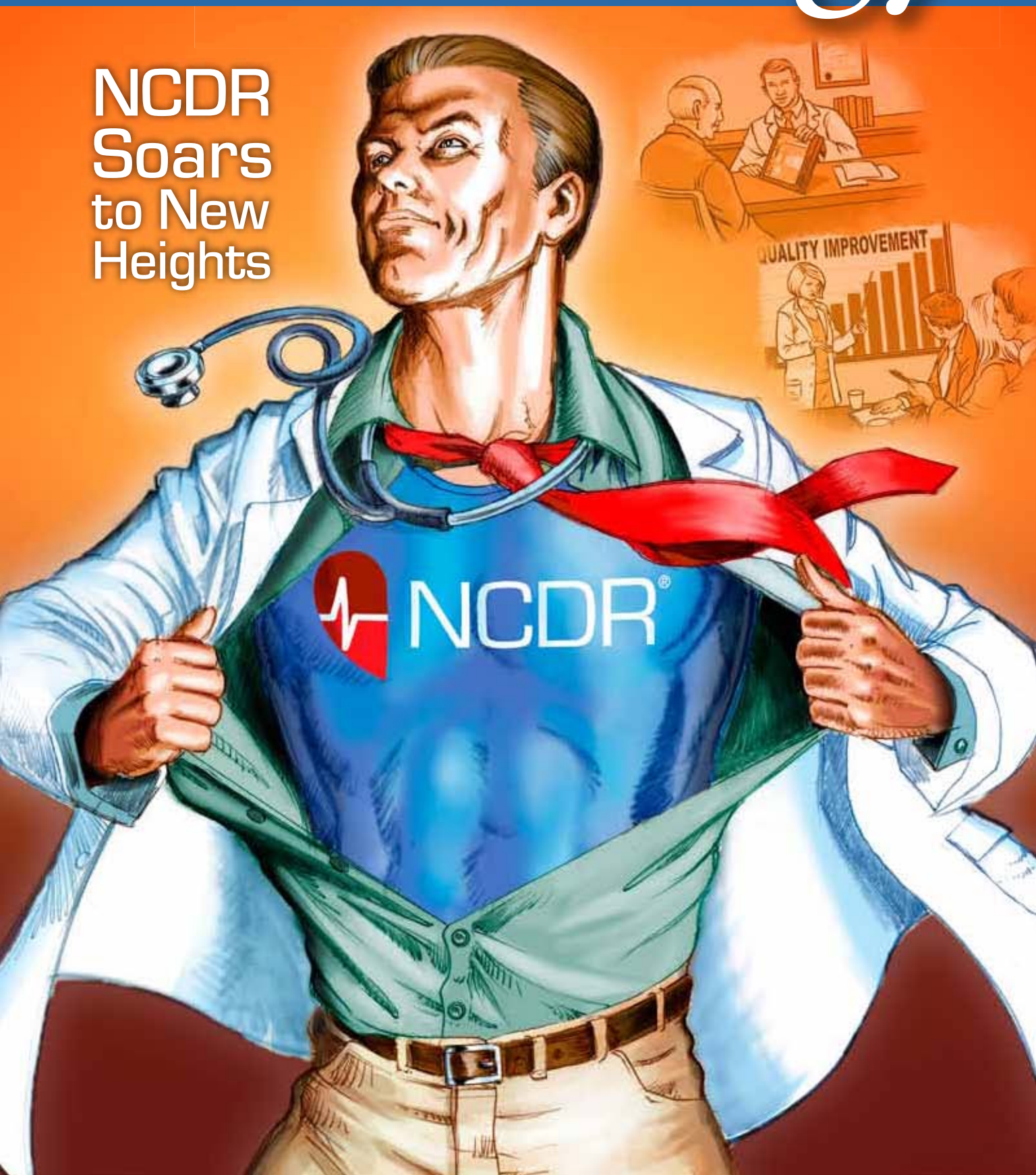
JULY - AUGUST 2010 VOL. 39 NO. 5

Cardiology

A MEMBER PUBLICATION OF THE AMERICAN COLLEGE OF CARDIOLOGY

NCDR Soars to New Heights



Indication

- Ranexa is indicated for the treatment of chronic angina.
- Ranexa may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.

IMPORTANT SAFETY INFORMATION

Contraindications

- Ranexa is contraindicated in patients:
  - Taking strong inhibitors of CYP3A (eg, ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir)
  - Taking inducers of CYP3A (eg, rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine, and St John's wort)
  - With clinically significant hepatic impairment

Warnings and Precautions

- Ranexa blocks I_{Kr} and prolongs the QTc interval in a dose-related manner.
- Clinical experience did not show an increased risk of proarrhythmia or sudden death.
- There is little experience with high doses (> 1000 mg twice daily) or exposure, other QT-prolonging drugs, or potassium channel variants resulting in a long QT interval.

Please see brief summary of prescribing information on adjacent page.

Ranexa is FDA approved as a first-line agent for treatment of patients with chronic angina

- Established efficacy in a 12-week clinical trial
  - Clinical trial endpoints included angina frequency, exercise duration, nitroglycerin use, time to ischemia (1-mm ST-segment depression), and time to angina[1]
- Hemodynamic neutrality
  - In controlled clinical trials, Ranexa caused minimal changes in mean heart rate (< 2 bpm) and systolic blood pressure (< 3 mm Hg)[2]
  - No dose adjustment is required in patients with heart failure or diabetes[2]
- Established safety and tolerability

Redefine your treatment landscape

Ranexa®
RANOLAZINE EXTENDED-RELEASE TABLETS
500 mg · 1000 mg

Adverse Reactions

- The most common adverse reactions (> 4% and more common than with placebo) during treatment with Ranexa were dizziness, headache, constipation, and nausea.

Dosage and Administration

- Begin treatment with 500 mg twice daily and increase to the maximum recommended dose of 1000 mg twice daily, based on clinical symptoms.
- Limit the dose of Ranexa to 500 mg twice daily in patients on moderate CYP3A inhibitors (eg, diltiazem, verapamil, aprepitant, erythromycin, fluconazole, and grapefruit juice or grapefruit-containing products).

Drug Interactions

- Do not use Ranexa with CYP3A inducers or strong CYP3A inhibitors (see Contraindications); modify the dose of Ranexa with moderate CYP3A inhibitors (see Dosage and Administration).
- P-gp inhibitors (eg, cyclosporine): may need to lower the dose of Ranexa based on clinical response.
- Doses of drugs transported by P-gp (eg, digoxin) or metabolized by CYP2D6 (eg, tricyclic antidepressants and antipsychotics) may need to be reduced.

1. Chaitman BR, Pepine CJ, Parker JO, et al. Effects of ranolazine with atenolol, amlodipine, or diltiazem on exercise tolerance and angina frequency in patients with severe chronic angina: a randomized controlled trial. *JAMA*. 2004;291:309-316. **2.** Ranexa (ranolazine extended-release tablets) [package insert]. Palo Alto, CA; Sept 2009.

GILEAD

Ranexa®
RANOLAZINE EXTENDED-RELEASE TABLETS
500 mg · 1000 mg

Brief Summary of Prescribing Information

These highlights do not include all the information needed to use Ranexa safely and effectively. See full prescribing information for Ranexa.

Ranexa (ranolazine) extended-release tablets

1. INDICATIONS AND USAGE
Ranexa is indicated for the treatment of chronic angina.

Ranexa may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.

2. DOSAGE AND ADMINISTRATION

2.1 Dosing Information
Initiate Ranexa dosing at 500 mg twice daily and increase to 1000 mg twice daily, as needed, based on clinical symptoms. Take Ranexa with or without meals. Swallow Ranexa tablets whole; do not crush, break, or chew.

The maximum recommended daily dose of Ranexa is 1000 mg twice daily.

If a dose of Ranexa is missed, take the prescribed dose at the next scheduled time; do not double the next dose.

2.2 Dose Modification
Dose adjustments may be needed when Ranexa is taken in combination with certain other drugs *[see Drug Interactions (7.1)]*. Limit the maximum dose of Ranexa to 500 mg twice daily in patients on diltiazem, verapamil, and other moderate CYP3A inhibitors. Down-titrate Ranexa based on clinical response in patients concomitantly treated with P-gp inhibitors, such as cyclosporine.

3. DOSAGE FORMS AND STRENGTHS
Ranexa is supplied as film-coated, oblong-shaped, extended-release tablets in the following strengths:
- 500 mg tablets are light orange, with GSI500 on one side
- 1000 mg tablets are pale yellow, with GSI1000 on one side

4. CONTRAINDICATIONS
Ranexa is contraindicated in patients:
- Taking strong inhibitors of CYP3A *[see Drug Interactions (7.1)]*
- Taking inducers of CYP3A *[see Drug Interactions (7.1)]*
- With clinically significant hepatic impairment *[see Use in Specific Populations (8.6)]*

5. WARNINGS AND PRECAUTIONS

5.1 QT Interval Prolongation: Ranolazine blocks I_{Kr} and prolongs the QTc interval in a dose-related manner.

Clinical experience in an acute coronary syndrome population did not show an increased risk of proarrhythmia or sudden death. However, there is little experience with high doses (> 1000 mg twice daily) or exposure, other QT-prolonging drugs, or potassium channel variants resulting in a long QT interval.

6. ADVERSE REACTIONS

6.1 Clinical Trial Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 2,018 patients with chronic angina were treated with ranolazine in controlled clinical trials. Of the patients treated with Ranexa, 1,026 were enrolled in three double-blind, placebo-controlled, randomized studies (CARISA, ERICA, MARISA) of up to 12 weeks duration. In addition, upon study completion, 1,251 patients received treatment with Ranexa in open-label, long-term studies; 1,227 patients were exposed to Ranexa for more than 1 year, 613 patients for more than 2 years, 531 patients for more than 3 years, and 326 patients for more than 4 years.

