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Three Obstacles Hinder Efforts to Improve Quality

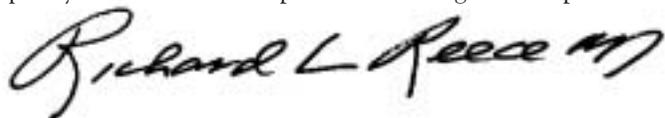
Since the Institute of Medicine published its report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, three years ago, the IOM has been working to identify ways that will most improve the care the health system delivers. Earlier this year, the IOM reported that five methods are being used to improve care quality: quality measurement, information and communications technology, care coordination, patient self-management support, provider financial incentives, and community coalition building. The IOM is analyzing how these methods are being used to improve care for patients with asthma, depression, diabetes, and heart failure, and to improve pain control for patients with advanced cancer.

The IOM has found that three main obstacles stand in the way of nationwide quality improvement. The first obstacle is inertia, or resistance to change. The U.S. health system is based on quick, reactive, episodic, and compartmentalized responses to acute disease. The patients the IOM is studying have chronic ailments that require providers who can deliver methodical, measured, and coordinated care and who can treat patients outside of traditional office and hospital settings. Most of the management of these patients requires coordination of care among multiple allied professionals and enlightened self-care by patients.

The second obstacle is a lack of financial incentives for health professionals. Most physicians and hospitals are not reimbursed adequately to care for patients outside of traditional settings. Reimbursement based on improved outcomes sounds like a great idea, but it requires hospitals and doctors to invest in costly electronic medical record systems. Without this technology, health systems cannot deploy performance measures and gather data, experts say, because doing so is simply unaffordable.

The third obstacle is the slowness in shifting from a provider-centered to a patient-centered system. Donald Berwick, MD, president and CEO of the Institute for Healthcare Improvement, in Boston, contends that a patient-centered system requires that patients be seen on the day they call for an appointment, that every hospital have open visiting hours, and that patients be allowed to shop online and compare providers. A patient-centered system, Berwick says, also requires standardized and transparent records, patient-owned medical records, electronic prescribing, electronic medical records in every physician's office, and electronic health records in every patient's hand.

None of these obstacles will be overcome quickly. Even so, we must make every effort to do just that, because what is truly at stake behind improving the quality of care is whether patients live longer or die prematurely.



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Initiatives Should Focus on Physician-Patient Relationship

Many physician consultants hail the growth of pay-for-performance initiatives, saying that such initiatives help to focus attention on improving quality of care. But some experts who have studied the business case for quality care argue that these initiatives may be missing the big picture. Instead of focusing on pay for performance, they argue, all quality initiatives should be based on recognition of and support for the physician-patient relationship.

“The most significant reason that quality health care has lagged in America is the failure of systems to acknowledge the critical and unique role physicians play in making quality initiatives real,” says Alice Gosfield, a health care attorney in Philadelphia. “Current discussions about pay for performance miss some essential points, particularly whether the efforts necessary to earn the additional money are sufficiently rewarded by the amount of payment received.” Gosfield, a former chairman of the board of directors of the National Committee for Quality Assurance (NCQA) in Washington, D.C., has written extensively about enhancing the quality of care through incentive systems.

Net Results

Under most current pay-for-performance (called P4P) initiatives, hospitals and physicians are paid an additional sum of money for rendering services that further quality, Gosfield says. Yet the net result of most P4P initiatives is that they will have little effect on some of the most difficult problems the health care system faces, particularly the problem of overuse of services, says James Reinertsen, MD, a rheumatologist and CEO of The Reinertsen Group, a consulting firm in Alta, Wyo. He is also a senior fellow in the Institute for Healthcare Improvement, in Boston. Reinertsen and Gosfield have collaborated on

several studies and have cowritten articles about the physician’s role in providing quality care.

P4P payment methodologies, including those of the federal Centers for Medicare & Medicaid Services (CMS), fall into one of three categories, Gosfield says. Under one category, the programs pay a bonus when a physician meets a certain threshold of behavior. For example, a physician who meets the NCQA Diabetes

with a control group, such as the Medicare Physician Group Practice Demonstration.

“There’s no question that in P4P, where additional payments are made on top of other monies they are already receiving, physicians will experience increased revenue in return for some measure of demonstrated quality,” says Gosfield in “The Doctor-Patient Relationship as the Business Case for Quality: Doing

The result of most P4P initiatives is that they have little effect on such difficult problems as overuse of services, says James Reinertsen, MD, of The Reinertsen Group.

Physician Recognition Program standards gets paid \$100 per diabetic patient per year in a program called Bridges to Excellence.

In the second category, a pool of providers is arrayed normatively and each one is compared against the others. The best performers get paid a premium based on their relative status with respect to the performance of others, as in the newly formed CMS Premier Hospital Quality Incentive Demonstration Project.

In the third category, physicians or other providers are offered a potential pool of money that they can receive only if they meet certain thresholds and provide savings when compared

Well by Doing Right,” an article published in the spring issue of the *Journal of Health Law*. “The real question, however, is whether the efforts necessary to earn the additional money are sufficiently rewarded by the amount of payment received.”

Regulatory Environment

Many P4P programs make payments based on data produced by health plans, Gosfield explains. But reports show that physicians are so concerned about inaccuracies in the data that health plans produce (and upon which their bonuses are based) that they have their staff check the data. In other words, physicians are expect-

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Five Principles for Improving Quality

One way to improve the quality of health care is to adopt five principles that would improve how care is delivered, says Alice Gosfield, a health law attorney in Philadelphia. Each principle is important for organizations seeking to foster quality improvement in the health care system, she says. “Bringing all five of these principles together would revolutionize health care delivery in this country,” she adds. Those five principles are

1. Standardizing, or encouraging the use of, evidence-based medicine, as well as standardizing forms for documentation.
2. Simplifying: “The wide variety of financial incentives, contractual obligations, documentation requirements, utilization review systems, medical management programs in managed care entities, and administrative burdens that have no relevance to the delivery of evidence-based medicine should be removed from the physician practice environment,” says Gosfield.
3. Making all physician activities clinically relevant, including payment methodologies, documentation requirements, design of information technology support mechanisms, manpower resource planning, and recruiting.
4. Engaging the patient (in treatment choices for example).
5. Fixing public accountability at the locus of control.

