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*In the past 10 years, numerous reports have demonstrated that the quality and performance of America's health care system is far inferior to what it should be. Medical errors in hospitals and other health care settings kill or maim patients rather than cure them of their ills. Too many patients don't receive evidence-based care processes that improve health outcomes. Many stakeholders, including patients and consumers, private and government purchasers of health care, regulators and accreditors, and health plans and providers, are demanding more accountability from our health care system. In response to the urgent demand, performance measurement and public reporting of quality information are bringing greater accountability to the health care system.*

*The largest health care purchaser, the Center for Medicare and Medicaid Services (CMS), uses a multi-pronged strategy to stimulate quality improvement in the health services for its beneficiaries using performance measurement to provide information*

*about health care providers and encourage thoughtful, data-driven choices by patients and consumers. Building on the public reporting of performance and quality data, Medicare also has begun several demonstration projects using payment incentives for reporting of health data and improved performance.*

*Using national standardized measures endorsed by the National Quality Forum, CMS works with stakeholder coalitions and collaborations such as the Hospital Quality Alliance and the AQA Alliance (formerly the Ambulatory Care Quality Alliance) to implement performance measurement programs for hospitals and physicians. Public reporting of hospital performance from 2002-*

*2005 has demonstrated significant improvements, particularly in the low performers. Additional performance measures are added every year to provide a more complete picture of hospital performance and provide all stakeholders with information about the quality of hospital services.*

## What the PCP Should Know about National Quality Initiatives— For the Hospital and the Office

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Various stakeholders, including public and private purchasers, are demanding performance information for individual physicians. Collecting performance data from physicians is more challenging because there is no existing infrastructure for data transmission outside of claims data. This year, CMS's Physician Voluntary Reporting Program and the AQA pilot studies will test various data collection methods that will develop the urgently needed mechanisms to collect data from physician offices.

Primary care physicians must become knowledgeable and aware of the various national quality initiatives that will affect the practice of medicine and reimbursement for services over the next 5-10 years. Performance measurement is an effective means to bring accountability to the health care system and drive quality improvement.

—The Editor

## Introduction

- As many as 98,000 deaths per year are due to errors in hospital care.<sup>1</sup>
- A RAND Health study found that only 54.9% of patients received recommended care.<sup>2</sup>
- According to the Dartmouth Atlas of Health Care, almost one-third of Medicare spending for chronically ill patients is unnecessary.<sup>3</sup>

For a long time the U.S. health care system was assumed to be safe and effective, though somewhat costly, in addressing the health needs of Americans. The performance measurements above, however, tell a shockingly different story of a system that is not safe, effective, or efficient in spite of consistently increas-

ing costs that approach 16% of our country's gross domestic product (GDP).

Health care has lagged far behind other industries in using data to evaluate the performance of its primary business, namely delivering health care services to customers. Various stakeholders such as private and government payers, patients and consumers, health care regulators and policy makers, and health services researchers are demanding data to assess performance of health care systems, facilities, and individual providers. The growing demands for accountability of the health care system create an urgent need for performance measures that provide information addressing the six aims of the health care system: to be effective, safe, patient-centered, efficient, timely, and equitable.<sup>4</sup> Numerous programs have been created by government and private entities to collect and share data about health care delivery performance and publish report cards in newspapers, magazines, and on web sites.

## Medical Errors and Patient Safety

The Institute of Medicine's 2000 landmark report "To Err is Human: Building a Safer Health System"<sup>5</sup> identified the monumental problem of medical errors and focused attention on reducing risk for patients in the health care system. In testimony before the Senate Committee on Finance on May 17, 2006, the Centers for Medicare and Medicaid Services (CMS) Administrator Mark McClellan stated that CMS wants to eliminate payments for "never events"—those events that occur when a patient experiences a negative consequence of care that results in unintended injury, illness, or death.

Other payers of health care support CMS's position. The Leapfrog Group<sup>6</sup> is made up of more than 170 companies and organizations that buy health care. Suzanne Delbanco, CEO of The Leapfrog Group, notes that a "never event" occurs when there is an inexcusable failure in the delivery of health care services. The Leapfrog Group's mission is to reduce preventable medical mistakes and improve the quality and affordability of health care. Paying for never-events runs directly contrary to these aims.<sup>7</sup>

In 2002, the National Quality Forum (NQF)<sup>8</sup> defined 27 "serious reportable events" that should not occur within a safe health care facility.<sup>9</sup> Six types of serious reportable events include: surgical events (e.g., surgery being performed on the wrong patient), product or device events (e.g., using contaminated drugs), patient protection events (e.g., an infant discharged to the wrong person), care management events (e.g., a medication error), environmental events (e.g., electric shock or burn), and criminal events (e.g., sexual assault of a patient).