At recommended doses, about 6% of patients discontinued treatment with Ranexa because of an adverse event in controlled studies in angina patients compared to about 3% on placebo. The most common adverse events that led to discontinuation more frequently on Ranexa than placebo were dizziness (1.3% versus 0.1%), nausea (1% versus 0%), asthenia, constipation, and headache (each about 0.5% versus 0%). Doses above 1000 mg twice daily are poorly tolerated.

In controlled clinical trials of angina patients, the most frequently reported treatment-emergent adverse reactions (> 4% and more common on Ranexa than on placebo) were dizziness (6.2%), headache (5.5%), constipation (4.5%), and nausea (4.4%). Dizziness may be dose-related. In open-label, long-term treatment studies, a similar adverse reaction profile was observed.

The following additional adverse reactions occurred at an incidence of 0.5 to 2.0% in patients treated with Ranexa and were more frequent than the incidence observed in placebo-treated patients:

Cardiac Disorders – bradycardia, palpitations

Ear and Labyrinth Disorders – tinnitus, vertigo

Gastrointestinal Disorders – abdominal pain, dry mouth, vomiting

General Disorders and Administrative Site Adverse Events – peripheral edema

Respiratory, Thoracic, and Mediastinal Disorders – dyspnea

Vascular Disorders – hypotension, orthostatic hypotension

Other (< 0.5%) but potentially medically important adverse reactions observed more frequently with Ranexa than placebo treatment in all controlled studies included: angioedema, renal failure, eosinophilia, blurred vision, confusional state, hematuria, hypoesthesia, paresthesia, tremor, pulmonary fibrosis, thrombocytopenia, leukopenia, and pancytopenia.

A large clinical trial in acute coronary syndrome patients was unsuccessful in demonstrating a benefit for Ranexa, but there was no apparent proarrhythmic effect in these high-risk patients.

Laboratory Abnormalities
Ranexa produces small reductions in hemoglobin A1c. Ranexa is not a treatment for diabetes.

Ranexa produces elevations of serum creatinine by 0.1 mg/dL, regardless of previous renal function. The elevation has a rapid onset, shows no signs of progression during long-term therapy, is reversible after discontinuation of Ranexa, and is not accompanied by changes in BUN. In healthy volunteers, Ranexa 1000 mg twice daily had no effect upon the glomerular filtration rate. The elevated creatinine levels are likely due to a blockage of creatinine's tubular secretion by ranolazine or one of its metabolites.

7. DRUG INTERACTIONS

7.1 Effects of Other Drugs on Ranolazine: Ranolazine is primarily metabolized by CYP3A and is a substrate of P-glycoprotein (P-gp).

CYP3A Inhibitors
Do not use Ranexa with strong CYP3A inhibitors, including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir. Ketoconazole (200 mg twice daily) increases average steady-state plasma concentrations of ranolazine 3.2-fold *[see Contraindications (4)]*.

Limit the dose of Ranexa to 500 mg twice daily in patients on moderate CYP3A inhibitors, including diltiazem, verapamil, aprepitant, erythromycin, fluconazole, and grapefruit juice or grapefruit-containing products. Diltiazem (180–360 mg daily) and verapamil (120 mg three times daily) increase ranolazine steady-state plasma concentrations about 2-fold *[see Dosage and Administration (2.2)]*.

Weak CYP3A inhibitors such as simvastatin (20 mg once daily) and cimetidine (400 mg three times daily) do not increase the exposure to ranolazine in healthy volunteers.

P-gp Inhibitors
Down-titrate Ranexa based on clinical response in patients concomitantly treated with P-gp inhibitors, such as cyclosporine *[see Dosage and Administration (2.2)]*.

CYP3A and P-gp Inducers
Avoid co-administration of Ranexa and CYP3A inducers such as rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine, and St. John's wort. Rifampin (600 mg once daily) decreases the plasma concentration of ranolazine (1000 mg twice daily) by approximately 95% by induction of CYP3A and, probably, P-gp.

CYP2D6 Inhibitors
The potent CYP2D6 inhibitor, paroxetine (20 mg once daily), increases ranolazine concentrations 1.2-fold. No dose adjustment of Ranexa is required in patients treated with CYP2D6 inhibitors.

Digoxin
Digoxin (0.125 mg) does not significantly alter ranolazine levels.

7.2 Effects of Ranolazine on Other Drugs: *In vitro* studies indicate that ranolazine and its O-demethylated metabolite are weak inhibitors of CYP3A, moderate inhibitors of CYP2D6 and moderate P-gp inhibitors. Ranolazine and its most abundant metabolites are not known to inhibit the metabolism of substrates for CYP 1A2, 2C8, 2C9, 2C19, or 2E1 in human liver microsomes, suggesting that ranolazine is unlikely to alter the pharmacokinetics of drugs metabolized by these enzymes.

Drugs Metabolized by CYP3A
The plasma levels of simvastatin, a CYP3A substrate, and its active metabolite are each increased about 2-fold in healthy subjects receiving simvastatin (80 mg once daily) and Ranexa (1000 mg twice daily). Dose adjustments of simvastatin are not required when Ranexa is co-administered with simvastatin.

The pharmacokinetics of diltiazem is not affected by ranolazine in healthy volunteers receiving diltiazem 60 mg three times daily and Ranexa 1000 mg twice daily.

Drugs Transported by P-gp
Ranexa (1000 mg twice daily) causes a 1.5-fold elevation of digoxin plasma concentrations. The dose of digoxin may have to be adjusted.

Drugs Metabolized by CYP2D6
Ranolazine or its metabolites partially inhibit CYP2D6. There are no studies of concomitant use of Ranexa with other drugs metabolized by CYP2D6, such as tricyclic antidepressants and antipsychotics, but lower doses of CYP2D6 substrates may be required.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy—Pregnancy Category C: In animal studies, ranolazine at exposures 1.5 (rabbit) to 2 (rat) times the usual human exposure caused maternal toxicity and misshapen sternebrae and reduced ossification in offspring. These doses in rats and rabbits were associated with an increased maternal mortality rate. There are no adequate well-controlled studies in pregnant women. Ranexa should be used during pregnancy only when the potential benefit to the patient justifies the potential risk to the fetus.

8.3 Nursing Mothers: It is not known whether ranolazine is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions from ranolazine in nursing infants, decide whether to discontinue nursing or to discontinue Ranexa, taking into account the importance of the drug to the mother.

8.4 Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

8.5 Geriatric Use: Of the chronic angina patients treated with Ranexa in controlled studies, 496 (48%) were ≥ 65 years of age, and 114 (11%) were ≥ 75 years of age. No overall differences in efficacy were observed between older and younger patients. There were no differences in safety for patients ≥ 65 years compared to younger patients, but patients ≥ 75 years of age on ranolazine, compared to placebo, had a higher incidence of adverse events, serious adverse events, and drug discontinuations due to adverse events. In general, dose selection for an elderly patient should usually start at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease, or other drug therapy.

8.6 Use in Patients with Hepatic Impairment: Ranexa is contraindicated in patients with clinically significant hepatic impairment. Plasma concentrations of ranolazine were increased by 30% in patients with mild (Child-Pugh Class A) and by 60% in patients with moderate (Child-Pugh Class B) hepatic impairment. This was not enough to account for the 3-fold increase in QT prolongation seen in patients with mild to severe hepatic impairment *[see Contraindications (4)]*.

8.7 Use in Patients with Renal Impairment: In patients with varying degrees of renal impairment, ranolazine plasma levels increased up to 50%. The pharmacokinetics of ranolazine has not been assessed in patients on dialysis.

8.8 Use in Patients with Heart Failure: Heart failure (NYHA Class I to IV) had no significant effect on ranolazine pharmacokinetics. Ranexa had minimal effects on heart rate and blood pressure in patients with angina and heart failure NYHA Class I to IV. No dose adjustment of Ranexa is required in patients with heart failure.

8.9 Use in Patients with Diabetes Mellitus: A population pharmacokinetic evaluation of data from angina patients and healthy subjects showed no effect of diabetes on ranolazine pharmacokinetics. No dose adjustment is required in patients with diabetes.

Ranexa produces small reductions in HbA1c in patients with diabetes, the clinical significance of which is unknown. Ranexa should not be considered a treatment for diabetes.

10. OVERDOSAGE
High oral doses of ranolazine produce dose-related increases in dizziness, nausea, and vomiting. High intravenous exposure also produces diplopia, paresthesia, confusion, and syncope. In addition to general supportive measures, continuous ECG monitoring may be warranted in the event of overdose.

Since ranolazine is about 62% bound to plasma proteins, hemodialysis is unlikely to be effective in clearing ranolazine.

Please see full prescribing information at www.Ranexa.com.

To report SUSPECTED ADVERSE REACTIONS, contact Gilead Sciences, Inc, at 1-800-GILEAD-5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Rx only

Manufactured for: Gilead Sciences, Inc, Foster City, CA 94404 USA

Ranexa Prescribing Information, September 2009

21-526-GS-007 09SEP09

RAN4510 2/10

NCDR Providing Answers

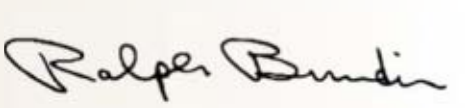
The goal of the ACC's National Cardiovascular Data Registry (NCDR®) has been all along to help hospitals – and now practices – measure and manage care. The College, through NCDR, has real opportunities to help improve quality and enhance performance and decision making on both a broad scale, as well as at the individual level. This issue of *Cardiology* magazine highlights the headway we're making in harnessing these opportunities and using NCDR data to identify trends, outcomes and opportunities for future research.

Our cover story takes a look at the first-ever NCDR report on "Treatments, Trends and Outcomes of Acute Myocardial Infarction (AMI) and Percutaneous Coronary Intervention (PCI)." This report, which draws from the ACTION Registry®-Get with the Guidelines ™ and the CathPCI Registry® provides a "big picture" look at AMI and PCI treatment in U.S. hospitals. Authors **John C. Messenger, M.D., F.A.C.C., Matthew T. Roe, M.D., M.H.S., F.A.C.C.,** and **John S. Rumsfeld, M.D., Ph.D., F.A.C.C.,** highlight the key findings of the report and its implications for cardiovascular professionals.

