A New Era of Measurement

Office physicians may feel that the world is looking over their shoulder every time they examine a patient or write a prescription—and in some ways they're right. Projects to measure and improve the quality of healthcare are proliferating, and they're spreading from hospitals to physicians' offices.

Chapter in Brief:

- *As more physicians become aware of how traditional quality measurement techniques can apply to what they do, they themselves are looking for ways to measure outcomes and do better.*
- *In the 1950s and 1960s, the Japanese used total quality management (TQM) to transform their manufacturing industry. Now the same concepts are being applied to healthcare in this country.*
- *While no one argues about the importance of delivering high-quality care, measuring quality can be tricky. Some worry about "teaching to the test"—changing practices in order to increase scores without significantly improving overall health.*
- *Another concern is how the role of the patient and other external factors will affect quality measures. For example, what responsibility does the physician have for a patient who doesn't follow through with a recommended treatment plan?*
- *Despite its challenges, quality measurement is a concept that's here to stay, experts say. Preliminary results from some practice leaders show it leads to both improved health and lower healthcare costs.*

For the treatment of hypertension

BYSTOLIC.

Significant blood pressure reductions with a low incidence of side effects.[1-3]

Bystolic®
(nebivolol) tablets
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Important Safety Information

Patients being treated with BYSTOLIC should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported following the abrupt cessation of therapy with beta blockers. When discontinuation is planned, the dosage should be reduced gradually over a 1- to 2-week period and the patient carefully monitored.

BYSTOLIC is contraindicated in severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

BYSTOLIC should be used with caution in patients with peripheral vascular disease, thyrotoxicosis, in patients treated concomitantly with beta blockers and calcium channel blockers of the verapamil and diltiazem type (ECG and blood pressure should be monitored), severe renal impairment, and any degree of hepatic impairment or in patients undergoing major surgery. In patients who have compensated congestive heart failure, BYSTOLIC should be administered cautiously. If heart failure worsens, discontinuation of BYSTOLIC should be considered. Caution should also be used in diabetic patients as beta blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia.

Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc). When BYSTOLIC is administered with fluoxetine, significant increases in d-nebivolol may be observed (ie, an 8-fold increase in AUC).

In general, patients with bronchospastic disease should not receive beta blockers.

BYSTOLIC should not be combined with other beta blockers.

The most common adverse events with BYSTOLIC versus placebo (approximately ≥1% and greater than placebo) were headache, fatigue, dizziness, diarrhea, nausea, insomnia, chest pain, bradycardia, dyspnea, rash, and peripheral edema.

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Please see brief summary of Prescribing Information on adjacent page.

References: 1. BYSTOLIC [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2008. **2.** Data on file. Forest Laboratories, Inc. **3.** Saunders E, Smith WB, DeSalvo KB, Sullivan WA. The efficacy and tolerability of nebivolol in hypertensive African American patients. *J Clin Hypertens.* 2007;9:866-875.

44-1014950 01/09

Bystolic®
(nebivolol) tablets
2.5 mg, 5 mg, 10 mg and 20 mg

Rx Only

Brief Summary: For complete details please see full Prescribing Information for BYSTOLIC.

INDICATIONS AND USAGE
BYSTOLIC is indicated for the treatment of hypertension. BYSTOLIC may be used alone or in combination with other antihypertensive agents.

CONTRAINDICATIONS
BYSTOLIC is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), or severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

WARNINGS
Abrupt Cessation of Therapy
Patients with coronary artery disease treated with BYSTOLIC should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with β-blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Even patients without overt coronary artery disease should be cautioned against interruption or abrupt discontinuation of therapy. As with other β-blockers, when discontinuation of BYSTOLIC is planned, patients should be carefully observed and advised to minimize physical activity. BYSTOLIC should be tapered over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, it is recommended that BYSTOLIC be promptly reinstituted, at least temporarily.

Cardiac Failure
Sympathetic stimulation is a vital component supporting circulatory function in the setting of congestive heart failure, and β-blockade may result in further depression of myocardial contractility and precipitate more severe failure. In patients who have compensated congestive heart failure, BYSTOLIC should be administered cautiously. If heart failure worsens, discontinuation of BYSTOLIC should be considered.

Angina and Acute Myocardial Infarction
BYSTOLIC was not studied in patients with angina pectoris or who had a recent MI.

Bronchospastic Diseases
In general, patients with bronchospastic diseases should not receive β-blockers.

Anesthesia and Major Surgery
If BYSTOLIC is to be continued perioperatively, patients should be closely monitored when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used. If β-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

The β-blocking effects of BYSTOLIC can be reversed by β-agonists, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Additionally, difficulty in restarting and maintaining the heartbeat has been reported with β-blockers.

Diabetes and Hypoglycemia
β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nonselective β-blockers may potentiate insulin-induced hypoglycemia and delay recovery of serum glucose levels. It is not known whether nebivolol has these effects. Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be advised about these possibilities and nebivolol should be used with caution.

