due to adverse effects of medical care per 1,000 people, by race and gender, 2007-2008



**Source:** Centers for Disease Control and Prevention, National Center for Health Statistics, National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey, 2007-2008.

**Denominator:** U.S. Census Bureau estimated civilian noninstitutionalized population on July 1, 2007, and July 1, 2008.

**Note:** Ambulatory care includes visits to office-based physicians, hospital outpatient departments, and hospital emergency departments.

- In 2007-2008, the rate of ambulatory care visits due to adverse effects of medical care was higher for females compared with males (Figure 3.3).

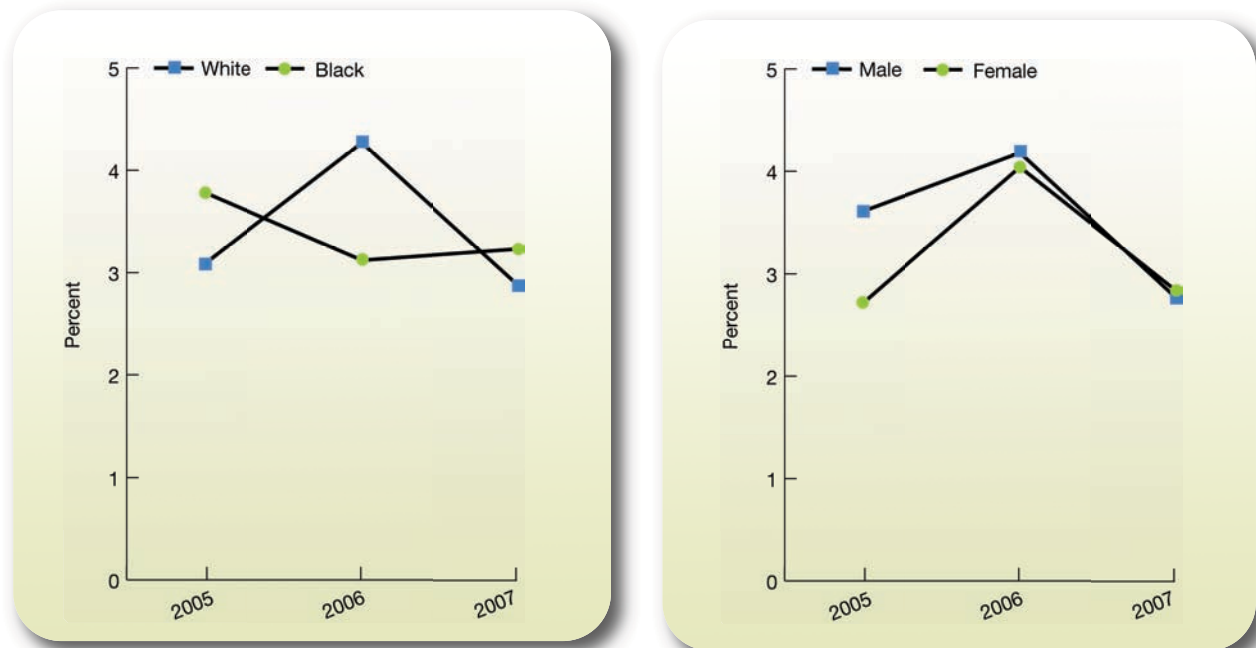
Also, in the NHQR:

- In 2007-2008, the rates of ambulatory care visits due to adverse effects of medical care were higher for residents of metropolitan areas compared with residents of nonmetropolitan areas and for all age groups compared with the group ages 0-17.

## Outcome: Mechanical Adverse Events

Sometimes patients need a central venous catheter inserted into a major vein in the neck, chest, or groin to administer medication or fluids, obtain blood for tests, and take cardiovascular measurements. Patients who require a central venous catheter tend to be severely ill. The placement and use of these catheters can result in mechanical adverse events, including bleeding; hematoma; perforation; pneumothorax; air embolism; and misplacement, occlusion, shearing, or knotting of the catheter.

**Figure 3.4. Composite: Mechanical adverse events associated with central venous catheter placement, by race and gender, 2005-2007**



**Source:** Centers for Medicare & Medicaid Services, Medicare Patient Safety Monitoring System (MPSMS), 2005-2007.

**Denominator:** Adult hospitalized Medicare fee-for-service discharges from the MPSMS sample with central venous catheter placement.