NQF's report recommends a national state-based event reporting system to improve the quality of patient care. As of April 2006, 25 states require licensed health care facilities to report at least some kinds of adverse events related to health care;<sup>10</sup> numerous health care error reporting systems are in operation; and there is growing evidence that these efforts have been bringing positive change to the quality of care delivered.<sup>11</sup>

The overall safety and quality of care in a hospital depends on many policies and practices within its operations. In May 2003

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NQF published “Safe Practices for Better Healthcare: A Consensus Report”<sup>12</sup> that endorsed 30 safe practices that should be universally used in applicable clinical care settings to improve patient safety. Research shows that if three of the safe practices (Computer Physician Order Entry, Intensive Care Unit Physician Staffing, and Evidence-Based Hospital Referral) were implemented in all urban hospitals in the United States, up to 65,341 lives could be saved, as many as 907,600 serious medication errors each year would be prevented,<sup>13</sup> and \$41.5 billion could be saved.<sup>14</sup>

In 2001 The Leapfrog Group launched their Hospital Quality and Safety Survey to provide consumers and purchasers of health care with the information they need to make informed health care choices and promote transparency within health care. The survey includes all of the 30 NQF-endorsed safe practices. After completion of the online Leapfrog hospital survey, each hospital’s relative ranking compared with other hospitals is displayed on the Leapfrog Web site ([www.leapfroggroup.org](http://www.leapfroggroup.org)). Any hospital in the United States may complete the Leapfrog Hospital Quality and Safety Survey. Leapfrog Group employer members make the survey data available to all their enrollees. They also commit to work to implement incentives and rewards for safety, high-quality, and value in health care.

In 2005, two of the “To Err is Human” authors, Lucien Leape, MD, of the Harvard School of Public Health, and Donald Berwick, MD, of the Institute for Healthcare Improvement, summarized the impact of the Institute of Medicine (IOM) report and the progress made toward reducing risks to patients in the health care system<sup>15</sup>:

- Few people doubt that preventable medical injuries are a serious problem.
- A new health care mantra has been adopted from the IOM report—bad systems and not bad people lead to most errors.
- A broad array of stakeholders have embraced the cause of improving patient safety.
- Congress has allocated \$50 million annually for patient safety research.
- Physicians, nurses, therapists, and pharmacists have become more aware of safety hazards and are committed to making improvements.
- JCAHO requires hospitals to implement safety practices for accreditation.

However, the authors note that progress is “frustratingly slow” and the reasons lie in the very “culture of medicine.” The changes required to improve safety may be perceived as threats to physician autonomy and authority. Many physicians and other providers are unwilling to discuss or admit to error because of concerns about malpractice liability. Lack of leadership within hospitals, health plans, and physician practices; a reimbursement system that is not aligned with or supportive of patient safety goals; and a limited number of measures to gauge progress are formidable challenges to improve patient safety and reduce medical errors.

Leape and Berwick expect to see dramatic progress in the next five years in the following areas:

## Table 1. CMS Physician Voluntary Reporting Program 16 Starter Measures

- Aspirin at arrival for acute myocardial infarction
- Beta-blocker at time of arrival for acute myocardial infarction
- Hemoglobin A1c control in patients with Type I or Type II diabetes mellitus
- Low-density lipoprotein control in patients with Type I or Type II diabetes mellitus
- High blood pressure control in patients with Type I or Type II diabetes mellitus
- Angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker therapy for left ventricular systolic dysfunction
- Beta-blocker therapy for patients with prior myocardial infarction
- Assessment of elderly patients for falls
- Dialysis dose in end-stage renal disease patients
- Hematocrit level in end-stage renal disease patients
- Receipt of autogenous arteriovenous fistula in end-stage renal disease patients
- Antidepressant medication during acute phase for patients diagnosed with new episode of major depression
- Antibiotic prophylaxis in surgical patients
- Thromboembolism prophylaxis in surgical patients
- Use of internal mammary artery in coronary artery bypass graft surgery
- Pre-operative beta-blocker for patients with isolated coronary artery bypass graft

- implementation of electronic health records;
- wide diffusion of proven and safe practices;
- spread of teamwork and safety; and
- full disclosure to patients following injury.