Thyrotoxicosis
β-blockers may mask clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of β-blockers may be followed by an exacerbation of the symptoms of hyperthyroidism or may precipitate a thyroid storm.

Peripheral Vascular Disease
β-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. Caution should be exercised in these patients.

Non-dihydropyridine Calcium Channel Blockers
Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, caution should be used in patients treated concomitantly with these agents and ECG and blood pressure should be monitored.

PRECAUTIONS
Use with CYP2D6 Inhibitors
Nebivolol exposure increases with inhibition of CYP2D6 (see **Drug Interactions**). The dose of BYSTOLIC may need to be reduced.

Impaired Renal Function
BYSTOLIC should be used with caution in patients with severe renal impairment because of decreased renal clearance. BYSTOLIC has not been studied in patients receiving dialysis.

Impaired Hepatic Function
BYSTOLIC should be used with caution in patients with moderate hepatic impairment because of decreased metabolism. Since BYSTOLIC has not been studied in patients with severe hepatic impairment, BYSTOLIC is contraindicated in this population (see **CLINICAL PHARMACOLOGY, Special Populations** and **DOSAGE AND ADMINISTRATION**).

Risk of Anaphylactic Reactions
While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated challenge either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

In patients with known or suspected pheochromocytoma, an α-blocker should be initiated prior to the use of any β-blocker.

Information for Patients
Patients should be advised to take BYSTOLIC regularly and continuously, as directed. BYSTOLIC can be taken with or without food. If a dose is missed, the patient should take the next scheduled dose only (without doubling it). Patients should not interrupt or discontinue BYSTOLIC without consulting the physician.

Patients should know how they react to this medicine before they operate automobiles, use machinery, or engage in other tasks requiring alertness.

Patients should be advised to consult a physician if any difficulty in breathing occurs, or if they develop signs or symptoms of worsening congestive heart failure such as weight gain or increasing shortness of breath, or excessive bradycardia.

Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be cautioned that β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nebivolol should be used with caution in these patients.

Drug Interactions
BYSTOLIC should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide, are used concurrently. Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

BYSTOLIC should not be combined with other β-blockers. Patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, should be closely monitored, because the added β-blocking action of BYSTOLIC may produce excessive reduction of sympathetic activity. In patients who are receiving BYSTOLIC and clonidine, BYSTOLIC should be discontinued for several days before the gradual tapering of clonidine.

CYP2D6 Inhibitors: Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.) (see **CLINICAL PHARMACOLOGY, Drug Interactions**).

Carcinogenesis, Mutagenesis, Impairment of Fertility
In a two-year study of nebivolol in mice, a statistically significant increase in the incidence of testicular Leydig cell hyperplasia and adenomas was observed at 40 mg/kg/day (5 times the maximally recommended human dose of 40 mg on a mg/m^2 basis). Similar findings were not reported in mice administered doses equal to approximately 0.3 or 1.2 times the maximum recommended human dose. No evidence of a tumorigenic effect was observed in a 24-month study in Wistar rats receiving doses of nebivolol 2.5, 10 and 40 mg/kg/day (equivalent to 0.6, 2.4, and 10 times the maximally recommended human dose). Co-administration of dihydrotestosterone reduced blood LH levels and prevented the Leydig cell hyperplasia, consistent with an indirect LH-mediated effect of nebivolol in mice and not thought to be clinically relevant in man.

A randomized, double-blind, placebo- and active-controlled, parallel-group study in healthy male volunteers was conducted to determine the effects of nebivolol on adrenal function, luteinizing hormone, and testosterone levels. This study demonstrated that 6 weeks of daily dosing with 10 mg of nebivolol had no significant effect on ACTH-stimulated mean serum cortisol $AUC_{0\text{-}120\ min}$, serum LH, or serum total testosterone.

Effects on spermatogenesis were seen in male rats and mice at ≥40 mg/kg/day (10 and 5 times the MRHD, respectively). For rats the effects on spermatogenesis were not reversed and may have worsened during a four-week recovery period. The effects of nebivolol on sperm in mice, however, were partially reversible.

Mutagenesis: Nebivolol was not genotoxic when tested in a battery of assays (Ames, *in vitro* mouse lymphoma $TK^{+/-}$, *in vitro* human peripheral lymphocyte chromosome aberration, *in vivo* Drosophila melanogaster sex-linked recessive lethal, and *in vivo* mouse bone marrow micronucleus tests).

Pregnancy: Teratogenic Effects. Pregnancy Category C:
Decreased pup body weights occurred at 1.25 and 2.5 mg/kg in rats, when exposed during the perinatal period (late gestation, parturition and lactation). At 5 mg/kg and higher doses (1.2 times the MRHD), prolonged gestation, dystocia and reduced maternal care were produced with corresponding increases in late fetal deaths and stillbirths and decreased birth weight, live litter size and pup survival. Insufficient numbers of pups survived at 5 mg/kg to evaluate the offspring for reproductive performance.