—MS

(Continued from page 3)

ed to respond to the incentives of the payment systems in order to render quality services to their patients, but these incentives do not necessarily produce the desired result, Gosfield notes.

In fact, most approaches to quality improvement occur in a regulatory and punitive environment, Gosfield charges. “Quality is now unequivocally a fraud and abuse issue and is increasingly a focus of enforcement attention,” she says in her article. The Stark and federal antikickback laws and regulations can be viewed as quality related because they address the issue of utilization, she adds. Many states have laws that mirror the federal antireferral laws.

“Despite the detail and broad sweep of these quality-focused regulations, they have not improved health care,” Gosfield continues. “They have not engaged physicians or persuaded

them that quality initiatives merit their attention. Physicians see most of these penalties, regulations, sanctions, and disincentives as enormous hassles aimed at the miscreant few among whom they do not number themselves. Indeed, if these laws and programs had engaged physicians, we would not be considering today whether there is a business case for quality.”

Straight Talk

Increasingly, health plan CEOs are aware of the strong business case that exists for improving the quality of health care, say Gosfield and Reinertsen. Earlier this year, Reinertsen coauthored a report by Ernst & Young, CPAs in New York, *Straight Talk About Clinical Quality From Health Care CEOs*. The report concluded that health care leaders are clear that clinical quality has moved

to the forefront of their organizational strategic agendas. “In many instances, these organizations have always had a significant focus on quality, but it has sharpened and intensified, at least as seen by the CEOs, during the past year or two,” the report says.

Ernst & Young conducted a one-day discussion that included about two dozen health plan CEOs. Although pay-for-performance models have received a lot of attention, the CEOs had several concerns, according to the report. One of their primary concerns was that the focus of virtually all P4P programs is on the subset of problems characterized by underuse of health care services (for example, foot exams for patients with diabetes, appropriate medications for congestive heart failure, and various preventive services).

The participants in the discussion viewed the problems of overuse and misuse as more difficult to address. It is extremely difficult to pay physicians bonuses for not delivering a service, for example, even if the current practice of overuse is clearly harmful. On the issue of misuse, current measurement methods for determining that a procedure or treatment was delivered badly are underdeveloped, says the report.

Cost of Bonuses

As bonuses are paid out in P4P programs, the payments for all other services hospitals and doctors provide may have to be reduced. The CEOs echoed Gosfield’s concern that there are considerable costs associated with achieving the bonuses, ranging from investment in quality infrastructure for training and information systems to the staffing and supply costs of delivering services not now being delivered. For all those reasons, the CEOs concluded that the effect on current P4P programs is on the margins of health care delivery.

"The net effect of the overuse focus is that these pay-for-performance models will likely have little influence on some of the biggest quality challenges we face," concludes the Ernst & Young report.

To address these concerns, Gosfield and Reinertsen have proposed a model that they call the "unified field theory applied." The core of their UFT-A model lies in improving quality by enhancing the ability of physicians to spend more and better time with patients. Gosfield and Reinertsen have established a Web site that explains their efforts in more detail (at www.uft-a.com).

Applying Science

"The fundamental policy challenges to improve quality are to eliminate those aspects of the current environment that steal touch time from the doctor-patient relationship and to support those measures that enhance optimized time and touch," Gosfield says. "Time and touch are critical to a physician's approach and treatment of a patient. They affect a physician's ability to grasp the subtleties in each patient's situation and are significant when fashioning an effective approach to the patient. Time and touch are essential to optimal communication, which implements appropriate treatment. To customize the application of science, the physician must listen, explain, examine, comfort, teach, treat, perform procedures or surgery, and otherwise address the specific and variable needs of the individual patient. This touch time is what defines the art of medicine."

In working with physicians, Gosfield says she found that they were angry "all the time about everything." In fact, they were so angry that they were unable to help themselves, she adds. "Physician anxiety does not turn on a perceived loss of autonomy alone,"

Nine Elements to Improve Care

The "locus of control" in the health care system is at the heart of the physician-patient relationship, says Alice Gosfield, a health law attorney in Philadelphia. During a patient visit, physicians are capable of controlling only two fundamental aspects of care, she says: the application of the science that is appropriate to their patient's needs and the quality of their doctor-patient interactions. Seeking to improve the quality of the relationship between physicians and patients, Gosfield and James Reinertsen, MD, identified the following nine elements that can enhance these two aspects of care:

1. Payers and physicians should select clinical practice guidelines.
2. Clinical practice guidelines should be translated into applicable ICD-9 and CPT codes. Payers should foster the use of clinically relevant documentation systems that support the medical necessity of the services provided and enumerate the care actually provided to each patient.
3. Note standards should be in easily accessible templates. Claims reporting can be standardized into documentation templates that reflect evidence-based medicine and that save time by virtue of standardization.
4. The full pathway of care, not just care administered by physicians, should be documented. Considering the full pathway implied by guidelines can add greater strength and scope to its application.
5. Appropriate deviation should be accommodated. This element addresses the frequent resistance to the application of guidelines as cookbook medicine, Gosfield says. For example, the typical patient with congestive heart failure may also have diabetes and hypertension. A physician might follow one preferred regimen in the absence of those exacerbating factors, but would have to follow a different branch if those other conditions exist.
6. Patients should be engaged.
7. Services should be priced according to an analysis of the cost of providing those services. This step can aid in constructing a budget for delivering care, says Gosfield.
8. Compliance should be measured.
9. Analyze and refine.

—MS

Gosfield recounts. "Rather, there is a very complex confluence of disparate policy, legal, and market forces that whipsaw physicians in their daily lives, to which they respond as if these forces are unrelated to each other. What was needed, I thought, was a unitary platform upon which more of their activities could be based."

To improve quality systemwide, physicians must play an aggressive role in promoting quality, concludes

Reinertsen. "The early efforts to channel the attention of physicians to the quality of care are transitional models," he says. "Physicians must work with payers and purchasers on payment systems that drive a comprehensive agenda and make a better business case for high quality."