Also in this issue, **William J. Oetgen, M.D., M.B.A, F.A.C.C.,** provides an overview of a study of clinical data from the first full year of the PINNACLE Registry ™. The study shows varying compliance rates with ACCF/American Heart Association (AHA) cardiac performance measures, as well as gaps in care. It also highlights the importance of registry participation as a means of improving both patient outcomes and quality of care. Speaking of participation, **Colleen Balius, B.S.N., R.N.,** provides a unique, first-hand perspective on just how easy it is to participate in her article "Comparing Effectively with NCDR."

Outside of NCDR, don't miss the great article on **Sandra Lewis, M.D., F.A.C.C.,** and her daughter **Lisa Rosenbaum, M.D.,** an ACC Fellow in Training. The article compares their professional experiences and profiles what is obviously a family passion for cardiology. On the science front, **David Holmes Jr., M.D., F.A.C.C.,** provides insight into the new ACCF/AHA clinical alert on clopidogrel, while another article looks at the recent decision by a Food and Drug Administration (FDA) advisory panel to keep rosiglitazone (Avandia) on the market. In addition, don't miss the overviews of the Centers for Medicare and Medicaid Services proposed 2011 Medicare Physician Fee Schedule and the final rule defining "meaningful use" of an electronic health record. Both rules have implications on the practice of cardiology that we should all be aware of.

I'm excited about all of the great things we're doing as a profession to make sure our patients are getting the best care at both the national and international level (see the China article on page 23). Whether it's through our registries, clinical documents or even family connections, we are making a difference and paving the way for future generations of cardiovascular professionals and saving the lives of countless patients. I think this issue of *Cardiology* is a tribute to all of that hard work.



Ralph G. Brindis, M.D., M.P.H., F.A.C.C.
President

July – August 2010

Cover illustration by Miracle Studios

What's Happening with AMI and PCI in U.S.?

NCDR Provides Answers

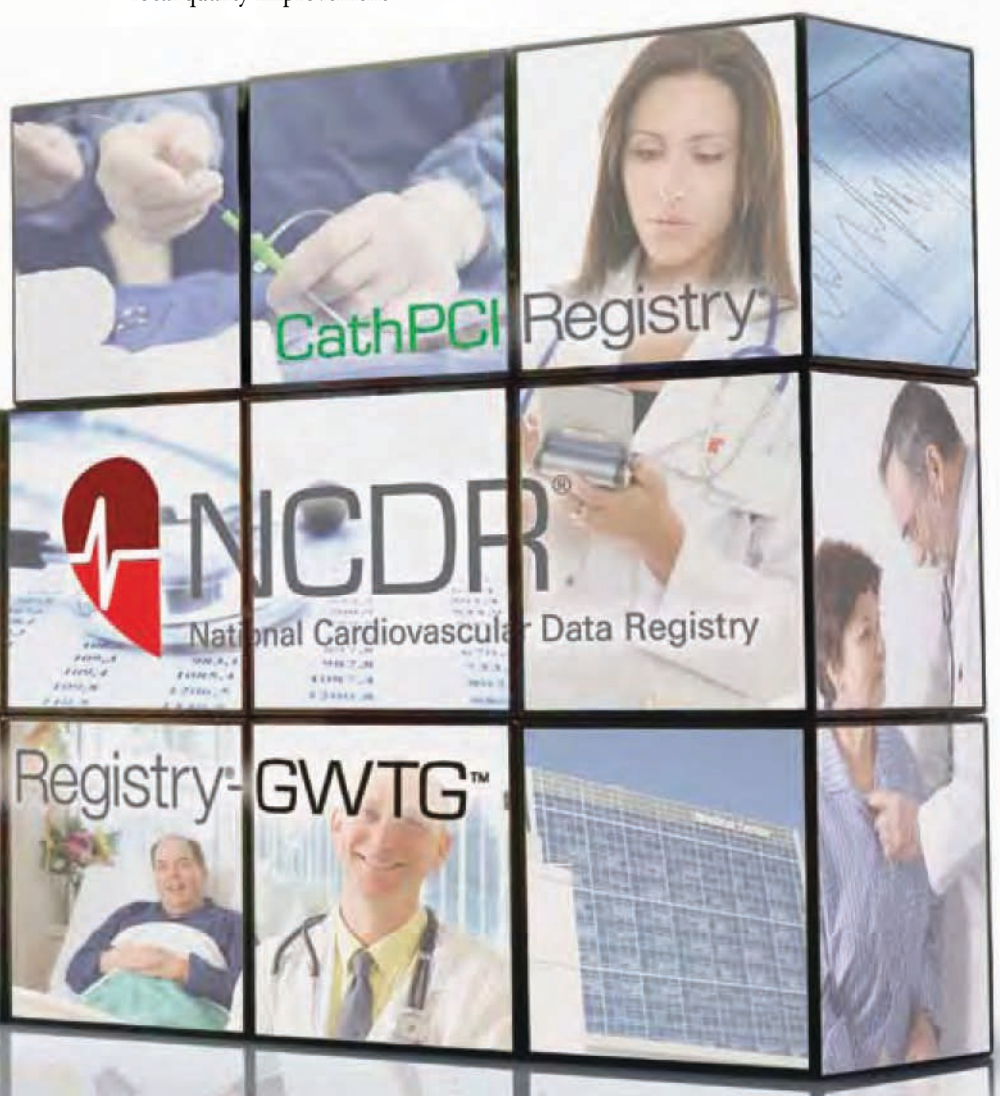
By John C. Messenger, M.D., F.A.C.C.;
Matthew T. Roe, M.D., M.H.S., F.A.C.C.;
and John S. Rumsfeld, M.D., Ph.D., F.A.C.C.

Results of clinical trials may be publicly presented and updates on clinical guidelines published, but do we know how the results and updates are being implemented in contemporary cardiovascular (CV) practice? Now, for the first time and thanks to a National Cardiovascular Data Registry (NCDR®) report on "Treatments, Trends and Outcomes of Acute Myocardial Infarction (AMI) and Percutaneous Coronary Intervention (PCI)," we have a broad picture of recent changes in CV care with in-hospital AMI treatment and PCI.

The report draws from two sources: the NCDR ACTION Registry®-Get with the Guidelines™ (AR-G) and the CathPCI Registry®, which profile AMI and PCI care respectively. NCDR registry participants submit in-hospital data routinely and receive quarterly feedback reports with benchmarked treatment and outcome data to focus and target local quality improvement activities. This report compiles in-hospital data from the last three to five years to provide a "big picture" look at AMI and PCI treatment at U.S. hospitals.

These snapshots of NCDR-participating hospitals across the U.S. tell a story of successes and refinements with procedures and treatments and opportunities for continued improvement.

These snapshots of NCDR-participating hospitals across the U.S. tell a story of successes and refinements with procedures and treatments and opportunities for continued improvement.



The AR-G, which is a partnership of the ACC and the American Heart Association (AHA), includes data from January 2007 through June 2009, reflecting the in-hospital treatment of 131,980 AMI patients from 250 participating centers. Comparisons in the report were drawn from the first two quarters of 2007 and 2009 respectively.

The NCDR CathPCI Registry, a partnership effort with the Society for Cardiovascular Angiography and Interventions since 2005, focuses on diagnostic cardiac catheterization and PCI. The patient population is larger at 1,708,247 with 436 participating hospitals in 2005 and 959 hospitals in 2009. The comparisons are drawn from the first two quarters of 2005 and 2009 respectively.

The extensive details of the NCDR report are available in the *Journal of the American College of Cardiology* (J Am Coll Cardiol 2010;56:254-263) and online at ACC's new website, *CardioSource.org*. The purpose of this article is to describe how patients undergoing PCI and treatment for AMI are being cared for in the U.S., as well as what changes have occurred over time and to discuss possible implications for practitioners.

Overall, the report provides positive information that indicates improvements in reperfusion times for STEMI patients and improved adherence to clinical guideline recommendations for medications for both STEMI and NSTEMI patients. The report also highlights decreased rates in overdosing of antithrombotics with NSTEMI patients.

Continued on next page

Continued from previous page

As for the "how" of PCI procedures, the data in the report indicate that PCI procedures have become more complex with the availability and use of multiple types of stents and delivery techniques, as well as changes in medications used in the cath lab for PCI procedures. Data in the report show a decrease in the use of drug-eluting stents, perhaps related to the questions of stent thrombosis raised once the devices were in use, but a shift towards use of newer generation drug-eluting stents is indicated by the data, too. Despite the increased complexity of PCI procedure and changing patterns of drug-eluting stent use, the data show that peri-procedural bleeding and vascular complications have decreased with time while mortality rates remain low, but unchanged.

Registry data can offer a reality check and complement clinical trial results when new guideline recommendations or updates are being considered.

Implications for CV Professionals

Clearly, the CathPCI Registry has its pulse on what is happening with PCI in the U.S. with more than 1,000 participating hospitals. PCI is being used routinely in the U.S., but it can't be said that we have reached all our quality improvement goals. We still need to work on increasing the use of PCI in higher-risk patients who typically are not selected to undergo PCI. We need to identify what features best characterize high-quality PCI, and for the best results, we need more complete participation in this registry by CV practices and hospitals.

The same is true for the AR-G, which reveals many details about improvement in the use of guideline recommendations but points to areas needing improvement. When we look at what proportion of patients in the report received 100 percent of guideline-recommended medical care — and account for patients with contraindications — we find that only 60 percent of patients receive all recommended medications. However, only a small proportion of U.S. hospitals are participating regularly in AR-G, so all CV practices and professionals should interpret the data as indicating that all U.S. hospitals need to participate in a nationwide registry for acute MI care to identify targets for local quality improvement and to optimize acute MI care at all hospitals.