In studies in which pregnant rats were given nebivolol during organogenesis, reduced fetal body weights were observed at maternally toxic doses of 20 and 40 mg/kg/day (5 and 10 times the MRHD), and small reversible delays in sternal and thoracic ossification associated with the reduced fetal body weights and a small increase in resorption occurred at 40 mg/kg/day (10 times the MRHD). No adverse effects on embryo-fetal viability, sex, weight or morphology were observed in studies in which nebivolol was given to pregnant rabbits at doses as high as 20 mg/kg/day (10 times the MRHD).

Labor and Delivery

Nebivolol caused prolonged gestation and dystocia at doses ≥5 mg/kg in rats (1.2 times the MRHD). These effects were associated with increased fetal deaths and stillborn pups, and decreased birth weight, live litter size and pup survival rate, events that occurred only when nebivolol was given during the perinatal period (late gestation, parturition and lactation).

No studies of nebivolol were conducted in pregnant women. BYSTOLIC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Studies in rats have shown that nebivolol or its metabolites cross the placental barrier and are excreted in breast milk. It is not known whether this drug is excreted in human milk.

Because of the potential for β-blockers to produce serious adverse reactions in nursing infants, especially bradycardia, BYSTOLIC is not recommended during nursing.

Geriatric Use

Of the 2800 patients in the U.S.-sponsored placebo-controlled clinical hypertension studies, 478 patients were 65 years of age or older. No overall differences in efficacy or in the incidence of adverse events were observed between older and younger patients.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Pediatric studies in ages newborn to 18 years old have not been conducted because of incomplete characterization of developmental toxicity and possible adverse effects on long-term fertility (see **Carcinogenesis, Mutagenesis, and Impairment of Fertility**).

ADVERSE REACTIONS

The data described below reflect worldwide clinical trial exposure to BYSTOLIC in 6545 patients, including 5038 patients treated for hypertension and the remaining 1507 subjects treated for other cardiovascular diseases. Doses ranged from 0.5 mg to 40 mg. Patients received BYSTOLIC for up to 24 months, with over 1900 patients treated for at least 6 months, and approximately 1300 patients for more than one year. In placebo-controlled clinical trials comparing BYSTOLIC with placebo, discontinuation of therapy due to adverse events was reported in 2.8% of patients treated with nebivolol and 2.2% of patients given placebo. The most common adverse events that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%) and bradycardia (0.2%).

Adverse Reactions in Controlled Trials

Table 1 lists treatment-emergent signs and symptoms that were reported in three 12-week, placebo-controlled monotherapy trials involving 1597 hypertensive patients treated with either 5 mg, 10 mg or 20-40 mg of BYSTOLIC and 205 patients given placebo and for which the rate of occurrence was at least 1% of patients treated with nebivolol and greater than the rate for those treated with placebo in at least one dose group.

Table 1. Treatment-Emergent Adverse Events with an Incidence (over 6 weeks) ≥1% in BYSTOLIC-Treated Patients and at a Higher Frequency than Placebo-Treated Patients

	Placebo (n = 205) (%)	Nebivolol 5 mg (n = 459) (%)	Nebivolol 10 mg (n = 461) (%)	Nebivolol 20-40 mg (n = 677) (%)
Headache	6	9	6	7
Fatigue	1	2	2	5
Dizziness	2	2	3	4
Diarrhea	2	2	2	3
Nausea	0	1	3	2
Insomnia	0	1	1	1
Chest pain	0	0	1	1
Bradycardia	0	0	0	1
Dyspnea	0	0	1	1
Rash	0	0	1	1
Peripheral edema	0	1	1	1

Other Adverse Events Observed During Worldwide Clinical Trials

Listed below are other reported adverse events with an incidence of at least 1% in the more than 5300 patients treated with BYSTOLIC in controlled or open-label trials, whether or not attributed to treatment, except for those already appearing in **Table 1**, terms too general to be informative, minor symptoms, or events unlikely to be attributable to drug because they are common in the population. These adverse events were in most cases observed at a similar frequency in placebo-treated patients in the controlled studies.

Body as a Whole: asthenia.

Gastrointestinal System Disorders: abdominal pain

Metabolic and Nutritional Disorders: hypercholesterolemia and hyperuricemia

Nervous System Disorders: paraesthesia

Laboratory

In controlled monotherapy trials, BYSTOLIC was associated with an increase in BUN, uric acid, triglycerides and a decrease in HDL cholesterol and platelet count.

Events Identified from Spontaneous Reports of BYSTOLIC Received Worldwide

The following adverse events have been identified from spontaneous reports of BYSTOLIC received worldwide and have not been listed elsewhere. These adverse events have been chosen for inclusion due to a combination of seriousness, frequency of reporting or potential causal connection to BYSTOLIC. Events common in the population have generally been omitted. Because these events were reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency or establish a causal relationship to BYSTOLIC exposure: abnormal hepatic function (including increased AST, ALT and bilirubin), acute pulmonary edema, acute renal failure, atrioventricular block (both second- and third-degree), bronchospasm, erectile dysfunction, hypersensitivity (including urticaria, allergic vasculitis and rare reports of angioedema), myocardial infarction, pruritus, psoriasis, Raynaud's phenomenon, peripheral ischemia/claudication, somnolence, syncope, thrombocytopenia, various rashes and skin disorders, vertigo, and vomiting.