—Reported and written by Martin Sipkoff, in Gettysburg, Pa. More information on quality improvement is available on our Web site (see page 16).

AF Guidelines: New Research Influences Practice and Revisions

Clinical research since the 2001 publication of the ACC/AHA/ESC *Guidelines for the Management of Patients With Atrial Fibrillation* has generated interesting implications for treatment. This research has built on existing guideline recommendations and is driving upcoming revisions to the guidelines.

The guidelines were developed jointly by the American College of Cardiology in Bethesda, Md.; the American Heart Association in Dallas; and the European Society of Cardiology, in Sophia Antipolis, France. The executive summary was published in the October 2001 issue of the *Journal of the American College of Cardiology*. The guideline development committee plans to revise the guidelines based on new research findings; committee members began meeting in August.

While it is premature to predict the forthcoming revisions, Eric Prystowsky, MD, a committee member and a widely known expert in AF, says certain topics are likely to be reviewed.

Revisions Considered

“We need to consider recent studies on the safety and efficacy of new antiarrhythmic drug therapies,” Prystowsky offers. “We will also revisit the primary cure of atrial fibrillation with radiofrequency ablation, a tech-

on anticoagulation strategies, especially thrombin inhibitors. We need to update the sections dealing with rate and rhythm control with new study findings that confirm that both approaches are legitimate.”

Prystowsky is an electrophysiologist with The Care Group, a practice of more than 125 physicians in Indianapolis. He is also editor in chief of both the *Journal of Cardiovascular Electrophysiology* and *MedscapeCRM.com*, and past president of the Heart Rhythm Society, in Natick, Mass.

“New drugs are now nearing the completion of their trials,” notes James Reiffel, MD, a professor of clinical medicine at Columbia University in New York and an expert in the AF field. “If data are available in a published form before the guidelines are finalized, these findings will be referenced and may imply the role for other drugs in the treatment of atrial fibrillation.” The guidelines will undoubtedly be revised again and again, he adds. “The frequency of

risk of stroke. Ongoing research has confirmed and even amplified the importance of anticoagulation therapy in these patients.

AFFIRM Trial Results

For example, the Atrial Fibrillation Follow-Up Investigation of Rhythm Management (AFFIRM) trial results have emphasized the importance of pairing anticoagulation therapy with treatment for AF. Results indicated that adverse events were lower in AF patients who were on anticoagulation medication, while the majority of strokes occurred in participants in whom anticoagulation therapy had been stopped or in whom the dosage was subtherapeutic.

“The AFFIRM trial compared the incidence of stroke in patients treated with a rhythm control or a rate control strategy and found that there was no significant difference in stroke incidence; in fact, stroke incidence was slightly greater in the rhythm control group,” notes Albert Waldo, MD, a cardiac electrophysiologist and the Walter H. Pritchard Professor of Cardiology and Professor of Medicine at Case Western Reserve University in Cleveland. “AFFIRM researchers found that 57% of the strokes in the rhythm control group occurred in patients who were not taking an oral anticoagulant. Furthermore, 22% of strokes occurred in patients who were taking warfarin, but whose international normalized ratio (INR) was less

The guideline development committee began meeting earlier this year to revise the guidelines.

nique that was in its early stages of development when the 2001 guidelines were written. In particular, we should examine data on the long-term risk of heart failure in the ablate and pace strategy. There are new data

updates will be determined by new research findings,” he says.

The 2001 guidelines emphasized the importance of anticoagulation therapy for patients with AF, a condition that significantly increases the

than 2.0, meaning that they were not achieving the therapeutic range.”

“This very meaningful finding from AFFIRM should be a wake-up call for physicians who treat patients with atrial fibrillation,” asserts Andrew E. Epstein, MD, professor of medicine in the Division of Cardiovascular Disease at the University of Alabama at Birmingham and an expert in AF. “Physicians are starting to absorb the message that patients who are at high risk of stroke should be on anticoagulation therapy indefinitely, even if the AF symptoms disappear.”

The implications are especially important for patients with risk factors for stroke, Waldo notes. Atrial fibrillation patients are often prescribed an oral anticoagulant prophylactically to prevent stroke. Physicians may suggest that patients who achieve sinus rhythm may discontinue the anticoagulant therapy, believing that they are no longer at risk for stroke because the AF is no longer present.

Asymptomatic Patients

Discontinuing anticoagulation therapy upon restoration of sinus rhythm is not appropriate for two reasons. “First, if patients who are minimally symptomatic or asymptomatic are on medications that slow the ventricular response in atrial fibrillation, they may not know that they are having recurrences of atrial fibrillation,” Epstein points out. In fact, he notes that of AFFIRM participants in whom stroke occurred, only 32% in the rhythm-control group and 69% in the rate-control group had concurrent AF. “When patients tell their physician that they feel fine, the absence of discernable palpitations is interpreted as the absence of AF, when, in fact, the patients have asymptomatic atrial fibrillation and remain at a high risk for stroke.”

Second, other factors besides the fibrillation may be responsible for an increased risk of stroke in AF patients. “Evidence exists that endothelial changes in the atria increase thrombogenicity,” Epstein states, adding that other risk factors in patients with AF include existing cerebrovascular disease, an underlying predisposition to a stroke by itself.

The most recent study supporting the continuation of anticoagulation therapy in asymptomatic AF patients was published in the Jan. 7 issue of the

The 2001 guidelines emphasized the importance of anticoagulation therapy for patients with AF.

Journal of the American College of Cardiology. The investigators, led by Carsten Israel, MD, tracked 110 highly symptomatic AF patients who were monitored constantly via an implantable device (a pacemaker with dedicated functions for AF detection and electrogram storage). The study found that of patients with a history of AF in whom AF recurred, the recurring AF was asymptomatic in 38%, and in these patients, the episode lasted longer than 48 hours. Among study participants, 16% developed asymptomatic AF that lasted more than 48 hours even after they had been documented to be in sinus rhythm for at least three months.

Given this array of evidence, basing a diagnosis of AF solely on the presence of fibrillation symptoms in a patient is “unfounded,” Epstein says.