**Note:** Mechanical adverse events include allergic reaction to the catheter, tamponade, perforation, pneumothorax, hematoma, shearing off of the catheter, air embolism, misplaced catheter, thrombosis or embolism, knotting of the pulmonary artery catheter, and certain other events.

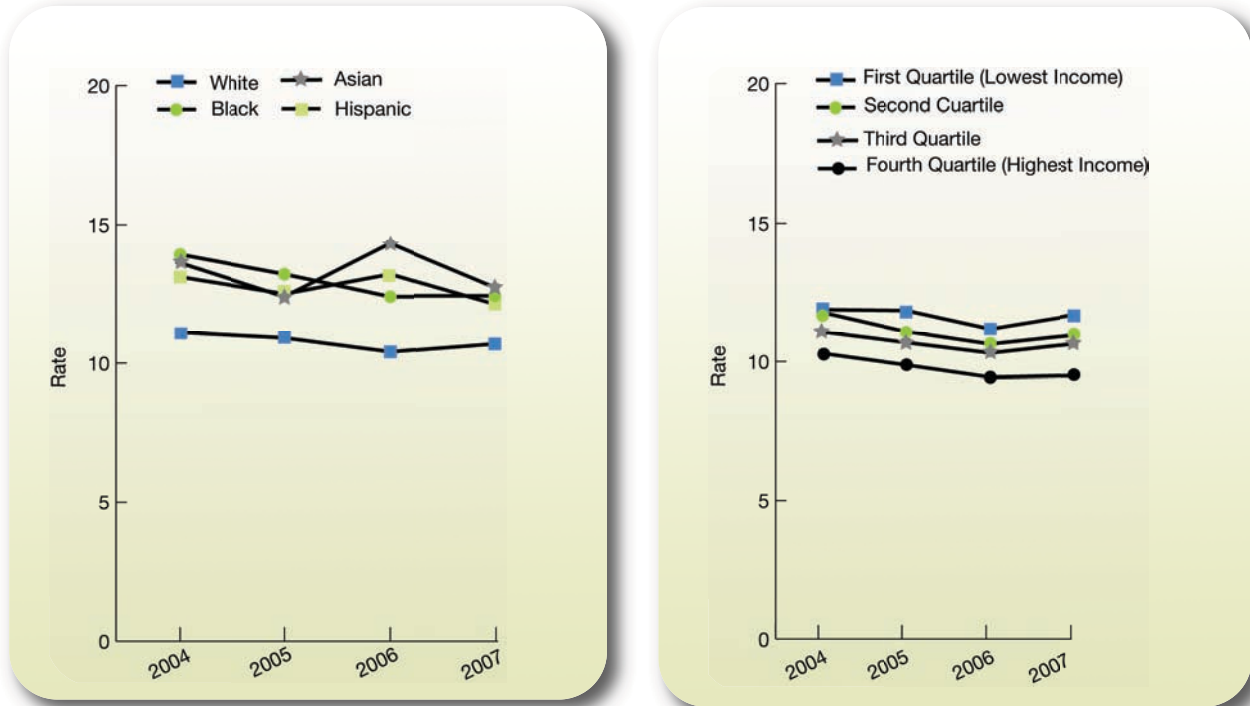
- From 2005 to 2007, there was no statistically significant change overall or for any race or gender for medical adverse events associated with central venous catheter placement (Figure 3.4).

## Outcome: Postoperative Respiratory Failure

Respiratory failure is not uncommon after surgery and may necessitate reintubation or prolonged mechanical ventilation. Causes include oversedation, exacerbation of underlying cardiovascular or respiratory conditions, and ventilator-associated pneumonia. Although some cases of respiratory failure cannot be prevented, close attention to risk factors can reduce rates.

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**Figure 3.5. Postoperative respiratory failure per 1,000 elective-surgery discharges after an operating room procedure, by race/ethnicity and income, 2004-2007**



**Source:** Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004-2007.

**Denominator:** All elective hospital surgical discharges age 18 and over, excluding patients with respiratory disease, circulatory disease, neuromuscular disorders, obstetric conditions, and secondary procedure of tracheostomy before or after surgery or as the only procedure.