OVERDOSAGE

In clinical trials and worldwide postmarketing experience there were reports of BYSTOLIC overdose. The most common signs and symptoms associated with BYSTOLIC overdosage are bradycardia and hypotension. Other important adverse events reported with BYSTOLIC overdose include cardiac failure, dizziness, hypoglycemia, fatigue and vomiting. Other adverse events associated with β-blocker overdose include bronchospasm and heart block.

The largest known ingestion of BYSTOLIC worldwide involved a patient who ingested up to 500 mg of BYSTOLIC along with several 100 mg tablets of acetylsalicylic acid in a suicide attempt. The patient experienced hyperhidrosis, pallor, depressed level of consciousness, hypokinesia, hypotension, sinus bradycardia, hypoglycemia, hypokalemia, respiratory failure and vomiting. The patient recovered.

Due to extensive drug binding to plasma proteins, hemodialysis is not expected to enhance nebivolol clearance.

If overdose occurs, BYSTOLIC should be stopped and general supportive and specific symptomatic treatment should be provided. Based on expected pharmacologic actions and recommendations for other β-blockers, the following general measures should be considered when clinically warranted:

Bradycardia: Administer IV atropine. If the response is inadequate, isoproterenol or another agent with positive chronotropic properties may be given cautiously. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary.

Hypotension: Administer IV fluids and vasopressors. Intravenous glucagon may be useful.

Heart Block (second or third degree): Patients should be carefully monitored and treated with isoproterenol infusion. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary.

Congestive Heart Failure: Initiate therapy with digitalis glycoside and diuretics. In certain cases, consideration should be given to the use of inotropic and vasodilating agents.

Bronchospasm: Administer bronchodilator therapy such as a short-acting inhaled β_2-agonist and/or aminophylline.

Hypoglycemia: Administer IV glucose. Repeated doses of IV glucose or possibly glucagon may be required.

In the event of intoxication where there are symptoms of shock, treatment must be continued for a sufficiently long period consistent with the 12-19 hour effective half-life of BYSTOLIC. Supportive measures should continue until clinical stability is achieved.

Call the National Poison Control Center (800-222-1222) for the most current information on β-blocker overdose treatment.

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Concern over the quality of healthcare is everywhere these days as costs spiral out of control and payers—federal and state governments, insurance companies, and employers—seek more bang for their buck.

The United States spends more than twice as much per capita as most other developed countries on healthcare, according to the Organization for Economic Cooperation and Development (OECD), a consortium of 30 industrialized nations. If we were twice as healthy, we could argue that we're getting at least equal value for our money—but we're not. One indication is that the U.S. average life expectancy remains in the bottom third of OECD countries.

A 2007 study by the Commonwealth Fund, a foundation dedicated to health policy, reform, and performance improvement, compared healthcare in the U.S. to that in five other countries: Australia, Canada, Germany, New Zealand, and the United Kingdom. The U.S. ranked last in the overall quality of its care (defined as effective, safe, coordinated, and patient-centered), and last in a number of sub-areas, including safety, coordination of care, access, and efficiency.

While the absence of universal health coverage and disparities of care between the insured and the uninsured explained some of this data, they're not the whole story by any means. The U.S. also lags behind in adoption of information technology in healthcare, and it lacks comprehensive national policies that promote quality improvement for the healthcare system as a whole.

There's clearly change in the air. Rising healthcare costs invite increasing scrutiny on quality and value, from the government as well as traditional payers and consumers themselves, as "consumer-directed healthcare" drives more of the outlays and the decisions their way.

Moreover, as more physicians become aware of how traditional quality measurement techniques can apply to what they do, they themselves are looking for ways to measure outcomes and do better.

"No one likes report cards, but the starting point is to show doctors that they have room for improvement," says Peter Lee, executive director for national policy at the Pacific Business Group on Health, a California employer coalition. "Most think

they're doing just fine until they get performance information and see that 30 percent of their diabetics aren't doing well and 25 percent of their patients don't understand their meds. We've found that docs only want to provide the best care possible."

The Centers for Medicare and Medicaid Services are experimenting with ways to measure quality of care, including the Doctor's Office Quality Project and the Physician Quality Reporting Initiative (PQRI). In a number of states, notably Massachusetts, Minnesota, Wisconsin, Indiana, and California, independent not-for-profit organizations collect and disseminate data on how effectively physicians treat chronic conditions.

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Many insurers pay physicians for improved performance on specific quality targets. Even employers are getting into the act, with efforts like the Bridges to Excellence program, wherein participating physicians can reap thousands of dollars in extra payments annually for earning special certification in diabetes care, cardiac care, or spine care.