“I believe that the new ACC/AHA/ESC atrial fibrillation guidelines will very clearly state that once there is an indication to take an oral anticoagulant in the presence of AF, that oral anticoagulant should be continued for the foreseeable future, even if sinus rhythm seems to be maintained by drug therapy,” notes

Waldo.

An additional point to highlight is that patients at high risk of stroke should also be prescribed a beta blocker, Epstein comments. “Beta blockers have some degree of antiarrhythmic efficacy, especially when combined with a primary antiarrhythmic drug,” he explains.

“In addition, a beta blocker should always be used in conjunction with a class IC drug to prevent rapid conduction through the atrioventricular (AV) node if atrial flutter is caused by

this class of drugs as a proarrhythmic effect,” Epstein emphasizes.

Importance of Sinus Rhythm

Recent research has also highlighted the survival benefit of sinus rhythm. Epstein co-authored a study published in the March 30 issue of *Circulation* that analyzed the relationships in the AFFIRM study among sinus rhythm, treatment, and survival. The study examined whether the presence of sinus rhythm itself, independent of the treatment strategy, is associated with improved outcomes.

Study results indicated that the presence of sinus rhythm is associated with a lower risk of mortality (although whether sinus rhythm is a determinant of survival or a marker for other factors that determine survival remains unclear). However, currently available antiarrhythmic drugs were not associated with improved survival.

“The finding that sinus rhythm is important, but the beneficial effects of antiarrhythmic drugs are offset by associated adverse events indicates the need for new agents that restore and maintain sinus rhythm but are

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safer,” notes Epstein, adding that the study also revealed that anticoagulation therapy reduced mortality risk by 50%, indicating that pairing anticoagulation with a safe antiarrhythmic could significantly improve outcomes.

“Obviously when we use antiarrhythmic drugs, we are concerned that the benefit of these drugs could be outweighed by their toxicity,” says Steven Singh, MD, chief of cardiology at the Veterans Affairs Medical Center in Washington, D.C., and professor of medicine and pharmacology at Georgetown University. “Some studies have shown that these drugs are good at suppressing the arrhythmia but negatively impact patients’ health overall.”

While antiarrhythmic drugs do have side effects, the excess mortality of the rhythm control patients in the AFFIRM study was not due to sudden arrhythmic death. Singh points out that an analysis of cause-specific mortality in the AFFIRM study, led by Jonathan Steinberg, MD, and pub-

as a call to action to find safer drugs.”

New Techniques

Radiofrequency ablation to treat atrial fibrillation is an evolving technique in which radiofrequency energy is transmitted to the heart via a catheter to cauterize heart tissue responsible for triggering or maintaining arrhythmia. This technique relieves symptoms and improves functional capacity in patients with atrial fibrillation, but when it is used to destroy the AV node, a permanent pacemaker must be implanted. Catheter ablation is also being used to isolate the pulmonary veins that are often the source of ectopic beats that trigger paroxysmal atrial fibrillation.

New catheter ablation techniques are being used to improve outcomes in patients with atrial fibrillation. The July 19, 2004, issue of *The Medical Letter* reported: “One new approach has been to supplement pulmonary vein isolation with additional ablation lines. A second has been to

fibrillation symptoms six months after the procedures.

“The implications are significant, including the consideration that patients who are cured do not need to continue with anticoagulation therapy,” Waldo notes. But he cautions that long-term data are not yet available, since the technique is relatively new. “We will not know the outcomes of these patients for several years,” he says. The most common complication of left atrial catheter ablation is atrial flutter; more serious complications include atrial perforation and cardiac tamponade, thromboembolism, and atrio-esophageal fistula.

According to *The Medical Letter*, given the unknown long-term results and possible serious complications, new catheter ablation techniques cannot be justified as a first-line therapy in most patients. For now, the most appropriate indication is drug-refractory atrial fibrillation in which quality of life is impaired; patients who cannot tolerate anticoagulation therapy or who do not want to be anticoagulated over the long term may also be considered for radiofrequency ablation.

Although Waldo does not speculate on what the new ACC/AHA/ESC guidelines will recommend regarding new catheter ablation techniques, he does say that cardiologists and electrophysiologists consider the new developments to be important. “We should be optimistic that continued improvements in ablative techniques combined with still better understanding of the mechanisms of atrial fibrillation will result in predictably effective and safe application of this treatment in appropriate patients,” Waldo says.

—Reported and written by Deborah J. Neveleff, in North Potomac, Md. More information on quality improvement is available on our Web site (see page 16).

Researchers are reluctant to speculate on what the new ACC/AHA/ESC guidelines will recommend.

lished in the April issue of *Circulation*, demonstrated that both the rate control and the rhythm control groups had similar rates of arrhythmic and nonarrhythmic cardiac deaths, vascular deaths, ischemic stroke, and central nervous system hemorrhage. However, the rhythm control strategy was associated with an increase in noncardiovascular mortality due to pulmonary complications, such as pneumonia, and cancer.

“Sinus rhythm confers a mortality benefit, but the antiarrhythmic drugs are associated with increased mortality,” Singh summarizes. “The caveat is that most patients with atrial fibrillation need drugs to maintain sinus rhythm. This is a catch-22 and serves

first isolate the pulmonary veins and then search for additional sites that trigger episodes of atrial fibrillation. A third has been directed at isolating all or a large part of the left atrium, without isolating the pulmonary veins.”

Recent research has shown that in some patient cohorts, atrial fibrillation can be cured in 70% to 80% of patients using new catheter ablation techniques, Waldo notes. For example, in a study published in the Nov. 11, 2003, issue of *Circulation*, Hakan Oral, MD, and colleagues found that 88% of patients who underwent left atrial catheter ablation and 67% of patients in whom the pulmonary vein was isolated via segmental ostial catheter ablation were free of atrial

Rate vs. Rhythm Control: Properly Applying AFFIRM Findings

The Atrial Fibrillation Follow-Up Investigation of Rhythm Management trial was a randomized study of treatment of more than 4,100 patients with atrial fibrillation using either a rate control or a rhythm control strategy. AFFIRM's most publicized finding is that patients treated with a rhythm control strategy showed no survival advantage when compared with patients treated with a rate control strategy, and that a rate control strategy may result in fewer adverse events. The authors conclude that a rate control strategy may be initiated as first-line therapy in patients with atrial fibrillation.