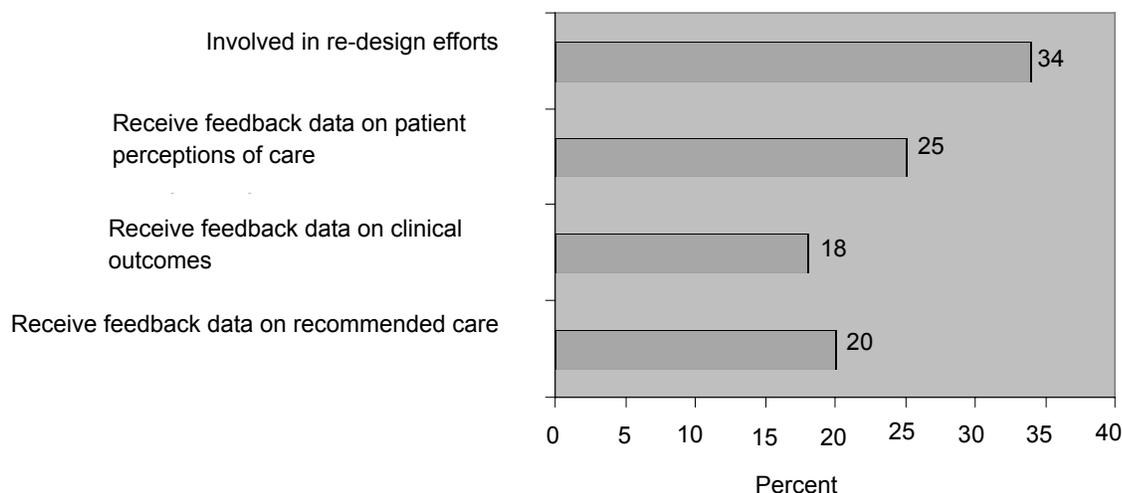
Leape and Berwick suggest that reformed reimbursement policies, regulation, public outrage, and the setting of “strict, ambitious, quantitative, and well-tracked national goals” could accelerate progress toward a safe health care system. In conclusion, the authors assert “we will not become safe until we choose to become safe.”

### Hospitals

In 2001 the Department of Health and Human Services (DHHS) announced the Quality Initiative to assure high quality health care to all Americans through accountability and public disclosure. The Hospital Quality Initiative’s goal is to improve hospitals’ quality of care by providing objective, easy to understand information on hospital performance to encourage consumers and their physicians to make better informed decisions on how to get the best hospital care, create incentives for hospitals to improve care, and support public accountability.

CMS, working with the Hospital Quality Alliance (HQA)—a public-private collaborative on hospital measurement and reporting—launched the hospital version in their family of Compare web tools at [www.medicare.gov](http://www.medicare.gov) in 2004. Similar to Medicare Compare, Nursing Home Compare, and Home Health Compare,

**Figure 1. Physician Participation in Performance Measurement and Quality Improvement**



Hospital Compare ([www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov)) reports valid, credible, and use-friendly information about the quality of care delivered in the nation's hospitals. Over 4000 hospitals report data on up to 20 performance measures, and participation by hospitals continues to grow. Another member of the HQA, the JCAHO also publishes similar information on hospital performance on its Quality Check web site ([www.qualitycheck.org](http://www.qualitycheck.org)). Quality Check reports information on performance of more than 15,000 JCAHO-accredited health care organizations and programs in the United States.

JCAHO examined hospital performance on 18 indicators from 2002-2004 of more than 3000 hospitals. The study found significant improvement on 15 of 18 measures—improvement ranged from 3 to 33%—and no significant deterioration. Low performing hospitals at the beginning of the study demonstrated greater improvement over two years than hospitals with high performance at baseline.<sup>16</sup>

Another analysis of the HQA national reporting initiative found that performance varied moderately among large hospital-referral regions, with top hospitals scoring 12-23% higher than low-performing hospitals on process of care measures for acute myocardial infarction and pneumonia. Small but significant increases of performance were found in academic hospitals, Northeast or Midwest facilities, and not-for-profit hospitals.<sup>17</sup>

CMS asked Mathematica Policy Research, Inc., to study how public reporting of quality information has influenced quality improvement efforts within hospitals.<sup>18</sup> Mathematica's assessment of CMS's Hospital Quality Initiative included a survey of hospital administrative leaders on internal effects of Hospital Compare and tried to identify difficulties faced by hospitals in making improvements. Mathematica's findings included:

- About 8 in 10 hospitals reported significant improvement on one or more of their scores.
- Approximately 60% of hospitals stated that they had substantial room for improvement on one or more Hospital Compare

indicators below the 50th percentile benchmark.