Coordinating Registry Data with Guideline Efforts

In recent years clinical guideline committees have made great strides in reviewing new clinical trial data and updating guideline recommendations accordingly. Registry data can offer a reality check and complement clinical trial results when new guideline recommendations or updates are being considered. One could only hope that in the future, clinical guideline committees could consider registry data along with clinical trial data when they are in the process of updating a guideline and incorporate the information in their deliberation. Nonetheless, registry data are essential to understanding how guideline recommendations are used in practice for acute MI patients and for patients undergoing PCI procedures.

Finally, all practitioners and hospitals need to consider the positive impact of having the data in this report, and if they are not already participating in these or other relevant registries*, it is time to make it happen.

Messenger is associate professor of medicine and director of Cardiac Cath Labs at the University of Colorado Denver, Aurora, Colo.; Rumsfeld is a cardiovascular outcomes researcher at the Denver Veterans Affairs Medical Center, and is associate professor of medicine at the University of Colorado Health Sciences Center; and Roe is associate professor of medicine, division of cardiovascular medicine at Duke University Medical Center and Duke Clinical Research Institute, Durham, N.C.

*** See the PINNACLE Registry article on p. 11 in this issue.**

Cardiology

July – August 2010
Vol. 39, No. 5

Cardiology
is published bimonthly by the American College of Cardiology, 2400 N Street NW Washington, DC 20037-1153.

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The Internet: Not Just for Patients

By Jon C. George, M.D.

The Internet has been available to consumers for more than two decades and as its uses have expanded, consumers have learned to take advantage of it to improve their health. Using multiple functions, they search medical topics or share health information with family and friends using e-mail or blogs. Some consumers join patient groups to discuss concerns, symptoms and provide support.

The Internet provides a wide array of sites for finding and posting health content. A simple Google™ or Bing™ search might return 100,000 or more results on a given disease or health problem. Patients may start a blog about their experiences with a disease, join a more structured group to connect with others with the same condition, or turn to more general social networking sites — such as Facebook, MySpace or Twitter — to tell their health stories.

A recent study by the Pew Internet and American Life Project found that of the 74 percent of U.S. adults online, 60 percent used the research to guide health care decisions for themselves or others for whom they were caretakers. They said that their research results —

- affected their decisions on how to treat an illness or health condition
- changed their approach to managing their own health or the health of another
- altered how they managed a chronic condition or managed pain

Patients with chronic illnesses, such as heart disease, tend to blog or participate in online discussions, listserves or online forums. Most physicians have many patients who come to the office ready to ask questions about what they have read online.

Websites exist that provide ratings for health care providers based on criteria such as peer recognition, patient satisfaction, consumer reviews, medical publications, etc. Some sites provide information about physicians' training backgrounds and career highlights, too.

Patients aren't the only ones online; health care providers increasingly make use of the Internet to submit claims, prescribe medications, verify insurance eligibility, order supplies and more. Other trends include online continuing medical education (CME), physician-only communities, patient interaction and education and telemedicine. Advances in health information technology have also made it easier to share patient records and medical imaging results with the click of a mouse.

The ACC has worked diligently to meet the growing online and mobile needs of the cardiovascular (CV) community. ACC's new website, *CardioSource.org*, includes **CardioSource Communities**, a site for networking, sharing information and asking questions. Through CardioSource Communities, CV professionals may post to forums, start groups, share interesting cases and comment on articles.

The College's **Lifelong Learning Portfolio** reflects the changing environment and movement towards online education. The portfolio serves as a one-stop shop to track Maintenance of Certification (MOC) and CME credits. As well, it provides opportunities to participate in performance improvement or pay-for-performance activities such as the Physician Quality Reporting Initiative (PQRI).

According to a recent ACC CardioSurve survey, more than 50 percent of participants said they use electronic applications or databases to participate in performance measurement activities. The ACC's *CardioSource.org* Website enables easier and more seamless access to these resources.

The ACC also recognizes the critical roles that the web and social media tools play in quality improvement. Initiatives such as the Door to Balloon (D2B) Alliance, Hospital to Home (H2H) and Imaging in FOCUS rely on online forums in which participants share best practices and challenges related to reducing D2B times, hospital readmissions or inappropriate imaging, respectively.

Roughly 75 percent of CV care providers use hand-held devices such as PDAs, Smartphones or iPhones, and a similar percentage wants more mobile and web-based applications. That's the reason the ACC is working to pilot new mobile applications that enable access to clinical guidelines and appropriate use criteria at the point of care. The College is also exploring ways to link registry use to recognition, reporting and even payment.

By pooling our collective knowledge, we can further enhance the care we provide to patients. Be sure to visit *CardioSource.org* and start sharing your knowledge today.

George is director of clinical research at Deborah Heart and Lung Center in Browns Mills, N.J., and a member of the ACC Interventional Scientific Council.

Reference

Fox, S. and Purcell, K. (2010). Chronic Diseases and the Internet. Pew Internet & American Life Project, Pew Research Center. Available: *pewinternet.org/Reports/2010/Chronic-Disease.aspx*.

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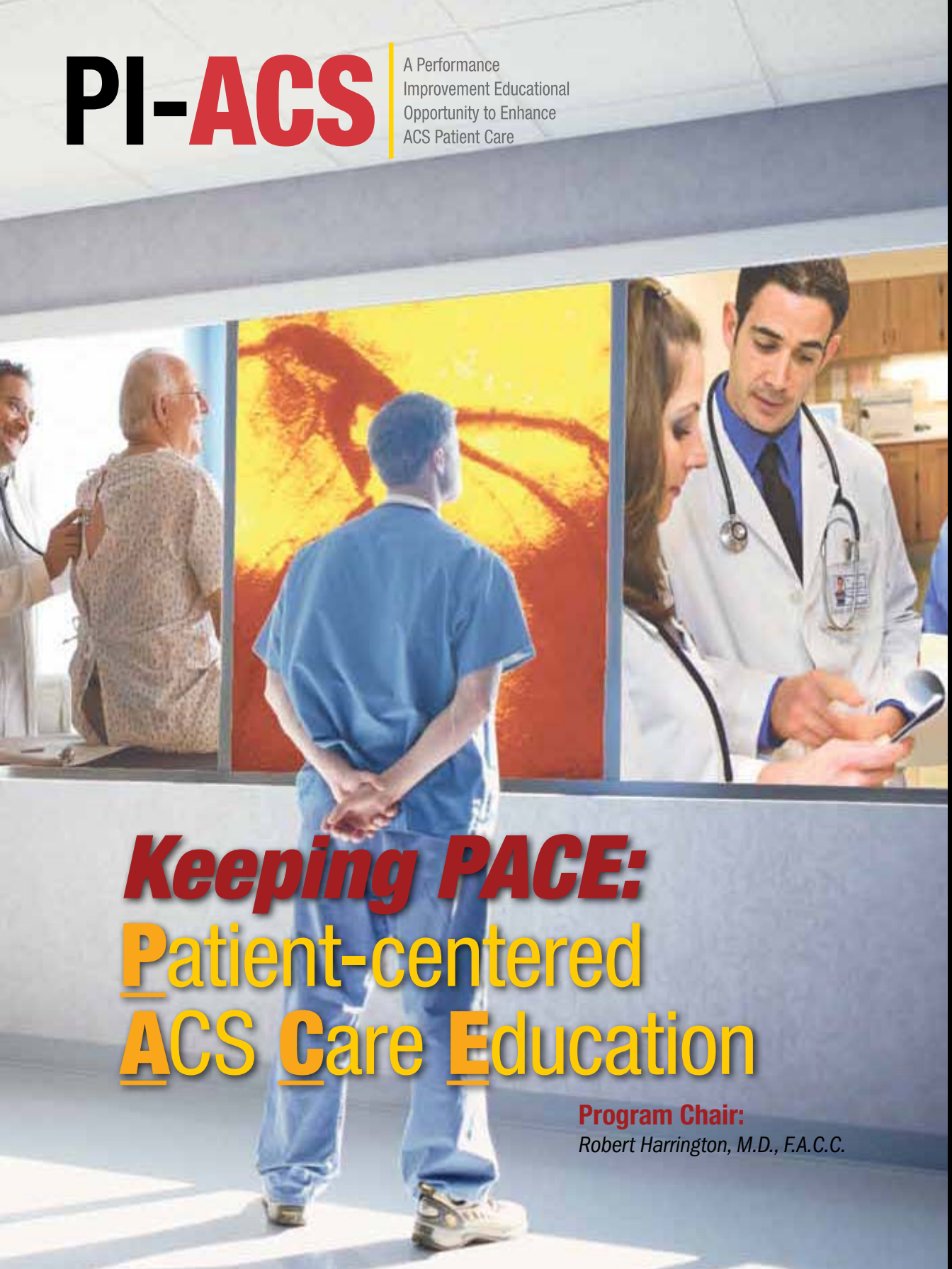
A Performance Improvement Educational Opportunity to Enhance ACS Patient Care



Keeping PACE:
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FDA Panel Votes to Keep Rosiglitazone on Market

Mixed Recommendations, Stronger Warnings Suggested

Following an intensive two-day hearing regarding the conflicting data surrounding rosiglitazone (Avandia), a U.S. Food and Drug Administration (FDA) advisory panel voted in late July to keep the drug on the market with the addition of warnings and stricter product labeling.

Of the 20 members who voted not to remove the drug, the overwhelming majority recommended that it include stricter labeling. Half of those votes suggested that rosiglitazone be restricted to prescription only by physicians with special knowledge in use of the drug. Some panelists also indicated that additional patient education is needed. Only three of the panelists voted to keep rosiglitazone on the market without additional product labeling. The 12 members recommending removal of rosiglitazone argued that pioglitazone works just as well without the known added risks of ischemic events.