AFFIRM has fostered a shift in atrial fibrillation treatment, and many articles recommend a rate control strategy as the first approach. However, design considerations and medication use specific to the AFFIRM population should be considered when extrapolating results to clinical practice. Furthermore, experts emphasize that AFFIRM findings are not relevant for all patients with atrial fibrillation. Therefore, a

Andrew E. Epstein, MD, professor of medicine in the Division of Cardiovascular Disease at the University of Alabama at Birmingham and an acknowledged expert on atrial fibrillation.

First, participants were at least 65 years of age or had at least one other stroke risk factor (such as hypertension; diabetes; heart failure; or prior history of a stroke, transient ischemic attack, or systemic embolus). Second,

including individuals with lone atrial fibrillation, Epstein emphasizes. "A more conservative and personalized approach to patient treatment is warranted," he says. "If a patient has had one episode that lasted four hours and stopped on its own, should that patient be prescribed a drug to be taken three times a day for life? It may be wiser to wait and see if the fibrillation returns."

A conservative strategy should be pursued if the atrial fibrillation occurred as a result of an unusual situation, such as a car accident, or if the patient is an endurance athlete who may have vagally mediated atrial fibrillation, Epstein says. This latter patient may be treated simply by advice to reduce exercise intensity.

Another important atrial fibrillation group, patients who are highly symptomatic, were also not part of the AFFIRM study population. "Treatment considerations for highly symptomatic patients should depend on individual patient characteristics, including heart rate," states Epstein.

Patients with a heart rate of 140 beats per minute, for example, are extremely uncomfortable and fatigued; symptoms are typically relieved by slowing the rate either with drug therapy or by ablation of the atrioventricular (AV) node and implantation of a

(Continued on page 10)

AFFIRM brought attention to the fact that many AF patients are not effectively anticoagulated.

rate control or a rhythm control strategy, as well as the particular therapeutic option, should be chosen based on careful consideration of each patient's health status, history, symptomatology, and other circumstances.

AFFIRM also brought attention to the fact that many patients with atrial fibrillation are not effectively anticoagulated. Achieving therapeutic levels of anticoagulation is crucial to preventing the occurrence of stroke. Furthermore, anticoagulation therapy should be continued even after sinus rhythm is achieved and maintained.

Patient Characteristics

The AFFIRM study population had two important characteristics, notes

participants were either minimally symptomatic or asymptomatic, meaning that their arrhythmia did not have a significant negative effect on their quality of life.

AFFIRM study results have been extrapolated too broadly in that some physicians have based treatment decisions on the findings even when caring for patients not represented by the AFFIRM study population, Epstein says. "Unfortunately, many physicians have extrapolated the results seen in the AFFIRM population to the overall population of patients with atrial fibrillation," he observes.

AFFIRM findings do not apply to patients who are under age 65 and do not have any stroke risk factors,

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pacemaker, Epstein says.

Pertinent questions to guide the choice of therapy for patients who are highly symptomatic and the ventricular response is controlled would include the following, says Epstein: Do they have rate response when they exercise? Do they have the brady-tachy syndrome? Would they benefit from a pacemaker that gives rate responsiveness when they are active? Should catheter ablation of atrial fibrillation be considered?

The crucial point is to fit therapy to the patient and to the circumstances. "That strategy means employing good doctoring skills: going to the bedside, taking a history, performing a physical

doses of amiodarone, and these counted as two different drugs. The extensive use of amiodarone in the study is not good or bad. It just reflects the pattern of cardiology practice today. Amiodarone use, especially as a primary therapy, is typical for the patient population studied by AFFIRM."

One message of the ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation, and a clear implication of recent clinical trials including AFFIRM, is that physicians should choose a therapy that best fits a patient's circumstances. "When a patient is anticoagulated and therefore protected from a stroke, we can try different therapies until we

These patients sometimes respond to vagolytic drugs, a nontraditional therapy for atrial fibrillation."

First-Line Therapy

In line with an individualized approach to therapy, physicians should not assume, based on AFFIRM, that a rate control strategy is always the best first choice for treatment.

"The AFFIRM findings indicate that either a rhythm control or a rate control strategy is fine, provided that the patient fits the criteria of the study," says Steven Singh, MD, chief of cardiology at the Veterans Affairs Medical Center in Washington, D.C., and professor of Medicine and Pharmacology at Georgetown University. Other trials that examined rate versus rhythm control include Rate Control vs. Electrical Cardioversion (RACE) for Persistent Atrial Fibrillation and two pilot studies, the Pharmacological Intervention in Atrial Fibrillation (PIAF) and the Strategies of Treatment of Atrial Fibrillation (STAF).

In the past, the practice was first to attempt to achieve and maintain sinus rhythm, and certainly, this strategy is appropriate for many patients, says Albert Waldo, MD, a cardiac electrophysiologist and the Walter H. Pritchard Professor of Cardiology and Professor of Medicine at Case Western Reserve University in Cleveland. "But recent trials have concluded that, in part because it has been so difficult to achieve and maintain sinus rhythm using antiarrhythmic drug therapy, many of the purported advantages of sinus rhythm simply have not been realized," he notes. "Therefore, when physicians see a new patient with atrial fibrillation and risk factors for stroke, they should consider whether a rhythm control or a rate control strategy would be the best first therapeutic

The crucial point is to fit therapy to the patient and to the circumstances.

examination, doing a lab evaluation, and then deciding on the best course of action based on the complete scenario," Epstein says.

While treatment decisions should be based on the patient's individual needs and clinical situation, these individualized decisions should be made in the context of accepted therapies, evidence-based medicine, and clinical guidelines, Epstein emphasizes.

Individualized Therapy

Another factor to remember when extrapolating AFFIRM study results to clinical practice is that amiodarone was widely used in the rhythm-control arm. "Patients were eligible for the study if they had not received amiodarone but had failed other traditional antiarrhythmic drug therapy," Epstein points out. "Furthermore, the choice of initial therapy was left to investigators and patients. As a result, a high percentage of AFFIRM participants ultimately ended up taking amiodarone at some time during the study. In addition, the study tested two different

identify one that is both effective and safe," says Epstein. "Watchful waiting can be an option as well." The guidelines were published in the October 2001 issue of the *Journal of the American College of Cardiology*.