- Significant decline in at least one measure was reported by 5% of hospitals.
- Of the hospitals noting a decline in performance, 28% attributed the fall in scores to documentation problems and 13% were due to a few outlier cases.

Mathematica asked the hospitals reporting a substantial room for improvement about the challenges and barriers they face in improving their results. Several key difficulties were identified:

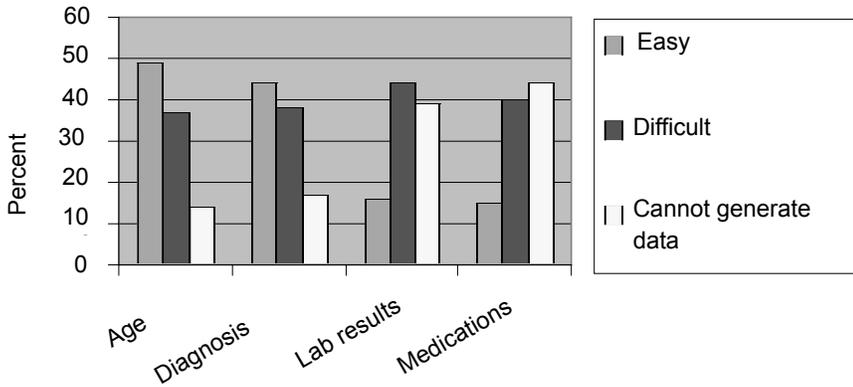
- The most common barrier was inaccurate documentation. When physicians or other hospital staff failed to document that appropriate care was given to a patient, or when data reporting processes were incomplete, the hospital's score declined.
- Failure to engage physicians in hospital quality improvement efforts was reported by a majority of senior executives and QI directors. Research by Mathematica and others confirms that physician and organizational resistance are fundamental barriers to improvement. Physician resistance can include workload issues that preclude them from facilitating or adopting changes, inadequate incentives, inconsistent alignment between hospital and physician payment schemes, low levels of computer literacy, and lack of involvement in quality improvement design and implementation processes.
- Insufficient resources were cited as another difficulty by the majority of hospitals, particularly resources for staff trained in quality improvement processes and resources to adopt health information technologies.
- Lack of hospital senior management leadership and support for quality improvement functions.

The Mathematica report notes that "increasing evidence shows that hospitals and other providers respond in substantive and positive ways to public reporting."

### Physician Offices

Increasingly, there has been an interest in measuring the per-

**Figure 2. Physician Access to Patient-Level Data Within their Record Systems**



As part of its overall quality improvement efforts, CMS launched the Physician Voluntary Reporting Program (PVRP) on January 1, 2006. This new program builds on Medicare's activities to significantly improve the health and function of patients by preventing chronic disease complications, avoiding preventable hospitalizations, and improving the quality of care delivered. Under this voluntary reporting program, physicians who choose to participate will help capture data about the quality of care provided to Medicare beneficiaries on 16 starter measures.

Physician practices will begin to submit data and receive data feedback on 16 core measures in 2006. (See Table 1.) The primary care measures are based on measures that are endorsed by NQF, are part of the Ambulatory Care Quality

formance of individual practitioners on evidence-based standards and outcomes as a way of encouraging and fostering continuous improvement. CMS's Physician Focused Quality Initiative<sup>19</sup> builds upon ongoing CMS strategies and programs in other health care settings in order to: 1) assess the quality of care for key illnesses and clinical conditions that affect many people with Medicare; 2) support clinicians in providing appropriate treatment of the conditions identified; 3) prevent health problems that are avoidable; and 4) investigate the concept of payment for performance.

The CMS Physician Focused Quality Initiative includes several related activities. The Doctor's Office Quality Project (DOQ) is designed to develop and test a comprehensive, integrated approach to measuring the quality of care for chronic disease and preventive services in the doctors' offices. The DOQ measurement set has three components: a clinical performance measurement set, the Physician Practice Connections tool,<sup>20</sup> and a patient experience of care survey. Physician Practice Connections is an evaluation program from the National Committee on Quality Assurance (NCQA) that recognizes physician practices using information systematically to improve the quality of patient care.