The panel was also tasked with making recommendations in eight additional areas, including safety of rosiglitazone as compared to pioglitazone and other hypoglycemic drugs. In evaluating whether rosiglitazone presents greater risk compared to non-thiazolidinedione (TZD) diabetes drugs and pioglitazone, the panel voted 18-6 in favor of the notion that sufficient evidence exists to support an increased risk of ischemic cardiac events with rosiglitazone as compared to non-TZDs. Nine voting members were unable to make a decision on this specific point. The panel also voted 21-4 when asked to determine whether rosiglitazone is less safe than pioglitazone. Eight panel members were unable to decide.

In addition to voting on whether or not the drug should remain on the market and specific safety concerns relative to comparable drugs, the panel was charged with recommending whether or not TIDE, the ongoing international trial designed to compare rosiglitazone to pioglitazone with respect to risk of myocardial infarction (MI), should continue. In a 20-10 vote, the panel recommended that TIDE carry on (one panelist did not vote and another two were no longer present at the FDA meeting).

Of the 20 members who voted not to remove the drug, the overwhelming majority recommended that it include stricter labeling.

Though the FDA panelists failed to reach a unanimous consensus on any of the nine recommendations, they agreed the available data are confusing and additional information is needed. They also seemed to agree that many flaws exist in the data presently available.

"Based on the panelists' comments, there were no easy answers here," said ACC President **Ralph Brindis, M.D., M.P.H., F.A.C.C.,** in a statement following the hearing. According to Brindis, until there is further evidence, physicians should continue working with their patients on a case-by-case basis to determine risks and benefits of rosiglitazone in considering available treatment alternatives.

The meeting marked the second time the FDA convened a panel to review data on rosiglitazone. The first advisory panel was held in 2007 following a publication in *The New England Journal of Medicine* linking the drug to heart disease risks. At that time, panelists determined that the drug should stay on the market and recommended the addition of a black box warning indicating that rosiglitazone should not be used for patients requiring insulin, patients with a history of coronary artery disease, congestive heart failure or long-term users of nitrates. To underscore the difficult nature of the task at hand, many of the same experts who voted to keep rosiglitazone on the market in 2007 voted to either remove or restrict the drug at this time.

As of press time, the FDA had not made a final decision on the fate of rosiglitazone. Though the agency is not obligated to follow the recommendations of its panel, it often does. Stay tuned to *CardioSource.org* for updates. You can also share your thoughts on the FDA decisions via the ACC in Touch blog.

Breaking News on TIDE Trial

The FDA on July 21 ordered enrollment in the TIDE trial to stop. Patients already enrolled in the trial can continue to participate. The FDA advisory panel did not vote on whether to halt enrollment in the TIDE trial.

ACC, AHA Clinical Alert Addresses FDA Clopidogrel Warning

By David Holmes Jr., M.D., F.A.C.C.

The March 2010 "boxed warning" on clopidogrel by the Food and Drug Administration (FDA) understandably raised many questions for practitioners and patients. For that reason, a writing committee of the ACC Foundation and the American Heart Association (AHA) has developed and published a clinical alert, "ACCF/AHA Clopidogrel Clinical Alert: Approaches to the FDA 'Boxed Warning'."*

The FDA alert is the third label warning in the past year to address the potential diminished effectiveness of clopidogrel with patients whose ability to convert the drug into its active form is compromised. The warning refers to patients who are poor metabolizers of clopidogrel, which relies on a patient's cytochrome P450 (CYP) system to be activated. A small number of patients with genetic polymorphisms that result specifically in decreased CYP2C19 metabolize clopidogrel poorly, which could lead to increased risk of cardiac, cerebrovascular and peripheral arterial events. The boxed warning also informs prescribers and patients as to the availability of genotype assays to determine impaired CYP2C19 function. However, the FDA is not recommending the assays, and the decision to test or not resides with the physician and patients.

The ACCF/AHA clinical alert provides important background to help cardiovascular professionals and other practitioners understand the issues and care for their patients. The contents provide extensive details including —

- detailed explanations on genetic variability, clopidogrel responses and other genetic polymorphisms
- status update on CYP2C19 genotyping assays and a review of the pharmacodynamic studies supporting the alert
- alternative dosing regimens with clopidogrel, use of other medications and a review of ongoing trials
- discussions of issues for consideration and recommendations for practice.

"...CV professionals should rely on their clinical judgment and adhere to the recommended guidelines for clopidogrel dosage."

However, some brief points here can help to provide perspective. The number of patients affected by this genetic polymorphism is in the minority. We know that genetic variability of CYP enzymes and perhaps other genetic polymorphisms may affect platelet function and for this minority of patients, the impact can be quite serious. Yet, the studies supporting this finding are essentially substudies drawn from larger trials related to other issues. This means that, for the most part, CV professionals should rely on their clinical judgment and adhere to the recommended guidelines for clopidogrel dosage. If a patient seems at risk for poor outcomes with the use of clopidogrel or is responding poorly to treatment with clopidogrel, commercially available genetic testing for CYP2C19 variants is possible. However, payers will not cover the costs and the tests are expensive.

We need to recognize that although pharmacogenomic testing is the focus of ongoing trials, it is still in the early stages and we have little solid information about its predictive value. In other words, we have pieces of information that help us connect the dots and that's what the clinical alert attempts to do, but the science of personalized medicine isn't there yet. For most patients, the answer to successful treatment resides in the use of acceptable alternative strategies and careful follow-up by their providers.

Cardiovascular professionals should review the ACCF/AHA clinical alert carefully, stay up-to-date on the issue and clinical guidelines, and use clinical "common sense" in caring for their patients.

Holmes is ACC president-elect and chair of the writing committee for the clopidogrel clinical alert.

* Available in the *Journal of the American College of Cardiology*, July 20, 2010, and available at *www.cardiosource.org*.

Registry Program Shows Varying Performances with Outpatient Care

By William J. Oetgen, M.D., M.B.A., F.A.C.C.

A study of clinical data from the first full year of ACC's PINNACLE Registry™, which measures quality of care for cardiac outpatients, reveals wide-ranging compliance rates with ACCF/American Heart Association (AHA) cardiac performance measures and gaps in care.

The PINNACLE Registry, formerly known as the Improving Continuous Cardiac Care Program or IC³, was launched in 2007 and is the first national office-based cardiac quality improvement registry in the U.S.

"Cardiac Performance Measure Compliance in Outpatients," a study of PINNACLE Registry clinical data from July 1, 2008, through June 30, 2009, has been published in the *Journal of the American College of Cardiology* (J Am Coll Cardiol 2010;56:8-14) and is online at *CardioSource.org*. The lead investigator of the study is **Paul S. Chan, M.D., M.S.,** of the Mid America Heart Institute and the University of Missouri, Kansas City, Mo.

This initial look at what is happening in outpatient care of cardiac patients sought to review compliance with ACCF/AHA performance measures for coronary artery disease (CAD), heart failure, hypertension and atrial fibrillation. The study also includes a secondary analysis of selected compliance measures with regard to sex or race.

The study sample represents some 14,000 patients from 27 U.S. cardiology practices. The information starts the more formal process of tracking and improving outpatient care for cardiac patients. The key findings point to:

- wide variations in the compliance rates ranging from 13 percent to 97 percent for CAD and heart failure performance measures
- no significant differences in compliance when assessed by sex and race

- the PINNACLE Registry's ability to assess all but one of the 25 pre-defined performance measures

This preliminary study emphasizes the need for more studies to examine trends in compliance with performance measures and the impact of compliance as it relates to patient outcomes, such as readmission rates. The PINNACLE Registry should help also in defining the characteristics of practices at the highest levels of improvement and performance.

In these study results, the numbers for compliance with CAD performance measures related to "screening for diabetes mellitus" and "cardiac rehabilitation referral" were disappointingly low. With heart failure, "initial laboratory tests on new heart failure diagnosis" were very low, also. Further analyses of the data will help determine if these numbers reflect what is really happening in outpatient cardiac care. As of June 2010, the PINNACLE Registry database contains more than 600,000 patient encounters.

Increased participation in the PINNACLE Registry will provide cardiovascular professionals with the information they need to improve quality of care and outcomes for cardiac outpatients. Initially, many busy practices were reluctant to sign up for "more paperwork or data input requirements." However, the PINNACLE Registry has improved its data collection methods by providing direct data extraction from electronic health records, thus reducing redundancy of effort.

Practices will also find an economic incentive because they will have a system that improves reporting of performance for the Physician Quality Reporting Initiative (PQRI). With PQRI, it truly is beneficial for a practice to provide the most complete information on its patients.

Most important, the PINNACLE Registry will provide a better picture of the quality of care that is being delivered and how it might be improved.

Oetgen, one of the PINNACLE investigators, is at Georgetown University School of Medicine, Washington, D.C.

CMS Releases Proposed 2011 Medicare Physician Fee Schedule

On June 25, the Centers for Medicare and Medicaid Services (CMS) released its proposed 2011 Medicare Physician Fee Schedule, which includes both payment and payment policy proposals for all physician services. Overall, the rule does not include any egregious policy proposals on the scale of those included in last year's fee schedule. That being said, while there were some positives, cardiovascular professionals will continue to feel the downstream impacts of policies that were finalized in 2010. As in past years, increases and cuts for cardiovascular services are dependent on the services provided by the practice. The following is a high-level overview of provisions in the rule affecting cardiology:

Practice Expense

CMS estimates the aggregate impact on cardiology to be negative 2 percent as a result of the second year phase-in of the cuts associated with the AMA Physician Practice Information Survey (PPIS). This was an expected reduction and there are no other provisions with major negative effects. However, the impact on practices depends on the mix of services.

Nuclear Imaging

In the 2010 rule, CMS substantially reduced the payment for myocardial perfusion imaging by reducing both the physician work value and the practice expense value. To make matters worse, because there was a new code for the service, CMS did not apply the four-year transition of the practice expense cuts and instead used the fully implemented value. In the proposed 2011 rule, CMS did not respond to requests from the ACC or members of Congress to phase-in the cuts over four years, so the proposed relative value unit (RVU) is nearly identical to that for this year.