Rather than immediately prescribing a drug based on its widespread use, physicians should consider whether another drug might better fit the patient's individual case. For example, patients with atrial fibrillation who do not have structural heart disease are good candidates for therapies such as class IC drugs or other therapeutic options. "The right approach to deciding on a treatment strategy for such patients is to first take a history," Epstein offers. "Next, these patients should undergo a thorough physiologic evaluation that would include thyroid function evaluation and an echocardiogram. Class IC drugs can be the right option for patients with no structural heart disease. In other cases, patients have vagally mediated atrial fibrillation, which occurs at night, after meals, and in athletes.

approach.” Waldo emphasizes that such a decision must be made on an individual patient basis.

But while rate control has been elevated to a possible first-line therapy, Waldo points out that rhythm control is still considered the primary therapy for certain patient groups. “There are some categories of patients who clearly deserve the chance to be converted to sinus rhythm,” he says. “For example, most experts believe that patients who are having atrial fibrillation for the first time deserve a rhythm control strategy initially to see if sinus rhythm can be achieved and maintained.”

As a rule, Waldo says, rhythm control is a good primary strategy for new patients with atrial fibrillation, for younger patients who do not want to be saddled with atrial fibrillation for decades, for patients who have atrial fibrillation infrequently (for example, only once or twice a year), and for patients with a reversible cause of

keep those patients in that arm of the study. This decision resulted in an unfair comparison of rhythm control and rate control because 40% of the people in rhythm control were actually in fibrillation.”

This result may have occurred because the protocol did not dictate a close follow-up of who was in sinus rhythm and who was in fibrillation, Singh notes. “The investigators performed an EKG every four months, but patients may have gone into fibrillation or sinus rhythm the day before or after the EKG,” he says.

Singh believes that every attempt should be made to restore a patient to sinus rhythm, at least for the first episode of atrial fibrillation. “Some patients restored to sinus rhythm—cardioversion either by drugs or electricity—may not have another episode in subsequent months or even years,” he observes. “Because of this, AFFIRM results have not per-

what constitutes a failure of therapy.”

Many patients are given antiarrhythmic therapy safely and achieve satisfactory results, Waldo notes, adding that the antiarrhythmic drugs are effective in about half of patients.

On the other hand, many patients do very well in atrial fibrillation, so a rate control strategy can be considered, Waldo continues. “Some patients remain terribly troubled and are highly symptomatic, often simply from having an irregular heart beat during atrial fibrillation,” he says. “In such patients, a rate control strategy as first choice is inappropriate.”

Importance of Anticoagulation

AFFIRM findings also underscore the importance of anticoagulation therapy to prevent stroke in patients with atrial fibrillation, especially for patients with one or more risk factors for stroke. All patients in the AFFIRM trial had one or more stroke risk factors and received anticoagulation therapy as specified by published guidelines. But thromboembolic complications occurred frequently after oral anticoagulation was discontinued or when therapy achieved subtherapeutic levels. Therefore, a major lesson from the AFFIRM study is that anticoagulation therapy should be continued indefinitely in patients with risk factors for stroke, even after they have achieved and maintained sinus rhythm.

If a patient fails to maintain sinus rhythm, Singh chooses a rate control strategy along with anticoagulation. “For patients who are highly symptomatic, ablation is a reasonable option,” he adds. “The bottom line is that the therapy must be individualized to the patient’s circumstances.”

—Reported and written by Deborah J. Neveleff, in North Potomac, Md. More information on quality improvement is available on our Web site (see page 16).

The findings of the AFFIRM study underscored the importance of anticoagulation therapy to prevent stroke in patients with atrial fibrillation.

atrial fibrillation (for example, hyperthyroidism or a pulmonary condition such as pneumonia).

Normal Sinus Rhythm

AFFIRM results may not fully indicate the benefits of a rhythm control strategy over a rate control strategy, Singh says. “Maintaining sinus rhythm with drug therapy is not easy, even with the best drugs we have,” he adds. “Most AFFIRM patients were paroxysmal and not in chronic atrial fibrillation. At the end of the study, only about 60% of the rhythm control group was truly in normal rhythm, while about 40% was still in fibrillation. But because of the intention to treat, the investigators had to

sueded me to try a rate control strategy first. I try a rhythm strategy initially, and then move to a rate control strategy if the patient fails rhythm-control therapy.”

But Singh cautions that physicians must define failure carefully. “If I try antiarrhythmic therapy in a symptomatic patient and the patient does not have a recurrence for six months, then I would not define that as a failure of drug therapy,” he says. “On the other hand, if the patient has recurrent attacks every month, then I would say that he or she has failed to maintain sinus rhythm. The frequency of the attacks, the duration of the sinus rhythm, and the patient’s symptom status should be used to define

EMRs Can Help Improve Quality

Under managed care, physicians are finding that they need to increase efficiency in their offices so that they can see more patients while continuing to deliver appropriate and timely care. Using information systems can help them do just that, says David Koeller, president and CEO of InteGreat Inc. (www.igreat.com), a company in Scottsdale, Ariz., that provides electronic medical record (EMR) systems.

"I often hear from doctors that revenue is increasing at a much slower rate than overhead costs are rising," Koeller explains. "So physicians need to see more patients in a shorter amount of time in order to generate additional revenue. Leveraging the efficiencies of EMR technology can improve the quality of care by enabling access to complete patient data at the moment it is needed. Computerized entry of patient information also can alleviate or reduce the administrative burden of medical practice, so that physicians and nurses can find more time to care for patients."

Enhancing Quality

EMRs provide a number of functions that help physicians enhance both efficiency and quality of care. "Physicians should look for a system that will give them quick access to laboratory, radiology, and transcription reports," Koeller offers. "They should look for the ability to write electronic prescriptions. Certainly, they should find a system that allows computerized access to a patient's health summary. These are all functions that will enhance quality of care as well as efficiency."