Physicians who use such systematic processes are better able to:

- Monitor their patients' medical histories;
- Work with patients over time, not just during office visits;
- Follow up with patients and with other providers;
- Manage populations, not just individuals, using evidence-based care;
- Assist patients to manage their own health better; and
- Avoid medical errors.

In another part of the Physician Focused Quality Initiative—the Doctor's Office Quality—Information Technology (DOQ-IT) project—CMS is working to support the adoption and effective use of information technology by physicians' offices to improve quality and safety for Medicare beneficiaries and all Americans. DOQ-IT seeks to accomplish this by promoting greater availability of high-quality affordable health information technology and by providing assistance to physician offices in adopting and using such technology.

Alliance (AQA) starter set, and will be used by the Quality Improvement Organization (QIO) programs for physician quality improvement in its eighth Scope of Work (8th SOW).

To date, NQF has endorsed approximately 70 more ambulatory care measures in areas of asthma/respiratory illness, bone and joint conditions, diabetes, heart disease, hypertension, medication management, obesity, prenatal care, and prevention/immunization and screening. Ongoing work at NQF seeks endorsement of measures in patient experience with care, efficiency, additional specialty areas, and special settings of care.

In 2004, four organizations—the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), America's Health Insurance Plans (AHIP), and the Agency for Healthcare Research and Quality (AHRQ)—joined together to promote and lead an effort for quickly determining how to most effectively and efficiently improve performance measurement, data aggregation, and reporting in the ambulatory care setting. Originally known as the Ambulatory Care Quality Alliance, the coalition now is known as the AQA Alliance because its mission has broadened to incorporate all areas of physician practice.<sup>21</sup>

AQA has identified a 26-measure "starter set" for primary care physicians, an eight-measure starter set for cardiology, and a 15-measure starter set for cardiac surgery. AQA is sponsoring six pilot projects that combine public and private information to measure and report on physician practice in a meaningful and transparent way for consumers and purchasers of health care. One difficulty for previous efforts to measure and report performance of physicians has been that it is conducted piecemeal. Physicians with patients covered by various public and private programs have their performance measured separately, often against different sets of measures, for each group. The pilot project, supported with funding from the CMS and AHRQ will test approaches to aggregating and reporting data on physician performance.

Engaging individual physicians in performance measurement for quality improvement remains a considerable challenge. The

**Table 2. Hospital Quality Alliance: Quality Measures 2004-2007**

	11/04	4/05	9/05	2006	2007 (EST)
<b>Acute Myocardial Infarction</b>					
• Aspirin at arrival	X				
• Aspirin prescribed at discharge	X				
• ACE inhibitor or ARB for LVSD	X				
• Beta-blocker at arrival	X				
• Thrombolytic agent within 30 minutes of arrival		X			
• PCI within 120 minutes of arrival		X			
• Adult smoking cessation advice/counseling		X			
<b>Heart Failure</b>					
• LVF assessment	X				
• ACE inhibitor or ARB for LVSD	X				
• Discharge instructions		X			
• Adult smoking cessation advice/counseling		X			
<b>Pneumonia</b>					
• Initial antibiotic received within 4 hours of arrival	X				
• Oxygen assessment	X				
• Pneumococcal vaccination status	X				
• Blood culture performed before first antibiotic received		X			
• Adult smoking cessation advice/counseling		X			
• Appropriate initial antibiotic selection			X		
• Influenza vaccination				X	
<b>Surgical Infection Prevention</b>					
• Prophylactic antibiotic received within 1 hour prior to surgical incision			X		
• Prophylactic antibiotics discontinued within 24 hours of surgery end time			X		
<b>Hospital—CAHPS</b>					
• Patient perception of hospital care					X

**Key:**  
 ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; LVSD = left ventricular systolic dysfunction; PCI = percutaneous coronary intervention; LVF = left ventricular dysfunction; CAHPS = Consumer Assessment of Healthcare Providers and Systems

2003 Commonwealth Fund National Survey of Physicians and Quality of Care of 1857 physicians found that only 20% receive any quality-of-care data about the care they provide. Slightly more receive information on patient perception of care. Only 34% of physicians have engaged in efforts to redesign their office or hospital systems to manage patient care better. (See Figure 1.)

Only 44% report that by using their record system it is easy to identify patients with certain diseases or conditions such as diabetes or asthma, and only 15% can identify patients taking certain medications such as warfarin. (See Figure 2.)<sup>22</sup>

Data-driven strategies and programs to stimulate improvements in quality, performance, and accountability use performance measures to track improvements in quality of the health care system. In addition to public reporting and accountability, incentive programs are increasingly being used to leverage improvement.