It's a bewildering array of players (which we'll sort out in Chapter 2). But to a surprising degree, they're all trying to do the same thing—improve outcomes and reduce costs for the treatment of high-cost chronic conditions like diabetes and congestive heart failure.

"I think there's a lot of noise out there, and it's almost overwhelming to try to wade your way through it; but if you look at what it would take to measure a few things on diabetes, it isn't that difficult," says Bruce Bagley, MD, medical director for quality improvement at the American Academy of Family Physicians. "There's pretty good consensus on the best ways to treat diabetes, coronary disease, asthma—the things that are the bread

"Never" Events

Some things should never happen in medical care, and last year Medicare decided that it wouldn't pay for those things. Other insurers have followed suit. Now hospitals are frequently on the hook for any costs associated with the following:

- Bedsores
- Two kinds of catheter-associated infections
- Air embolism
- Mediastinitis after coronary bypass surgery
- Infusing patients with the wrong blood type
- Leaving objects inside surgery patients
- In-hospital falls

According to a 2007 survey by the Leapfrog Group, an employer coalition, more than 600 hospitals—or 52 percent of those that responded to the survey—have agreed not to bill for these things, acknowledging that, like car mechanics, they shouldn't get paid for making matters worse.

This summer Medicare expanded the "never" event list to include the following:

- Surgical-site infections following certain elective procedures
- Some cases of poor control of blood sugar
- Deep-vein thrombosis/pulmonary embolism following knee or hip replacement

Other "never events" under consideration include the following:

- Legionnaires' disease
- Lung collapse resulting from medical treatment
- Delirium
- Ventilator-associated pneumonia
- Staph infection in the bloodstream
- Disease associated with *Clostridium difficile* infection

and butter of chronic illness care."

Physicians who can take steps to improve their treatment of patients with these conditions—and just as important, can document that treatment and the improvements—could be in a position to reap monetary rewards as the payment system changes to take quality of care into account.

There's a lively debate about whether some of these, especially delirium and *C. difficile*, are 100-percent preventable, and they may never be adopted. But the listing is just one more sign

of changing times, when payers are looking for value for their money and believe they know what value looks like—or what it doesn't look like. The "nonpayment for nonperformance" trend has yet to hit outpatient care, where life-threatening mistakes are less likely and their costs less obvious; but office physicians should prepare themselves for a future when they have to actively justify deviation from defined practice guidelines.

A Short History of Quality Measurement

Two waves began to converge in the mid-1980s and ultimately resulted in the quality measurement tsunami now engulfing U.S. healthcare. One was the concept of total quality management (TQM), a manufacturing philosophy developed during World War II. In the 1950s and 1960s, the Japanese used the approach to transform their manufacturing industry—particularly of automobiles—from a synonym for mediocrity into an international role model for excellence.

TQM and its related acronym CQI (for "continuous quality improvement") held that quality could best be improved by examining not just individual processes or workers, but an entire system, and continually adjusting and refining procedures. Originating in the work of quality gurus W. Edwards Deming and Joseph Juran, the process re-engineering that characterizes TQM became almost a religion in Japan. Among its precepts was that high quality costs less because it reduces waste and failure, and increases overall productivity. By the 1980s Japanese automotive and electronic products were demonstrably superior to their U.S. counterparts, and U.S. manufacturers were on the ropes. They began to embrace the same business philosophy in hopes of getting the same results. In 1987, Congress established the Malcolm Baldrige National Quality Award to recognize U.S. companies that had adopted a systematic approach to achieving the highest possible quality.

About the same time, healthcare costs were starting to become a major issue.

In the previous era of cost-based reimbursement, providers had no pressing financial need to curb the amount of resources used per patient, and hence no motivation to examine that use in order to see whether its effectiveness was borne out by clinical

studies. New drugs, accepted as safe and effective by the Food and Drug Administration, routinely took the place of older drugs and were assumed to be an improvement. Physicians decided what was best for the patient, and they made their decision without much outside scrutiny.

All that began to change as healthcare costs began to increase. Employers turned to managed care, and payers started to play a greater role in determining how health services were used. Medicare's adoption of the prospective payment system in 1983, which linked hospital payments to the diagnosis of the patient and the resources expected to be used (rather than, in most cases, the resources actually used), started pressing providers to limit what they did for patients.

Despite these attempts at controlling costs, an aging population and a profusion of new drugs, technologies, and treatments kept the nation's healthcare bill growing much faster than the inflation rate, and healthcare's share of gross domestic product kept climbing.

Healthcare experts started wondering if Total Quality Management—or something like it—could do for healthcare the same things it had done for industry: improve quality and productivity and cut the costs of failure.

One precept of TQM is that variation is the enemy of quality. Healthcare economists have long decried the level of variation in U.S. healthcare practices. Physicians' techniques and habits are a combination of what they've learned in medical school and their training, what their own experience tells them, and what they learn from reading medical journals and taking CME courses. Since this cluster of experiences is never the same for any two physicians, practice patterns have varied wildly. For example, healthcare economist John Wennberg of Dartmouth College, who has made it his life's work to study unexplained variation in healthcare, analyzed Medicare expenditures for the last two years of a beneficiary's life and found that patients in New Jersey were running up bills twice as high as those in Utah—with no discernable difference in outcomes or the quality of care.