What's more, the system should offer a single, unified source of information on each patient. "This can be achieved with data downloaded into an EMR via a real-time interface with the lab system, the radiology system, the practice's transcription system, and other practice systems so that

physicians can access all data through one single sign-on," explains Koeller. "Most groups already have historical data stored electronically on disparate systems that can be linked in this way. Often, physicians do not access most of the data available to them because they find the systems difficult to use. Furthermore, an interface with legacy systems is valuable because groups all over the country have major financial

investments in their existing systems and want to continue using them."

Koeller points out that physicians should not focus on all of the features available in a certain system, even though such functionality is important. Rather, they should consider the following more important questions: "Will I use these functions?" "Will this solution help me offer better quality of care?" "Can I implement this solution?" "What is the training time required for physicians and additional staff?" "Will the implementation have a negative effect on my productivity?"

"Simple questions such as these are crucial when assessing technology purchase decisions, but this is not the way most electronic health care systems are purchased," he notes.

Improving Efficiency

Technology also can streamline aspects of a practice that are not related to patient care. "Physicians may

see patients for eight hours a day, but then have to spend four hours catching up on documentation," Koeller says. "EMR solutions greatly increase productivity by enabling patient information to be entered directly into the electronic system in the form of a centralized database."

Furthermore, some Web-based EMR systems enable remote management of administrative duties. "For

EMRs provide a number of functions that help physicians enhance both efficiency and quality of care.

example, physicians may prefer to handle administrative tasks by accessing patient data from their home PC," Koeller says.

EMR systems also improve the efficiency of the practice. Staff can spend a significant amount of time reviewing charts for nonvisit patient activity, such as calls regarding insurance coverage or a prescription refill. "Typically, nurses are involved in such activities and therefore must spend a significant amount of time not taking care of patients in the medical sense, but doing clerical work, trying to find files, and researching information," Koeller observes. An EMR can give nurses quick access to patient data and eliminate the need for time-consuming chart pulls.

Despite the many advantages of such systems, physicians have been slow to adopt technologies that could enhance the quality and efficiency of care. One reason for such reluctance is

that many systems have not been user-friendly, Koeller explains. But there have been dramatic improvements in adoption rates as new technology, such as the wireless tablet PCs and hand-writing recognition software, have made these systems more attractive.

Over the past few years, vendors have been focusing on the physicians who are resistant to embracing technology. "About 15% to 20% of physicians in most physician organizations are not computer literate," Koeller says. "It is a challenge for vendors to develop a simple, intuitive system that will encourage use by all physicians, not just those who are technically savvy. Only after a certain level of comfort with technology is reached will physicians want to explore more of the system's functionality.

"The number one failure of many systems over the last 20 years is that they started from a technology level that was too high to get the support needed from those physicians," he continues. "There are EMR systems in physician organizations that, even after three to five years, have achieved only 30% to 60% acceptance. Most physician organizations never come close to 100% acceptance of an EMR system. Full physician acceptance will provide the greatest value for the organization."

Older physicians may be a little more reluctant, but if the EMR system is simple enough, they will use it, Koeller adds. "Sometimes, older physicians are more likely to use systems that are browser-based because they are familiar with that interface from their experience with e-mail, online shopping, or Internet searches for information."

In the future, technology will have a positive effect on the quality and efficiency of health care organizations, Koeller believes. In a few years, physicians will not be able to practice

EMR Form Follows Function

The key to getting the most from any electronic system is to buy one with the right functions to meet the physician group's needs, says David Koeller, president and CEO of InteGreat Inc. (www.igreat.com), in Scottsdale, Ariz. To match functions with a practice's needs, Koeller says physicians should address four key issues when considering such systems.

1. They should look for a system that will take them less than 30 minutes to learn to use effectively, he notes. "They will not be able to learn to use every feature in this short time, but they should be able to quickly learn the basic functions that they need to enhance their patient care and operational efficiency," he says.
2. They should find a system that will be available to them anywhere at any time. "Web-based applications, which can be accessed from any computer with Internet access, offer this capability," Koeller says, adding that access to information at the point of care significantly increases the value of such systems. "With the proper security, this type of system can enable physicians to do from any PC whatever they can do in the clinic. Such access is critical because physicians cannot be guaranteed that they will have their computer with them when they need to access information."
3. They should look for a system that will not adversely affect productivity. "Many studies indicate that organizations should expect anywhere from a 10% to 20% loss of productivity during the implementation phase of an EMR," observes Koeller. "I believe just the opposite. A proper approach to an EMR implementation should have an immediate and positive effect on a physician's productivity. What is important here is both the design of the system and the vendor's implementation strategies." An EMR system that requires physicians to understand all of the functionality from day one may require too much training time and affect workflow to such a degree that they see fewer patients in the first six to 12 months of use.
4. They should find a system that will adapt to the way they practice medicine. "Most physicians do not want to change their practice workflow in order to use an EMR solution," Koeller states. —DJN

medicine without integrating technology into their practices, he predicts. "Patients are demanding that health care organizations enable greater patient access to data and more direct electronic involvement with providers," he says.

In addition, payers are seeing a dramatic reduction in claims management costs when the right information is available to physicians at the point of care, Koeller says. "Over the

next few years, physicians will completely change their opinion of EMRs and other health care technologies," he says. "Technology adoption is a major strategy by which we can not only cut down on health care costs, but improve the quality of care as well," he adds.

—Edited by Deborah J. Neveleff, in North Potomac, Md. More information on quality improvement is available on our Web site (see page 16).

Integrating Physicians, Hospitals Would Help Solve Many Problems

By Richard L. Reece, MD, contributing editor

Whether it comes from a physician-oriented model (such as the Mayo Clinic's) or an HMO-model (such as Kaiser Permanente's), the solution to many of health care's most daunting challenges is integration, says Daniel Beckham, president of The Beckham Co., a health care consulting firm in Bluffton, S.C.

"Unfortunately, integration has become a loaded term," Beckham explains. "In many minds, integration means deal-making and making acquisitions and trying to force a physician practice to fit into an organization." Rather, integration in health care means managing the connection between the pieces of the health system so that excellent care can be delivered quickly and more affordably, he says.