Practice Expense and Malpractice RVUs

CMS has proposed some changes to the technical underpinnings of the RVUs, including reallocating the shares of total physician fee schedule payments for each of the RVU components – physician work, practice expense and malpractice expense. Under the proposal, all practice expense and malpractice RVUs would be adjusted slightly upward to reflect data showing that practice expenses and malpractice expenses have grown relative to physician earnings. Since the entire payment pool must remain budget neutral, this would require a downward adjustment to work RVUs, but CMS proposes instead a decrease to the conversion factor in order to maintain stable work RVUs. CMS projects that the reallocation will be neutral for overall cardiology payments.

Equipment Utilization

Under the new health reform law, CMS must establish the equipment utilization rate for CT, MR and PET at 75 percent. CMS had previously set the equipment utilization rate for this equipment at 90 percent, phasing in reduced payments over four years. The impact on cardiology payments will be minimal due to other fee schedule provisions that determine the payment for CT and PET and the limited use of MR in the office.

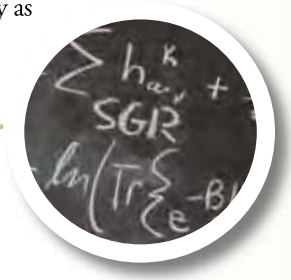
Multiple Procedure Reductions

As part of health reform implementation, CMS is proposing to further increase the reduction for the technical component of imaging services on adjacent body parts from 25 percent to 50 percent. In addition, CMS has proposed expanding the number of procedures included under this policy. No commonly provided cardiology procedures are included on the list.

Self-Referral

The new health reform law requires that physician practices furnishing PET, CT or MRI under the in-office ancillary services exception to the physician self-referral (Stark) law provide a notice to patients referred for such services of their ability to obtain those services elsewhere.

The notice must include a list of other sources of the services. Under the law, CMS also has the discretion to include other radiology services. The good news is that CMS is not interested in expanding this provision to services beyond the three explicitly mentioned in the statute. In addition, despite the provision's statutory effective date of Jan. 1, 2010, CMS has determined that it cannot be effective without a regulation. Thus, the notice and disclosure requirement will not go into effect until the final Medicare Physician Fee Schedule is implemented in January 2011 and will not apply to services furnished at any point during 2010. This eliminates concerns that the regulations would somehow be made retroactive to services furnished as early as January 2010.



SGR

The proposed rule includes CMS' estimate of the 2011 conversion factor based on current law and does not reflect the six-month patch signed into law in June. Congress will have to act again to prevent the 2011 sustainable growth rate (SGR)-related cuts, currently estimated at 6 percent on top of the 21.5 percent cut that must be averted before Dec. 1.

PQRI

The proposed rule includes some changes to the Physician Quality Reporting Initiative (PQRI). However, these changes will likely have minimal impact on cardiologists. The biggest change is the lowering of the threshold for successful participation in claims-based PQRI decreases from 80 percent on three measures to 50 percent on three measures. Since most cardiology measures may only be reported through a registry, the impact is rather minimal. As part of this rule, CMS is required to propose a reduced bonus payment of 1 percent of allowed charges for successful participation in PQRI in 2011.

Value-Based Purchasing

Part of the reform bill includes an allowance for CMS to adjust physician payments based on quality starting in 2015. In the proposed rule CMS begins the process of defining a quality physician. The ACC will work closely with CMS to ensure that if such an adjustment is in place in 2015, it uses the validated performance measures with risk adjustments and appropriate accountability.

The proposed rule is open for public comment until August 24. The College, as always, will submit detailed comments and meet with CMS staff as needed. Stay tuned to *The Advocate*, *CardioSource.org* and *Cardiology* for more information. For questions, please contact *advocacydiv@acc.org.*

Important Notice

It's important for cardiology practices to realize that although CMS projects the impact of the proposed 2011 rule on cardiology to be negative 2 percent, the actual impact may vary from practice to practice. First, CMS' projections reflect the estimated change in payments for the entire pool of services reported by cardiologists. Practices providing a mix of services that differ from the service mix provided by cardiologists as a whole, will see different impacts. In addition, the RVUs and payment policies implemented in 2011 may still change when the final rule is released in early November. The most significant issue for cardiology that is not addressed in this proposed rule is the implementation of new bundled CPT codes for reporting diagnostic cardiac catheterization and lower extremity revascularization. The new codes will be officially published when the AMA publishes CPT 2011 this fall. Interim RVUs for the new codes won't appear until publication of the final rule. The ACC will provide a detailed overview once the new codes are published.

CMS Releases 'Meaningful Use' of Health IT Rule

Rule Defines What Requirements Physicians, Hospitals Must Meet to Qualify for Incentive Payments

The Centers for Medicare and Medicaid Services (CMS) on July 13 released its much-anticipated final rule that defines the criteria for "meaningful use" of electronic health records (EHR) under the EHR Incentive Program. The EHR Incentive Program provides up to $44,000 in incentives over five years under Medicare and $63,750 under Medicaid to physicians who can meet the requirements stipulated in the final rule. The rule includes a staged approach to adoption, with the requirements for participation progressively becoming more challenging over the course of the five-year program.

The ACC commented on the initial rule, articulating support for the staged approach so as to allow physicians and in particular, small practices, time to purchase and use health IT, and provided extensive feedback to CMS and the Office of the National Coordinator (ONC) for Health Information Technology, throughout the process. The final rule appears to indicate that CMS and ONC heard ACC's concerns.

To be defined as a "meaningful user" of an EHR, physicians must meet 15 required "core set" measures and five out of 10 optional "menu set" measures. This represents a departure from the proposed rule published in January in which the physician had to meet all 25 requirements in their entirety.

Rule Specifics

To be defined as a "meaningful user" of an EHR, physicians must meet 15 required "core set" measures and five out of 10 optional "menu set" measures. This represents a departure from the proposed rule published in January in which the physician had to meet all 25 requirements in their entirety. Within the measures, the metrics for satisfying compliance have been scaled back. For example, the final rule keeps the requirement of the proposed rule for use of computerized physician order entry (CPOE) but lowers the participation threshold. The proposed rule required that physicians run 80 percent of their orders through CPOE; the final rule requires that medications, lab tests, and radiology studies be ordered via CPOE, with the metric being that CPOE be used for at least 30 percent of the medication orders.

Additional flexibility has been added with respect to clinical quality measurement. The rule reduces the number of quality measures that must be reported to six. This includes a core set of three quality measures, three alternatives and three more that can be selected by the physician. The final rule eliminates the requirement that 3-5 specialty-specific measures be reported in favor of this more flexible approach to reporting quality metrics.

CMS and ONC also removed several requirements, primarily administrative transactions, from the list of requirements. The proposed rule required professionals to submit claims electronically, as well as to perform the HIPAA eligibility transaction. The ACC and other professional associations

successfully argued that these requirements were inappropriate at this time, especially with respect to the HIPAA eligibility transaction, which most health plans, including Medicare, have not fully implemented.

In addition, the final standards and certification criteria have been adjusted to require that certified systems be able to electronically produce reports for all measures, so professionals will not need to track compliance via paper-based processes.

Beginning in 2011, cardiovascular professionals can register to participate in the program. The reporting period for a provider's first year is any 90 consecutive days, so providers will be able to attest to success for 2011 in April. CMS anticipates making the first payments the following month.

ACC Actions, Resources

The College is reviewing the final rule and will provide additional information soon. Stay tuned to "The Advocate" and CardioSource.org/HealthIT for more detailed analysis of the rule in coming weeks. PDFs of the core and menu set measures, along with the clinical quality measures, are available on this page. You also can share your thoughts about the rule on ACC's blog, available at *blog.cardiosource.org*.

In addition, CMS has developed a comprehensive website that includes FAQs and other information about meaningful use and the federal incentive program in general. It is available at: *cms.gov/EHRIncentivePrograms*.

Medicare Enrollment Tied to EHR Incentive Program

The Centers for Medicare and Medicaid Services has announced that Provider Enrollment, Chain and Ownership System (PECOS) records will be used to verify Medicare enrollment prior to making any Medicare EHR incentive payments. Physicians planning to participate in the EHR incentive program must have enrollment information in PECOS as soon as possible.

Physicians enrolled in Medicare before November 2003 and who have not updated their Medicare enrollment information since then, must enroll in PECOS. Physicians enrolled in Medicare after November 2003, or those that have updated Medicare enrollment information since November 2003, are already in the PECOS system. For more enrollment information, including changes as a result of the new health reform law, go to *CardioSource.org/practice-management* and click on "Coding and Billing."

FDA Reviewing ARBs and Cancer Risks

In a notice posted on its website on July 15, the U.S. Food and Drug Administration (FDA) said it is conducting a review of angiotensin receptor blockers (ARBs) after a recently published study in *Lancet Oncology* suggested they may be associated with a small increased risk of cancer.

According to the notice, the FDA plans to review the available data on these medications, and evaluate additional ways to better assess a possible link between use of ARBs and cancer. The agency will update the public when this review is complete.

In the meantime, the FDA stresses that its review is ongoing and that the "benefits of these medicines continue to outweigh their potential risks." In addition, the agency recommends that ARBs continue to be used as recommended in their approved labels.

For more on the study, go to the ACC in Touch blog (*blog.cardiosource.org*) where **Jeffrey Anderson, M.D., F.A.C.C.,** chair-elect of the ACC/American Heart Association Task Force on Practice Guidelines and Vice Chair of the 2010 UA/NSTEMI Focused Update, discusses the issue. The September/October issue of *Cardiology* will feature additional commentary.

ACC Initiative Aims to Assist with EHR Selection Process

Selecting the right electronic health record (EHR) is dependent on a variety of factors, including practice goals, office size, technological capabilities and expertise, and cost. Unfortunately there is no "one-size-fits-all" product or process and it is no wonder that most practices consider the process to be daunting.