**Note:** White, Blacks, and Asians are non-Hispanic. Rates are adjusted by gender, age-gender interactions, comorbidities, and diagnosis-related group clusters.

- In 2007, the rate of postoperative respiratory failure for all other income groups was higher than for the highest income group (fourth quartile) (Figure 3.5).

Also, in the NHQR:

- In 2007, there were no statistically significant differences in the rate of postoperative respiratory failure among patients living in different geographic areas.

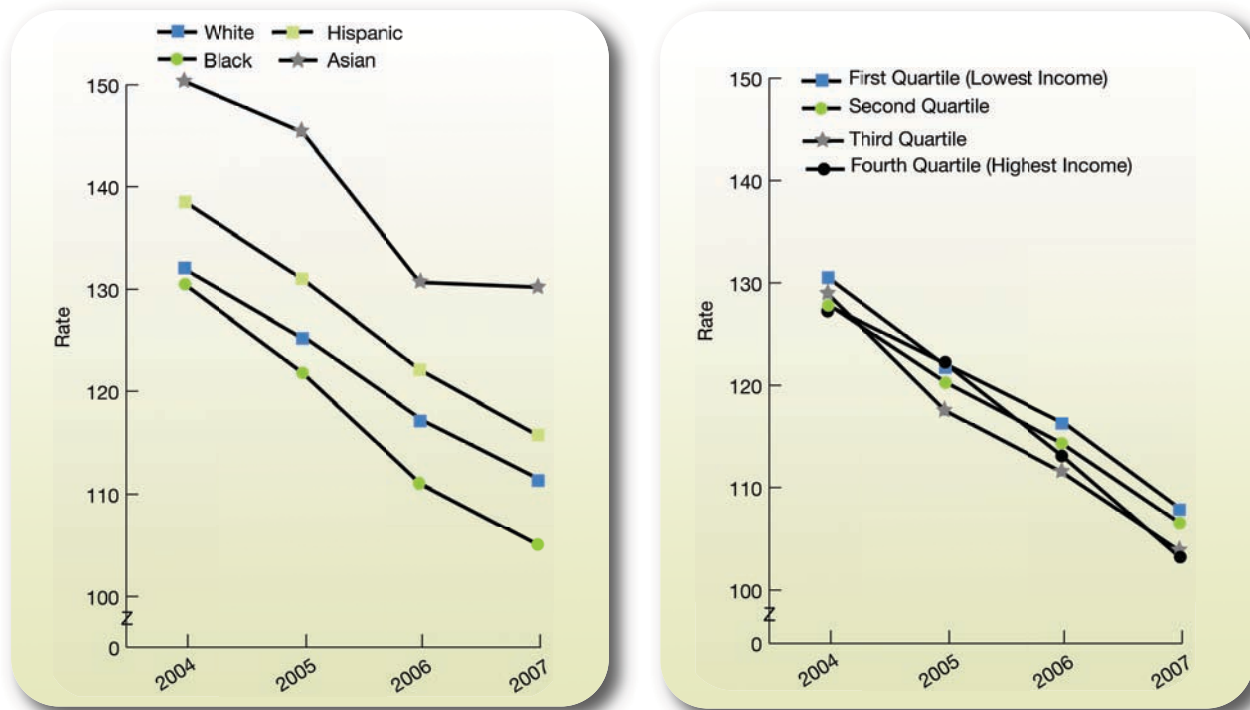
## Preventable and Premature Mortality Rates

### Outcome: Deaths Following Complications of Care

Many complications that arise during hospital stays cannot be prevented. However, rapid identification and aggressive treatment of complications may prevent these complications from leading to death. The indicator “deaths following complications of care,” also called “failure to rescue,” tracks deaths among patients whose hospitalizations are complicated by pneumonia, thromboembolic events, sepsis, acute renal failure, gastrointestinal bleeding or acute ulcer, shock, or cardiac arrest.<sup>14</sup>



**Figure 3.6. Deaths per 1,000 discharges with complications potentially resulting from care (failure to rescue), ages 18-74, by race/ethnicity and income, 2004-2007**



**Source:** Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004-2007.  
**Denominator:** Patients ages 18-74 years from U.S. community hospitals whose hospitalizations are complicated by pneumonia, thromboembolic events, sepsis, acute renal failure, gastrointestinal bleeding or acute ulcer, shock, or cardiac arrest.  
**Note:** Whites, Blacks, and Asians are non-Hispanic. Rates are adjusted by age, gender, comorbidities, and diagnosis-related group clusters.