In 1996, the Institute of Medicine launched an initiative to study how to assess and improve the quality of U.S. healthcare.

Small Changes, Big Difference

Many current quality measurement and pay-for-performance projects that involve office physicians are based on chronic conditions that meet the following criteria:

1) Are widespread,
2) Are costly to treat, especially if complications develop,
3) Can be substantially improved by interventions from office physicians,
4) Have treatment guidelines that are recognized as effective, and
5) Vary greatly in how they're actually treated.

According to the 2008 Dartmouth Atlas of Healthcare, whose principal author is noted healthcare economist John Wennberg, severe chronic illnesses highlight the shortcomings of the U.S. healthcare system: "Treating chronic disease is both enormously costly and not particularly effective. Most patients with chronic disease are treated in episodic fashion by multiple physicians, who rarely coordinate the care they deliver. As chronic disease progresses, the amount of care delivered and the costs associated with this care increase dramatically. Patients with chronic illness in their last two years of life account for about 32% of total Medicare spending, with much of it going toward physician and hospital fees (Medicare Part A and Part B) associated with repeated hospitalizations."

Diabetes is probably the single most popular initial focus for quality improvement projects, because both the starting point and the improvements can, for the most part, be easily defined by lab values.

Out of that work came two transformative studies: 1999's *To Err is Human: Building a Safer Healthcare System*, and 2001's *Crossing the Quality Chasm: A New Health System for the 21st Century*. Both were indictments of the notion that U.S. healthcare was the best in the world, and they laid out aims for improvement. The second established the STEEEP principles for defining quality healthcare: It should be safe, timely, effective, equitable, efficient, and patient centered.

Now came the tricky part: figuring out how to measure and improve healthcare quality.

Potential Pitfalls in Quality Measurement

James King, MD, president of the American Academy of Fam-

ily Physicians, has personal experience with using quality measurement and improvement protocols with his seven-physician practice in Selmer, Tenn. The practice has had an electronic health record system (EHR) in place for three years, which he says has made a significant difference in the quality of care it provides.

For example, last year the practice started using a protocol for administering pneumonia vaccine, which it had previously offered only sporadically and in conjunction with flu vaccine in the fall. Under the protocol, all patients who should have pneumonia vaccine were flagged in the EHR to receive it at their next visit, and a standing order gave nurses the freedom to administer the vaccine without first checking with the physician. The vaccination rate skyrocketed, and the practice ran out of vaccine within 48 hours after it started using the protocol—partial evidence of how poorly it had been doing at this measure.

Though an advocate of using practice protocols to improve quality, Dr. King sees several potential pitfalls. His practice is participating in Medicare's PQRI initiative (see Chapter 2), and although it's relatively easy to compile and submit the necessary data with the EHR, he thinks the project may be doomed without one. The 1.5-percent reimbursement incentive is just too low to justify plowing through charts to compile the data. "We're concerned that when the checks are cut, a lot of practices will say it's not worth it," Dr. King says.

In a broader sense, he's concerned that quality measurement projects aren't yet sophisticated enough to improve quality across the board. "We have to watch out for 'teaching to the test,'" Dr. King says. "If you measure something, you'll do better at it, and it can be to the detriment of other things."

Defining and measuring high-quality healthcare is difficult due to the complexity of many medical conditions, the varying levels of illness severity among patients with the same condition, and the many factors that go into treating a given condition—not just the actions of the physician, but those of hospital personnel, lab technicians, and nurses or physician assistants, not to mention the patients themselves. It's tempting to dismiss efforts at measurement as fundamentally flawed and invalid.

The problems include the following:

Agreeing on the measures. Should the physician be meas-

ured on what he does for the patient or on whether his intervention actually helped? Most quality measurement efforts start with "process" measures: Did the diabetic patient receive the appropriate examinations, tests, or medications? The next step is to measure "intermediate" outcomes, such as whether the hemoglobin A1C level is below 9 or 8 or 7. Few quality measurement initiatives have been around long enough to measure ultimate outcome measures, such as a drop in amputations or blindness or added years of non-impaired life.

Blue Cross and Blue Shield of Massachusetts has had a formal pay-for-performance program since 1999, and has struggled with how to gather data and how to use it. "In the first generation, we heard, 'Gee, it's just a lot of claims-based information, and there can be errors in it, and you shouldn't base your incentives on that,'" says Steve Fox, vice president of provider network management for Blue Cross and Blue Shield. "We've worked with physicians to understand better what's going on between the doc and the patient, and to move from process measures—the things that can be found in the claim—to outcomes measures, where we have to look beyond the claim and into the medical record. We've tried to look at both—whether the patient had the test, and what the doctor did with the information, and how much improvement has that patient had over time."