**Pay for Reporting**

Section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provides a strong incentive for hospitals to submit data for CMS’s Hospital Quality Initiative. The law requires that a hospital that does not submit performance data for the 10 initial measures (see Table 2) will receive a 0.4 percentage point reduction in its annual payment update from CMS for FY 2005, 2006, and 2007.

**Pay for Performance**

Stimulating improvement in performance through payment incentives is a rapidly growing strategy to promote quality improvement. The Leapfrog Group has developed a free access compendium of incentive and reward (also called “pay for performance”) programs aimed at improving health care.<sup>23</sup> The

compendium identifies 34 hospital programs and 53 programs targeting physicians in the United States.

The Leapfrog Hospital Rewards Program (LHRP) provides an opportunity for hospitals to participate in a pay-for-performance program that recognizes and rewards performance on both quality and efficiency, and provides an opportunity for hospitals to be part of a national quality improvement initiative and to receive comparative data about their performance relative to participating hospitals nationwide. The program ties financial incentives to hospital performance on measures already collected and reported through JCAHO and the Leapfrog Hospital Quality and Safety Survey, bringing private purchaser leverage to these nationally standardized measures.

CMS notes that quality of care has improved significantly in hospitals participating in the Premier Hospital Quality Incentive demonstration, a landmark Medicare pay-for-performance demonstration project. Medicare is awarding \$8.85 million to hospitals that showed measurable improvements in care during the first year of the program. Improvement in these evidence-based quality measures is expected to provide long-term savings because of their demonstrated relationship to improved patient outcomes, including fewer complications and fewer hospital readmissions.

In the Premier Demonstration, hospitals in the top 10% for a given condition were given a 2% bonus on their Medicare payments for that condition. Hospitals in the second 10% were given a 1% bonus. Hospitals in the remainder of the top percent got recognition for their quality but no bonus. Composite quality scores were calculated for each demonstration hospital by combining individual measures into an overall quality score for each clinical condition. Preliminary information from the second year of the demonstration shows that quality scores are continuing to improve at the hospitals in the demonstration in each of the five clinical conditions. Of note, the scores of the lowest performing hospitals are improving the most so the variation in performance between the top and the bottom performers is decreasing.<sup>24</sup>

The first pay-for-performance initiative for physicians under the Medicare program began in 2005. The Physician Group Practice (PGP) Demonstration rewards physicians for improving health and quality of services delivered to Medicare fee-for-service beneficiaries. The PGP Demo is mandated by Section 412 of the Benefits Improvement and Protection Act of 2000 and seeks to encourage coordination of Part A and Part B services; promote efficiency through investment in administrative structure and process; and reward physicians for improving health outcomes. A goal of the PGP Demonstration is to align incentives for physician groups to manage the overall care of their patients, especially those with chronic illness who account for a large part of Medicare expenditures.<sup>25</sup>

Primary care physicians must become aware of the serious problem of medical errors, patient safety, and under-performance of proven care processes that plague our health care system. Poor performance includes under-use, over-use, and misuse of proven, evidence-based processes of care that lead to improved outcomes. Public reporting of health care quality and performance

data is changing the dialogue between patients and providers and purchasers. The rapidly growing efforts of all stakeholders, including government and private purchasers of health care services, will profoundly affect the way medicine is practiced and compensated in the next 10 years. Physicians must become more engaged in quality improvement activities in their offices and hospitals. Physicians and providers who choose to resist the inevitable changes occurring in health care compound the problem. Physicians have a responsibility to be part of the solution to make the American health care system as great as it truly can be.

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### Physician CME Questions

6. According to a recent RAND health study, how many patients received recommended, evidence-based care that has been shown to improve health outcomes?
  - A. More than 90%
  - B. Two-thirds
  - C. 54.9%
  - D. Less than half
7. What are the six aims of the health care system?
  - A. To be safe, effective, patient-centered, timely, equitable, and efficient
  - B. To be beneficial, professional, private, accessible, insurance-based, and unregulated
  - C. To save lives, to reduce costs, to live longer, to have acceptable risks, to be affordable, and to be patient-driven
  - D. To be evidence-based, to be error-free, to provide shared decision making, to be coordinated, to be accessible, and to be affordable
8. How many states require at least some reporting of adverse events in licensed health care facilities?