In order to help cardiovascular professionals navigate the EHR selection process, the ACC has launched an "EHR Selection Initiative" that includes access to discounted consulting services, as well as online tools and resources. The consultants – who must meet ACC's minimum criteria – can help practices identify their specific needs; provide an understanding of the various EHR systems; and assist with contract and negotiation processes.

The following consultants are participating in the program:

- AC Group, Inc.
- Healthcare Informatics Associates (HIA)
- MedCo Data, LLC
- Physicians EHR, Inc
- Welch Allyn EHR Prep-Select Services

For more information on each consultant, as well as a complete list of the criteria they must meet, go to *CardioSource.org/healthit*. These items are included as part of the College's "EHR Toolkit."

Special Report from the AMA 2010 Annual Meeting

by Jerry D. Kennett, M.D., F.A.C.C.

The American Medical Association (AMA) held its 2010 annual meeting in Chicago in June. The two-week meeting included the inauguration of Cecil Wilson, M.D., as incoming AMA president, as well as consideration of more than 200 resolutions and reports, many of which were important to cardiology.

Dr. Wilson's inaugural address focused on the healing process he felt needed to occur as a result of the divisive health care reform debate. He emphasized both the positive aspects of the health care reform package, as well as outlined additional measures and revisions necessary to making the law better.

The majority of the meeting was focused on the many resolutions and reports debated at both the Reference Committee and House of Delegates (HOD) levels. The ACC submitted a resolution (Resolution 118) that focused on "Bundling of Existing CPT Codes and Transitioning Payment Changes" and included the following three resolves:

1. Our AMA strongly urges CMS to not treat bundling of existing services into a common code as a new procedure and new code.
2. Our AMA will work with CMS to smoothly transition codes where the cuts resulting from the identification of misvalued services are greater than 15 percent from the value of the existing codes by phasing in the code, or by some other method to ease transition.
3. The AMA RUC will take into consideration CMS willingness or reluctance to transition large payment reductions as it determines relative values for bundling services or other codes that come before the RUC as a result of the identification of potentially misvalued services.

This resolution, which was debated in Reference Committee A and adopted on the consent agenda by the HOD, is now AMA policy.

Another important resolution (Resolution 214), that came out of the AMA HOD, directs the AMA Board of Trustees (BOT) to immediately formulate legislation for an additional payment option in the Medicare Fee for Service program. This option would allow patients and physicians to freely contract, without penalty to either party, for a fee that differs from the Medicare payment schedule in a manner that does not forfeit benefits otherwise available to the patient. It further directs the AMA to have this legislative language available to AMA members no later than Sept. 30. This resolution is in addition to previous AMA policy that supports Medicare balance billing and the ability for physicians to freely contract with their patients.

Other issues important to the ACC and its membership were CEJA Report 1, which dealt with financial relationships with industry and continuing medical education. This item was highly debated and eventually was referred back to CEJA. Two resolutions on medical practice

Cardiology Well Represented at AMA Meeting

The ACC was well represented at the AMA's annual meeting by its leaders and staff. Delegates included Jerry D. Kennett, M.D., F.A.C.C.; Kim Allan Williams, M.D., F.A.C.C.; L. Samuel Wann, M.D.; and Suma Thomas, M.D., F.A.C.C.

Alternate delegates were Eugene Sherman, M.D., F.A.C.C.; Joseph Babb, M.D., F.A.C.C.; and James Fasules, M.D., F.A.C.C., who fulfilled a role as alternate delegate, as well as ACC staff.

Kathleen Blake, M.D., F.A.C.C., served as a delegate for the Heart Rhythm Society in its first year as an HOD member. The Section Council Meeting was held on June 12, and other ACC members in attendance included current AMA President James Rohack, M.D., F.A.C.C.; Steven R. West, M.D., F.A.C.C; Gregory Sachs, M.D.; Richard Schott, M.D., F.A.C.C.; Clay Hayes, M.D.; and Patrick Breaux, M.D., F.A.C.C.

guideline development were debated and referred to CEJA for subsequent report as well. As usual, the ACC delegation also supported all efforts regarding tobacco education and prevention, including those related to electronic cigarettes.

The ACC delegation did oppose a resolution (Resolution 216) introduced by interventional radiology, which involved direct physician supervision of non-physician providers performing invasive procedures. The ACC delegation expressed significant concern that the resolution would put unnecessary requirements on operators of fluoroscopic equipment in regard to radiation safety training and management. In addition, setting stringent credentialing requirements for non-physicians using fluoroscopy and CT for invasive procedures could have negative effects on cardiac cath labs and imaging modalities. Following discussion, the American College of Radiology actually removed part of the resolution dealing with training requirements and the resolution was referred to the AMA BOT.

Additional information regarding the many resolutions and reports is available on the AMA website.

Dr. Kennett is chair of the ACC Advocacy Steering Committee.

ACC Supports Medical Isotope Legislation

The ACC and the American Society of Nuclear Cardiology (ASNC) in July sent a letter to Sen. Christopher Bond (R-Mo.) urging action on H.R. 3276, the American Medical Isotope Production Act of 2009. According to the letter, "the legislation is beneficial in restraining the immediate threats arising from the lack of access to a reliable, consistent supply of medical isotopes that thousands of American patients rely on every day."

Molybdenum-99 (Mo-99) is a critical medical radioisotope of which its decay product Technetium-99m (Tc-99m) is used in more than 16 million nuclear medicine procedures annually across the nation. Physicians use Tc-99m for the diagnosis of heart disease, common cancers and other diseases. Unfortunately, the domestic supply of Mo-99 is entirely dependent upon aging foreign reactors that have faced extended shutdowns for repair and maintenance over the last few years. As a consequence, the U.S. supply has been repeatedly and significantly disrupted and many patients who need imaging with Tc-99m-based radiopharmaceuticals are facing lengthy delays, or are being forced to resort to alternative diagnostic and therapeutic procedures that may involve the potential of more invasive procedures, greater radiation dosage, lower accuracy and higher costs.

To read the full letter, go to *CardioSource.org* and click on "Imaging" under the Advocacy "Issues" section. More information on the medical isotope crisis is also available on the ASNC website (*www.asnc.org*).

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New Study Looks at Radiation Safety and Imaging

A recent study published July 7 in the *Journal of the American College of Cardiology*, found that cardiac imaging procedures lead to substantial radiation exposure for many patients in the U.S. The study looked at administrative claims to identify cardiac imaging procedures performed from 2005 to 2007 in 952,420 non-elderly insured adults in five U.S. health care markets. However, an editorial piece, also published on July 7, notes that further research is needed to clearly document the actual health risks of radiation exposure for patients with cardiovascular disease, including looking at cancer rates.

In addition to supporting the call for more research, the ACC has taken a multi-pronged approach to ensuring radiation safety that balances the intended benefits of the procedure against the radiation risk. The College's strategy includes:

1. setting standards through laboratory accreditation programs, appropriate use criteria (AUC), clinical practice guidelines and other standards documents;
2. developing requirements for training programs and competency, including how to minimize radiation doses during testing and procedures; and
3. implementing quality improvement programs aimed at lowering the dose for each scan or procedure performed.

The ACC also firmly believes that patients must be involved in the decision-making process regarding their care. For more information on the ACC's radiation safety efforts and to share your comments on the new study, visit the ACC in Touch blog (*blog.cardiosource.org/post/Radiation-Safety.aspx*). You can also go to the "Advocacy" section of *CardioSource.org* and click on "Issues" and then "Imaging." The ACC's "Imaging in FOCUS" initiative also offers medical imaging providers educational tools and resources to ensure the right test at the right time. For more information on FOCUS, visit: *CardioSource.org/FOCUS*.

CMS Begins Outreach on Imaging Accreditation Requirement

The Centers for Medicare and Medicaid Services (CMS) has started general outreach to enrolled physicians, non-physician practitioners and independent diagnostic testing facilities (IDTFs) about the need to become accredited to continue to provide advanced diagnostic imaging services to Medicare beneficiaries as of Jan. 1, 2012. Providers that have furnished advanced diagnostic imaging procedures within the last six months will receive the first of five letters in July urging them to begin the accreditation process as soon as possible in order to meet the 2012 deadline. The accreditation process can take up to nine months to complete. The ACC has developed an "Accreditation FAQ" to help answer any questions about the process. The FAQ, along with other accreditation information, can be accessed in the "Advocacy" section of *CardioSource.org*. Look for "Imaging" under the "Issues" section.

ACCF Risk Management Institute to Launch in August

Cardiovascular (CV) physicians and practices will soon have access to cardiology case-based risk management education tools and information with the August 2010 launch of the ACC Foundation Risk Management Institute (ACCRMI). The goal with ACCRMI is to help CV physicians and practices increase patient safety and reduce the risk of medical professional liability (MPL) claims.

"Effective risk management education should provide CV professionals with quick access to timely, cardiology-focused risk management information of real value," says **John G. Harold, M.D., M.A.C.C.,** chair of the MPL Working Group. "The information needs to have a demonstrably practical use, and when possible, risk management resources should be linked to quality improvement and claims prevention opportunities."

> **"Effective risk management education should provide CV professionals with quick access to timely, cardiology-focused risk management information"**
>
> John G. Harold, M.D., M.A.C.C., chair of the MPL Working Group

To that end, ACCRMI's education tools draw from real life in CV medicine because they are built from data regarding trends analysis gathered from closed medical professional liability claims involving the treatment of CV disease. The Physician Insurers Association of America (PIAA) shared the information from 23 years of closed claims (1986 to 2008) with ACC to help develop the ACCRMI.

"By reviewing these closed claims from different regions across the U.S., we were able to identify trends that provide a real-life basis for ACCRMI's information," adds **William J. Oetgen, M.D., M.B.A., F.A.C.C.,** co-chair of the MPL Working Group.

RMI participants will have access to many tools, including:

- case studies with cardiology-specific medical-legal commentary
- educational modules with CME/CE credit and access to an online forum
- e-alerts on time-sensitive risk management topics
- e-bulletins filled with real-life applications of techniques and procedures to reduce risk and limit exposure to professional liability claims.