How to attribute care. In any effort to measure healthcare quality, it's tempting to assume that the system is much tidier

and more systematic than it actually is. A patient with a chronic illness often needs the attentions of several providers; and while the primary care physician may write the order, he or she has little control over what happens next.

"The hard part is that we're held accountable for diabetic patients' having dilated eye exams, but they get a referral and then they don't go," says family physician Erica Swegler, MD, North Hills Family Medicine Center, Keller, Tex. "Or they do go, and we don't get a letter back that they did. It's the same thing with flu shots. It's great that they can get them at the grocery store, because it makes it more likely that they will. But the grocery store doesn't send us any documentation."

The role of the patient. What if you tell a patient to get a retinal exam or a mammogram or to quit smoking? Have you delivered high-quality care if the patient doesn't follow through? How could you possibly have done more?

The system has to be careful not to punish physicians for the inevitable shortcomings of their patients, says James Rohack, MD, a senior staff cardiologist at Scott and White Clinic, Temple, Tex., and president-elect of the American Medical Association. "The chronically ill patient who's most vulnerable and challenging is one who's noncompliant," he says. "You may practice in the inner city where transportation isn't good, there are a lot of single parents, and there's no access to good nutrition. So your patient is overweight, his blood pressure is up, his diabetes is out of control, and he can't afford his medications." If physicians are penalized because such patients aren't doing well, they are more likely than ever to choose not to practice in such unpromising environments.

Flawed data. Many health insurers rely on their claims data to measure the quality of office care even though the claim form was designed for payment and not quality measurement.

Marc Overhage, MD, executive director of the Indiana Health Information Exchange, is also an internist by training. He's associated with the Regenstrief Institute in Indianapolis, which has had electronic medical records since the early 1980s and uses its internal data in many quality improvement initiatives. "I've gotten reports from Medicare, Medicaid, United Healthcare, and they all went in the trash, not because I don't care

about doing a good job, but because they were all looking at different things, measuring them differently, and having incomplete data," he says. "It's hard to know what to do with them."

Even taking the data directly from patient charts has its pitfalls, says Peter Lee of the Pacific Business Group on Health. "It's not a matter of either-or between claims data and chart review," he says. "All data has flaws, whether it's electronic data from claims or pharmacy or labs, or charts. Virtually every source of data to do performance reports wasn't designed for that." He advocates installing stringent audit processes, regardless of the data source, and making sure that outcome measures are risk adjusted to reflect differences in patient populations.

"There must be no black boxes," Mr. Lee says. "Whoever is being measured needs to understand what the measures are."

A Glimpse of the Future

Intermountain Healthcare, an integrated delivery system based in Salt Lake City, gives a glimpse of the future of quality measurement. Under the direction of Brent James, MD, a legend in healthcare quality circles, the system's Institute for Healthcare Delivery Research has moved the entire system, and with it a significant subset of U.S. healthcare providers, toward evidence-based medicine by applying practice guidelines and quality measurement techniques to everything from prostatectomies to the treatment of depression. The institute provides continuing education courses for any provider interested in learning more about its methods.

Dr. James, who also serves as Intermountain's vice president for medical research, got some of his early quality measurement training under industrial quality guru W. Edwards Deming. He has devoted much of his career to reducing unexplained varia-

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tion in medical care. Under his leadership, Intermountain physicians have accomplished many milestones. For example, they've reduced elective induced labors at earlier than 39 weeks gestation from nearly 30 percent in 1999 to less than 4 percent in 2005, and reduced the incidence of ventilator-associated pneumonia (already relatively low) by 55 percent between 2004 and 2006. Intermountain is routinely on lists of American's top quality healthcare providers.

Dr. James believes that physicians only need to be persuaded that the evidence favors certain courses of treatment over others. "A lot of people talk about accountability, but I think it's almost entirely internal," he says. "When you show physicians how they stack up, and a clear road ahead, you don't have to motivate them." The trick is to align the financial incentives so that they

The Four Cornerstones

The federal government pays 44 percent of the nation's hospital bills and almost 30 percent of physician office bills. Like the Queen Mary, it moves slowly; but all other healthcare payers and players are drawn along in its wake.

On August 22, 2006, President Bush issued an Executive Order with the title "Promoting Quality and Efficient Healthcare in Federal Government Administered or Sponsored Healthcare Programs." The purpose is to steer Medicare and Medicaid and their contractors toward improvement in the "four cornerstones" of healthcare quality. Here are the four, with the government's explanations of what they entail:

1. Interoperable Health Information Technology (Health IT Standards): Interoperable health information technology has the potential to create greater efficiency in healthcare delivery. Significant progress has been made to develop standards that enable health information systems to communicate and exchange data quickly and securely to protect patient privacy. Additional standards must be developed, and all healthcare systems and products should meet these standards as they are acquired or upgraded.

2. Measure and Publish Quality Information (Quality Standards): To make confident decisions about their healthcare providers and treatment options, consumers need quality-of-care information. Similarly, this information is important to providers

match up with those professional motivations, although Dr. James points out he's seen many physicians make personal financial sacrifices for their patients if they believe it's in the patient's best interest.