Strength in Numbers

"This integration must occur in the context of the basics of delivering high-quality care: conferring dignity on and offering information to patients, pursuing teamwork, and applying information systems so that caregivers collaborate, yielding higher quality and more efficiency," Beckham says. "That's where the

of interactions. Health care managers need to focus on the interaction among the pieces, which won't be made easier when physicians are hunkered down in their specialty silos. But that is the trend, so we have to respond to it. Information systems are obviously important for promoting integration and high quality of care, but we also need some basic accountability for 'systemness.'"

Information systems, and particularly electronic medical record systems, have the potential to help leaders promote integration, enhance safety, and increase cost-effectiveness. Therefore, physicians need to be prepared for the eventuality that these systems will be used widely, Beckham advises.

Fostering Teamwork

Interaction requires teamwork, and Beckham believes that health care

in a group across the street; and there are a growing number of employed subspecialists. Eventually, someone realizes that the organization needs to integrate these otherwise independent players into a true team."

"This is the challenge for the industry overall," Beckham continues. "If teamwork is essential to managing the cost and quality of care, then we need to determine how to design a process that ensures a preselection of caregivers oriented to working as a team."

Hospitalists offer an example of teamwork, in part because the movement toward employing hospitalists has changed the relationship between hospitals and the larger physician community, particularly the primary care community. "The initial resistance of physicians is clearly an issue when hospitals and health systems first work to adopt hospitalist programs, but later, physicians who may have resisted the idea often become more positive," notes Beckham. "They come to appreciate the quality and efficiency benefits of having the hospitalist fill the gap when they cannot or do not want to go to the hospital."

Hospitals and Specialists

Integration between hospitals and specialists is occurring at a growing pace. Hospitals, many of which are marginally profitable, are turning to partnerships with specialists to enhance the

"Unfortunately, integration has become a loaded term," says Daniel Beckham, of The Beckham Co.

power is, and physicians have as much power in that regard as ever before."

Managing and monitoring how hospitals, specialists, and primary care physicians work together should be the responsibility of system leadership. "In a system, the challenge of leadership and management is not the management of actions," Beckham says. "It's the management

professionals can learn from those in other industries about the power of working together. "Teamwork, which is very important to service quality, is absolutely critical to effective management of both care quality and cost-effectiveness," he says. "In many hospitals and health care systems, there are both nurses and a hospitalist on the floor; there are employed PCPs

bottom line, Beckham says.

“Hospitals are trying to figure out how to secure more sustainable relationships with specialists,” he notes. “Specialists have higher incomes than PCPs, and they have money to invest in joint ventures for the creation of specialty centers. In some instances, the relationship involves employment. When hospitals directly employ some specialists, the question becomes, what is the inevitable evolution of that model? It may begin to look like a multispecialty group practice over time if the hospitals already own primary care practices.”

But given the financial resources of specialists, many of them are forgoing a formal partnership with a hospital and opening outpatient centers on their own. “Specialists are developing more entrepreneurial modes of practice, such as single-specialty hospitals, outpatient surgery centers, diagnostic centers, or single-specialty practices,” observes Beckham. “In that regard, they are positioned to make some significant inroads into health care.

“I am amazed at the level of investment in additional capacity that is being incurred by physicians, whether it is diagnostic capacity or outpatient surgery capacity,” Beckham continues. “Many physicians who are making those investments are securing them with their home mortgages. It is a big risk. So who will fight the hardest: the one whose house is on the line or the hospital administrator? This has the potential to be a bruising battle in many cities and towns nationwide.”

In many areas of the country, this trend is causing strife between specialists and hospitals. “Since physicians offer outpatient care, such centers logically are an extension of their practice model,” Beckham says. “Hospitals, on the other hand, regard outpatient centers as an extension of their past and current involvement in outpatient

ancillary services, and therefore view the specialists as intruding on the hospitals’ existing business.”

While the two sides have clashed, hospitals could learn from the experience of physicians in these ventures. Research has shown that some single-specialty centers have outcomes that are as good as or better than the outcomes at more traditional hospitals, Beckham explains. “From a quality perspective, then, this trend is healthy because it forces all players to get up on their game,” he notes.

Also, outpatient care delivered by hospitals often is not customer-centered or cost-effective, Beckham con-

Many specialists are opening outpatient centers without partnering with hospitals.

tinues. “The free-standing surgery centers are much better at responding to the needs of both patients and physicians,” he says. “A big hospital without that kind of responsiveness or sensitivity built into its management system will find it tough to compete against physician-owned centers.”

Hospitals and PCPs

In the 1980s and 1990s, many hospitals focused heavily on their relationships with primary care physicians, but today, hospitals have begun to question how primary care fits into their overall business strategy, Beckham notes. The hospitals that retained their relationships with PCPs may be well positioned for the future. “Many hospitals recognize that PCPs have a significant role in steering patients to specialists in the hospital, thereby generating revenue,” Beckham notes, adding that such revenue does not show up on the financial reports as being generated by PCPs.

Also, an affiliation among primary care practices, specialists, and the hospital can lead to higher quality of

care. “A primary care group owned by the hospital provides a relatively unified mechanism for attacking problems created by fragmentation,” Beckham says. “A well led primary care group can make significant contributions towards integrating care.”

What’s more, the losses that hospitals have associated with physician group ownership are diminishing, Beckham says. “One reason for that decline is that management systems have been put into place; productivity-based compensation systems, in particular, have reduced a lot of losses,” he explains. “As a result of such systems, there is significantly less

pressure today to divest those groups. The hospital-owned physician group will be around for the long haul.”

Beckham points out that hospitals have learned more about how to work with physicians and how to function better as partners with physician groups. When the trend toward hospital ownership of practices was starting, Beckham tried to encourage his hospital clients not to go to a straight employment model, but rather to adopt more of a partnership model. “In such a model, physicians retain a significant equity position in their practices and potentially roll that equity position into an equity position in a bigger group as the hospital purchases more practices,” he explains. “This strategy also substantially reduces the hospital’s financial exposure. Physicians who did not rely too heavily on the employment model have found it easier to bounce back after hospital divestment.”

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