- From 2004 to 2007, the rate of deaths following complications of care declined from 123.9 to 105.7 per 1,000 admissions of adults ages 18-74 (data not shown). A significant decrease was also seen among all racial, ethnic, and income groups during the same period (Figure 3.6).
- In 2007, Asians had a significantly higher rate of deaths following complications of care compared with Whites (130.2 per 1,000 compared with 111.3).

Also, in the NHQR:

- For those who were uninsured, the rates of deaths following complications of care were higher than for those with private insurance.

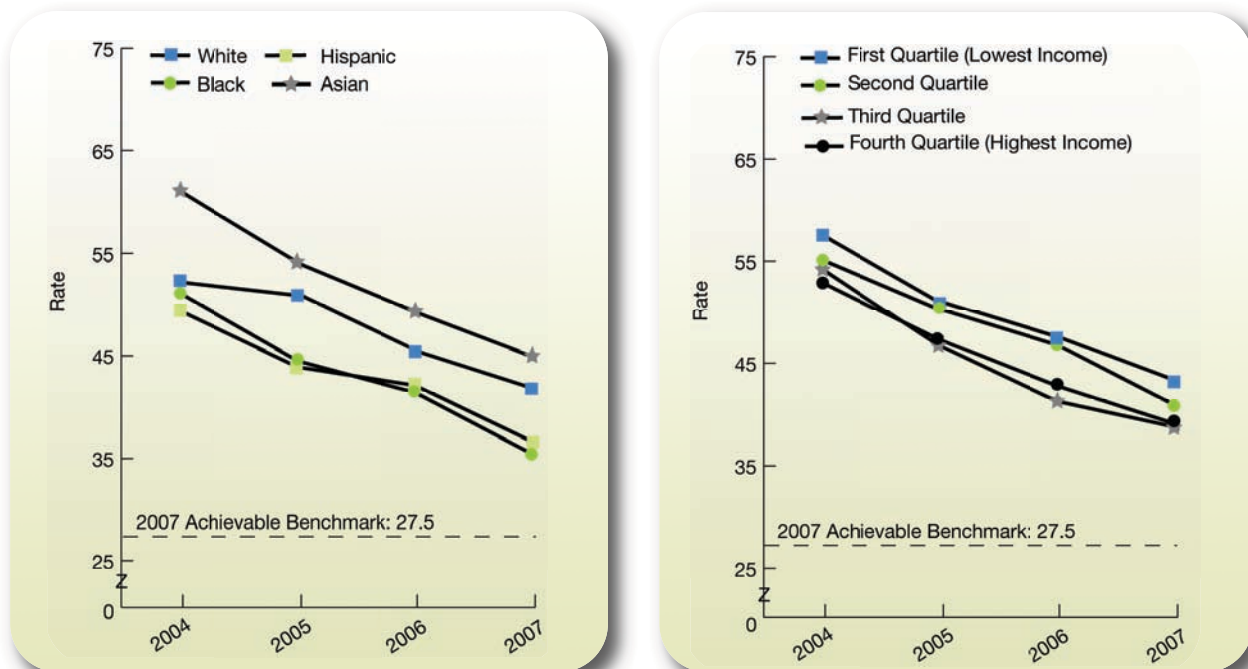
## 30-Day Mortality Rates

One of the goals for measurement specified by the NPP under the Safety priority is to reduce 30-day hospital mortality rates for conditions such as pneumonia. While national 30-day mortality rates due to pneumonia are not currently available for reporting, the in-hospital mortality rates per 1,000 hospital admissions with pneumonia are reported here. About two-thirds of patients who die within 30 days of hospital admission die inside the hospital, and the correlation between inpatient and 30-day mortality is high.<sup>15</sup>

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## Outcome: Inpatient Pneumonia Deaths

Figure 3.7. Deaths per 1,000 hospital admissions with pneumonia as principal diagnosis, age 18 and over, by race/ethnicity and income, 2004-2007



**Source:** Agency for Healthcare Research and Quality (AHRQ), Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, and AHRQ Quality Indicators, version 3.1.