A recent Intermountain initiative on treating childhood depression shows how their methods work. Pediatricians at Intermountain were frustrated at trying to treat children who came in over and over with somatic complaints that their doctors believed were caused by underlying depression. Health plans would pay for treating the physical symptoms, but not for treating depression, which fell under the mental health category. Pediatrician Wayne Cannon, MD, argued that if the children were properly diagnosed and treated for depression, their total cost of care would drop: psychiatric treatment costs would be

who are interested in improving the quality of care they deliver. Quality measurement should be based on measures that are developed through consensus-based processes involving all stakeholders, such as the processes used by the AQA (multi-stakeholder group focused on physician quality measurement) and the Hospital Quality Alliance.

3. **Measure and Publish Price Information (Price Standards):** To make confident decisions about their healthcare providers and treatment options, consumers also need price information. Efforts are underway to develop uniform approaches to measuring and reporting price information for the benefit of consumers. In addition, strategies are being developed to measure the overall cost of services for common episodes of care and the treatment of common chronic diseases.

4. **Promote Quality and Efficiency of Care (Incentives):** All parties— providers, patients, insurance plans, and payers—should participate in arrangements that reward both those who offer and those who purchase high-quality, competitively priced healthcare. Such arrangements may include implementation of performance-based reimbursement for providers or offering lower premiums for patients who take a greater role in controlling costs (such as through consumer-directed health plans).

Source: U.S. Dept. Of Health and Human Services, http://www.hhs.gov/valuedriven/fourcornerstones/index.html.

somewhat higher, but medical-surgical costs should shrink more than enough to offset that increase.

Intermountain experimented with a new model of care. Front-line staff at one clinic were trained to identify possible cases of depression with a short questionnaire. Patients so identified were treated first by the primary care physician, with patient education and medication. If those measures were ineffective, they were sent on for counseling with an on-site psychologist (a big expense for the clinic if reimbursement isn't there, Dr. James observes); and if that didn't work, they received two sessions a week with an off-site psychiatrist. Progress was measured by whether the patients were functioning better in their daily lives.

Using the same cost analysis model that a health plan would use, the researchers discovered that while detection rates had increased by 25 percent, the patients were being treated more effectively. The cost of treating a patient's depression went up $900 a year on average, but the average total cost of care for the same patient went down about five percent because of the drop in unnecessary medical treatment. Intermountain is now rolling out this care model to all its primary care providers, and Dr. James is optimistic that insurers will pay for it.

Dr. James says the key to identifying and adopting best practices is to be part of an organized system of care delivery either as an employee or as an affiliate. "Keep your eye open for that consolidator," Dr. James advises. "It will make you all the more successful on behalf of your patients; and in the long haul, that's how you'll protect your practice income."

Here to Stay

One thing seems evident: Quality measurement is here to stay, and the trend toward paying providers based on their quality of care will accelerate in the coming years. There's already evidence that measuring quality can improve it.

"Not only are many measures getting better, but for the ones we're reporting on, the gap between highest and lowest is closing," says Barbra Rabson, executive director of Massachusetts Health Quality Partners, which analyzes and disseminates claims data on many of the state's physician groups. "Public

information gets the attention of physician groups, and they can really focus," she continues. I can't say the improvement is because we've been reporting, but we know it's happening because we are measuring."

To come out ahead in the new world of quality measurement, it's important to understand what's being measured, how to provide data, and when and how to change what you're doing. In the process you won't just get better report cards—you may significantly improve your patients' lives.

The Patient Charter

If payers in your area publish physician rankings that seem capricious, skewed toward low-cost providers, or just impossible to understand, take heart. Change may be on the way.

To make sure that published physician performance information is consistent and that quality of care gets into every equation, a coalition of payers, employers, labor organizations, and consumer groups announced an agreement in April on a national set of principles to guide how physician performance is reported to consumers. The so-called "Patient Charter for Physician Performance Measurement, Reporting, and Tiering Programs" calls for relying on measures endorsed by the National Quality Forum (see Chapter 2), or, if NQF measures aren't available in a given area, those endorsed by the National Committee for Quality Assurance (NCQA) or the Joint Commission. It also specifies that physicians should be actively involved in deciding what constitutes the "grading scale" for assessing performance under the chosen measures, and says that the measures should be transparent and easily understood by all parties.

While the Charter hasn't yet yielded any concrete results, it's endorsed by many influential parties, including AARP, AFL-CIO, the Leapfrog Group, the National Business Coalition on Health, the National Partnership for Women and Families, and the Pacific Business Group on Health. Physician groups signing on include the American College of Physicians, the American Academy of Family Physicians, the American Medical Association, the American College of Cardiology, and the American College of Surgeons. Supporting insurers include Aetna, Cigna, UnitedHealthcare, and WellPoint, as well as the trade group AHIP.

Source: http://healthcaredisclosure.org/activities/charter/.