- A. 10
- B. 25
- C. 40
- D. 50

9. According to Mathematica Policy Research, Inc.'s Issue Brief, what percentage of hospitals stated that they had substantial room for improvement on one or more Hospital Compare indicators below the 50th percentile benchmark?
  - A. 60%
  - B. 10%
  - C. 25%
  - D. 40%
10. According to the 2003 Commonwealth Fund National Survey of Physicians and Quality of Care, what percentage of physicians have engaged in efforts to redesign their office or hospital systems to manage patient care better?
  - A. 90%
  - B. 50%
  - C. 34%
  - D. 10%
11. According to the 2003 Commonwealth Fund National Survey of Physicians and Quality of Care, what percentage of physicians receive feedback data on patients' perception and experience with care?
  - A. 90%
  - B. 60%
  - C. 25%
  - D. 5%
12. According to the 2003 Commonwealth Fund National Survey of Physicians and Quality of Care, what percentage of physicians can easily identify patients within their practice who have specific diagnoses or conditions, such as diabetes or asthma, from their record system?
  - A. 92%
  - B. 79%
  - C. 53%
  - D. 44%
13. According to the 2003 Commonwealth Fund National Survey of Physicians and Quality of Care what percentage of physicians can easily identify patients within their practice who are taking certain medications, such as warfarin, from their record system?
  - A. 100%
  - B. 75%
  - C. 50%
  - D. 15%

### CME Answer Key

6. C; 7. A; 8. B; 9. A; 10. C; 11. C; 12. D; 13. D

# PHARMACOLOGY WATCH



Supplement to Clinical Cardiology Alert, Clinical Oncology Alert, Critical Care Alert, Infectious Disease Alert, Internal Medicine Alert, Neurology Alert, OB/GYN Clinical Alert, Primary Care Reports, Travel Medicine Advisor.

## The Safety of Long-Acting Beta Agonist Inhalers

Do long-acting beta agonist inhalers increase the severity of asthma? Yes, according to the results from a large meta-analysis recently published in the *Annals of Internal Medicine*. Pooled data from 19 trials with nearly 34,000 participants found that the long-acting beta agonists salmeterol, formoterol, and eformoterol were associated with higher rates of asthma exacerbations, requiring hospitalization, (odds ratio 2.6 [95% CI, 1.6-4.3]) and life-threatening exacerbations (odds ratio 1.8 [CI, 1.1-2.9]), compared to placebo. In subgroup analyses, the odds ratio for hospitalizations was 1.7 for salmeterol and 3.2 for formoterol. The risk of hospitalization was especially high in children on long-acting beta agonists (odds ratio 3.5 [CI, 1.3-9.3]). The odds ratio for adults was 2.0 (CI 1.1-3.9). Although the rate of death was low, the odds ratio for asthma-related death was 3.5 (CI, 1.3-9.3).

In the largest of the studies included in the meta-analysis, the Salmeterol Multicenter Asthma Research Trial (SMART), in which 26,000 patients were followed for 6 months on salmeterol or placebo, there was a 2-fold increase in life-threatening asthma exacerbations and a 4-fold increase in asthma related deaths. The authors conclude that long-acting beta agonist use increases the risk of hospitalizations due to asthma, life-threatening asthma exacerbations, and asthma-related deaths. The authors also conclude that inhaled corticosteroids cannot adequately protect against the adverse effects of these drugs (*Ann Int Med*. 2006;144:904-912).

An accompanying editorial suggests that physicians should follow current guidelines

which emphasize use of inhaled corticosteroids as the first-line treatment for patients with mild-to-moderate persistent asthma. Only after maximal corticosteroid doses have been reached should long-acting beta agonist be considered (*Ann Int Med*. 2006;144:936-937).

The FDA met one year ago to discuss long-acting beta agonist and required black box warnings on the labeling for these drugs; however, there usage has changed very little in the ensuing year.

### **Treating Chronic Primary Insomnia**

Cognitive behavioral therapy is more effective than zopiclone for the treatment of chronic primary insomnia in older adults, according to a new study from Norway. In a randomized, double-blind, placebo-controlled trial, 46 adults (mean age, 60.8; 22 women) with chronic primary insomnia were randomized to cognitive behavioral therapy, sleep medication with zopiclone 7.5 mg each night, or placebo for 6 weeks. The cognitive behavioral therapy consisted of 6 weekly sessions lasting 50 minutes that covered sleep hygiene education, sleep restriction, stimulus control, cognitive therapy, and progressive relaxation techniques. The main outcome was

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polysomnographic data and sleep diaries, which were used to determine total wake time, total sleep time, sleep efficiency, and slow-wave sleep.