**Denominator:** All discharges age 18 and over with principal diagnosis code of pneumonia, excluding patients transferred to another short-term hospital and obstetric and neonatal admissions.

**Note:** Whites, Blacks, and Asians are non-Hispanic. Rates are adjusted by age, gender, age-gender interactions, and all patient refined-diagnosis related group risk of mortality score.

- From 2004 to 2007, the overall inpatient pneumonia mortality rate decreased from 55.2 per 1,000 admissions to 40.8 (data not shown). A significant decrease was also seen among all racial, ethnic, and income groups during the same period (Figure 3.7).
- In 2007, Blacks and Hispanics had a significantly lower inpatient pneumonia mortality rate than Whites (35.4 and 36.6 per 1,000 hospital admissions, respectively, compared with 41.7).
- In 2007, the lowest income group had a significantly higher inpatient pneumonia mortality rate than the highest income group (43.2 per 1,000 hospital admissions compared with 39.1).
- The 2007 top 4 State achievable benchmark was 27.5 per 1,000 hospital admissions.<sup>iv</sup> At the current rate of improvement, this benchmark could be attained in less than 3 years.
- Rates of improvement varied by race and ethnicity. Blacks could attain the benchmark in just over 1.5 years and Hispanics in just over 2 years. Whites and Asians would not attain the benchmark for almost 3 years.

<sup>iv</sup> The top 4 States that contributed to the achievable benchmark are Arizona, Colorado, Maryland, and Michigan.

## References

1. Kohn L, Corrigan J, Donaldson M, eds. *To err is human: building a safer health system*. Washington, DC: Institute of Medicine, Committee on Quality of Health Care in America; 2000.
2. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *Jama* 1998 Apr 15;279(15):1200-5.
3. Lesar TS, Lomaestro BM, Pohl H. Medication-prescribing errors in a teaching hospital. A 9-year experience. *Arch Intern Med* 1997 Jul 28;157(14):1569-76.
4. Classen DC, Pestotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. *Jama* 1997 Jan 22-29;277(4):301-6.
5. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *Jama* 2003 Mar 5;289(9):1107-16.
6. Shreve J, Van De Bos J, Gray T, et al. *The economic measurement of medical errors*. Schaumburg, IL: Society of Actuaries/Milliman; 2010.
7. Encinosa WE, Hellinger FJ. The impact of medical errors on 90-day costs and outcomes: an examination of surgical patients. *Health Serv Res* 2008 Dec;43(6):2067-85. Epub 2008 Jul 25.
8. *Aspden P, Corrigan J, Wolcott J, et al. Patient safety: achieving a new standard of care*. Washington, DC: Institute of Medicine, Committee on Data Standards for Patient Safety; 2004.
9. Board of Health Care Services. *Future directions for the National Healthcare Quality and Disparities Reports*. Washington, DC: Institute of Medicine; 2010.
10. Thomas EJ, Studdert DM, HR B, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;38:261-71.
11. Klevens RM, Edwards JR, Richards CL, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Hlth Rep* 2007;122:160-66.
12. Moore LJ, Moore FA, Todd SR, et al. Sepsis in general surgery: the 2005-2007 National Surgical Quality Improvement Program perspective. *Arch Surg* Jul;145(7):695-700.
13. Mayr FB, Yende S, Linde-Zwirble WT, et al. Infection rate and acute organ dysfunction risk as explanations for racial differences in severe sepsis. *Jama* 2010 Jun 23;303(24):2495-2503.
14. *Guide to Patient Safety Indicators version 3.1*. Rockville, MD: Agency for Healthcare Research and Quality; 2003. Available at: [http://www.qualityindicators.ahrq.gov/downloads/psi/word/psi\\_guide\\_v31.doc](http://www.qualityindicators.ahrq.gov/downloads/psi/word/psi_guide_v31.doc). Accessed November 17, 2009.
15. Rosenthal GE, Baker DW, Norris DG, et al. Relationships between in-hospital and 30-day standardized hospital mortality: implications for profiling hospitals. *Health Serv Res* 2000 Mar;34(7):1449-68.