Cognitive behavioral therapy (CBT) resulted in improved short-term and long-term outcomes compared with zopiclone on 3 of 4 outcome measures. CBT improved sleep efficiency from 81.4% to 90.1% at 6-month follow-up compared to a decrease from 82.3% to 81.9% with zopiclone. CBT resulted in better sleep architecture and less time awake during the night. Total sleep time was similar in all 3 treatment groups but, at 6 months, patients receiving CBT had better sleep efficiency than those taking zopiclone. The authors conclude that cognitive behavioral therapy is superior to zopiclone for management of insomnia, both in the short term and long-term. For most outcomes, zopiclone did not differ from placebo (*JAMA*. 2006;295:2851-2858).

Zopiclone is a new generation sleep medication available in Europe. The active isomer of zopiclone has been available in the United States since April 2005 (eszopiclone - Lunesta).

### ***New Breakthrough in Smoking Cessation?***

Varenicline, Pfizer's new smoking cessation drug, is the subject of 3 articles in the July 5 issue of *JAMA*. The drug, which is a partial agonist of the  $\alpha 2$  nicotinic receptor, blocks the action of nicotine but provides a lower level of stimulation of dopamine release to reduce craving and withdrawal symptoms. Two of the 3 articles compared varenicline to bupropion and placebo in combination with behavioral counseling over 12 weeks of treatment. In both studies, varenicline was significantly more effective than placebo or bupropion (*JAMA*. 2006;296:47-55, 56-63). In the third study, 12 more weeks of varenicline was found to be significantly more effective than placebo in maintaining abstinence. This study also found that after 24 weeks of treatment, the benefit of the drug was maintained up to one year (*JAMA*. 2006;296:64-71). An accompanying editorial points out that while the studies of varenicline are promising and the drug represents a new agent with a different mechanism of action, it is not a panacea for smoking cessation, with quit rates still under 50% in these studies (*JAMA*. 2006;296:94-95). These studies could not come at a better time for Pfizer, as the company plans to market the drug within the next few months under the trade name Chantix.

### ***FDA Actions***

The FDA has given Biogen-Idex approval to resume marketing natalizumab (Tysabri) for the treatment of relapsing forms of multiple sclerosis. The monoclonal antibody was initially marketed in November 2004, but was withdrawn four months later, after three patients developed progressive multifocal leukoencephalopathy (PML) in clinical trials. Subsequent trials have not shown any additional cases of PML, but the drug is limited to use in patients who have failed or have not tolerated alternative therapies for multiple sclerosis. The re-approval is a restricted distribution program which includes registration of patients, prescribers, infusion centers, and pharmacies and includes patient education materials. Patients are also required to have a brain MRI prior to initiation of therapy. More information is available at: [www.fda.gov/cder/drug/infopage/natalizumab/default.htm](http://www.fda.gov/cder/drug/infopage/natalizumab/default.htm).

Duramed Pharmaceuticals have received approval to market a new 91 day birth control regimen consisting of 84 days of levonorgestrel 0.15 mg with ethinyl estradiol 0.03 mg, and seven days of ethinyl estradiol 0.01 mg (Seasonique). This product differs from the company's other 91 day birth control regimen (Seasonale) in that it incorporates estradiol rather than placebo for the last seven days in order to reduce bloating and breakthrough bleeding. Both products result in four menstrual periods per year.

The FDA has approved Genentech's ranibizumab (Lucentis) for the treatment of neovascular (wet) age-related macular degeneration (AMD). The drug, which is injected intraocularly, inhibits vascular endothelial growth factor A which is thought to contribute to proliferation, vascular leakage, and angiogenesis. Many ophthalmologists have been using Genentech's other anti-angiogenesis drug bevacizumab (Avastin) for the treatment of AMD, although it is not approved for this indication. Compounded bevacizumab injected intraocularly is approximately \$17 per dose. Ranibizumab marketed as Lucentis is projected to cost approximately \$2000 per dose.

Two former blockbuster drugs are making the switch to generics. Sertraline (Zoloft- Pfizer) will be available later this year in both generic pill and liquid form. In 2005, Zoloft was the most popular antidepressant in the US. The FDA has also approved a generic form of simvastatin (Zocor) Merck & Co.'s enormously popular statin for the treatment of hypercholesterolemia. Generic simvastatin is currently available 5, 10, 20, 40, and 80 mg strengths. ■