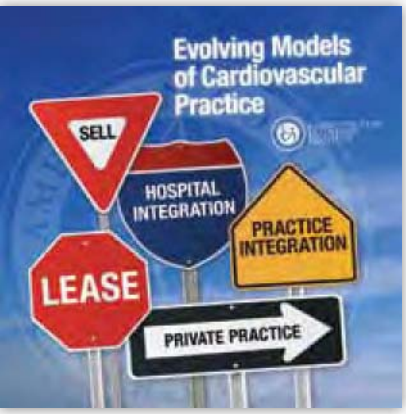
Also, participants will be eligible for discounts on insurance from partnering companies and significant discounts on programs from Emmi™ Solutions, which offers patient communications tools. In addition, the ACCRMI has formed a strategic partnership with the Risk Management and Patient Safety Institute (RM&PSI). RM&PSI is a national leader in clinical risk management practices and patient safety programs for health care institutions and providers.

The ACCRMI exemplifies ACC's strong and active commitment to assisting cardiologists with the improvement of their individual practices, the enhancement of quality and patient outcomes, and the visibility of cardiology as a medical resource for the general public.

To learn more about the ACCRMI, go to *CardioSource.org*, and click the "Practice Management" bar at the top.

Second "Evolving Models of Cardiovascular Practice Symposium" Proves Successful

Building on the success of the first "Evolving Models of Cardiovascular Practice" symposium held shortly after the Centers for Medicare and Medicaid Services (CMS) released the final 2010 Medicare Physician Fee Schedule, the ACC's Cardiovascular Leadership Institute (CLI) held a second symposium in June in Las Vegas.



The intensive two-day practice management symposium brought together more than 215 participants to hear from experts on the ground about the ins and outs of practice mergers and hospital integration. Topics included:

- Understanding Practice Financials
- Practice and Physician Alignment Models
- Governance Structure Pre- and Post-Transactions
- Compensation Models
- Hospital CEO Vantage Point of an Integrated System

Participants came away with the leadership skills, experiences and tools necessary to help their practices thrive despite the challenging health care environment. The program will be held again in early November. For more information on the November symposium, as well as practice management resources, go to *CardioSource.org/practice-management.*

CMS Technical Correction Update

The ACC has received word from the Office of Inspector General (OIG) that physicians will not have to charge their patients additional copay amounts as a result of the recent CMS technical corrections to the 2010 Medicare Physician Fee Schedule. While this is good news, the College is still waiting for guidance on when the adjusted payments from Medicare contractors will start. For more information on the new OIG policy, go to: *oig.hhs.gov/fraud/docs/alertsandbulletins/Retroactive_Beneficiary_Cost-Sharing_Liability.pdf.*

Practice Management Briefs

New Medicare Ordering/Referring Policy in Effect

As of July 6, individuals ordering or referring Medicare patients for "specialist services" must be in the Medicare provider enrollment database. The Centers for Medicare and Medicaid Services (CMS) has said it will not automatically reject claims submitted by providers that have attempted to enroll in PECOS. CMS has also said that "until the automatic rejections are operational, providers should not see any change in the processing of submitted claims, they will continue to be reviewed and paid as they have historically been reviewed and paid." The ACC continues to request that CMS issue additional guidance and instructions as soon as possible to allow for the education of physician practices and their staff around any changes in claims submission that must occur. For more information, go to *CardioSource.org/practice-management* and click on "Coding and Billing."

MRA Coverage Changes

All physicians, providers and suppliers submitting claims to Medicare contractors for Magnetic Resonance Angiography (MRA) services should note the following change. As of June 3, Medicare contractors now have the discretion to cover or not cover all indications of MRA and magnetic resonance imaging (MRI) that are not specifically nationally covered or nationally non-covered. Existing national coverage for both MRI and MRA will be maintained. For more information, go to: *www.cms.gov/MLNMattersArticles/downloads/MM7040.pdf.*

Donald Berwick Takes the Helm of CMS

President Obama in July appointed Institute for Healthcare Improvement CEO Donald Berwick to be the Centers for Medicare and Medicaid Services (CMS) Administrator. "For all the talk about health care in recent months, not many people truly understand the ins and outs of our nation's health care system. But Don understands the nuances, complexities and difficulties of our health care system and he has long worked side-by-side with physicians to increase the quality of health care while also lowering the cost of its delivery," ACC CEO Jack Lewin said in a statement.

CMS Urging Providers to Prepare Now for ICD-10 Transition

Medical coding in U.S. health care settings is slated to transition from ICD-9-CM to ICD-10 as of Oct. 1, 2013. Everyone who is covered by the Health Insurance Portability and Accountability Act (HIPAA) must make the transition, not just those who submit Medicare or Medicaid claims. The compliance dates are firm and not subject to change. Practices not ready will not have their claims paid. The ACC is encouraging practices to ask their clearinghouse, billing service or software vendor what needs to happen to be ready for ICD-10. For more information about ICD-10 Implementation, go to *CardioSource.org* and click on "Coding and Billing" in the Practice Management section. In addition, a special MLN Matters® Special Edition article is available on the CMS website at: *www.cms.gov/MLNMattersArticles/downloads/SE1019.pdf.*

It's in Their Blood: F.A.C.C. and F.I.T. Make Cardiology a Family Affair

"You don't want to be a doctor. You want to marry a doctor."

These words spoken by her mother were "fighting words" to **Sandra Lewis, M.D., F.A.C.C.,** who knew at age 10 that she wanted to be a doctor. Although discouraged by family and societal norms for women, her love for science and the desire to help people propelled her to where she is today. Lewis is a seasoned cardiovascular (CV) professional with nearly 30 years under her belt, and now her daughter, Lisa Rosenbaum, M.D., is a first-year cardiology fellow.

While their career choices are similar, this mother and daughter have had very different professional experiences. When Lewis began in medicine, she faced patients who distrusted her expertise and senior partners who doubted her ability to negotiate contracts — because she was a woman. In addition, Lewis was pregnant. Lisa was born during Lewis' first fellowship year.

However, the patient and partner reactions only made Lewis more determined to break down barriers. Calling her time at Stanford "magical," Lewis knew that something special was occurring and that she and her colleagues were on the cusp of change for women in medicine, particularly in cardiology. Teaching a new generation of young women to become physicians became a foundation for Lewis, who built her practice on those relationships and cutting edge research on women and heart disease, heart failure, heart transplant and interventional cardiology. Eventually, patient distrust of female doctors dissipated, and the culture of medicine evolved.

That evolution is apparent in her daughter's medical school and fellowship experiences. "There is so much support for being a woman in medicine now," says Rosenbaum. "At every stage of the experience, more doors are open than ever before, and the battle of being a woman in medicine is not nearly what it used to be."

Although separated by decades in training, their advice to women entering the field is the same: "don't be afraid." Working toward a career in cardiology may be tough; however, they both remind interested women that the traditional cardiologist's role is evolving as well. The many subspecialties available in cardiology today offer different lifestyle options for both women and men.

Rosenbaum finds that taking a nontraditional path is still not necessarily easy. Her generation faces a different kind of challenge because of the multiple opportunities to integrate with other academic fields. For example, Rosenbaum hopes to combine her interest in economics, health policy and the psychology of medical decision-making with cardiology to pave a unique career path. Creating a new pathway is a challenge. "It takes perseverance," she says. "But if my mom taught me anything, it is to keep at it."

Still, Rosenbaum says the greatest challenge for her and the field is restoring the positive social view of physicians that existed when her mother began her fellowship. Along with the eroded public perception, there exists also a pervasive sense that physicians are pressured increasingly by administrative duties and financial strains. "We need to make it a pleasure to practice again; otherwise, we will lose the best and the brightest to other fields," adds Rosenbaum.

Lewis' pleasure in practicing medicine is what her family always saw. For Rosenbaum, it really has been a "family business," as her parents, her aunts and uncles, and a grandfather are all physicians and all clearly loved their work. Now, Rosenbaum and her sister are physicians, too.

Rosenbaum knows that the support and wisdom of seasoned CV professionals is a key to growing in the field. For those entering the field without a built-in support network such as hers, she suggests that they find a mentor who cares about them, a person who wants to see them thrive. Rosenbaum looks forward to the day she can serve in that role herself.

Although separated by decades in training, their advice to women entering the field is the same — "don't be afraid."

Lewis practices cardiology at Legacy Good Samaritan Hospital in Portland, Ore., and is governor of the ACC Oregon Chapter and serves on the ACC Advocacy and Women in Cardiology committees. Rosenbaum is a first-year fellow in cardiology at Cornell University.

"We have an excellent working relationship with China in terms of education. The exchange of information between the cardiovascular communities in China and the U.S. is already helping to improve cardiovascular health in both countries. This new initiative will further strengthen these relationships."

former ACC President Alfred Bove, Ph.D., M.D., M.A.C.C.

ACC and China Collaborate on Education Centers, New Chapter

According to a study published in *Circulation* this past May, cardiovascular (CV) disease and death rates in China are projected to increase by as much as 73 percent by 2030. Given these alarming statistics, the American College of Cardiology (ACC) and the Chinese CV community are working together on several new initiatives aimed at facilitating exchanges of information and improving the heart health of the Chinese people.

One such initiative, the "ACC Education Centers & ACC Curriculum (in China)," was launched this past spring with the goal of creating a curriculum based on ACC educational resources and customized to meet the specific needs of the Chinese population. More than 7,000 CV professionals are expected to participate in the curriculum, which is being taught at more than 60 CV specialty hospitals in China designated as ACC Education Centers.

"We have an excellent working relationship with China in terms of education," said former ACC President **Alfred Bove, Ph.D., M.D., M.A.C.C.** "The exchange of information between the cardiovascular communities in China and the U.S. is already helping to improve cardiovascular health in both countries. This new initiative will further strengthen these relationships."

ACC CEO Jack Lewin and ACC President Ralph Brindis welcome the new China Chapter.

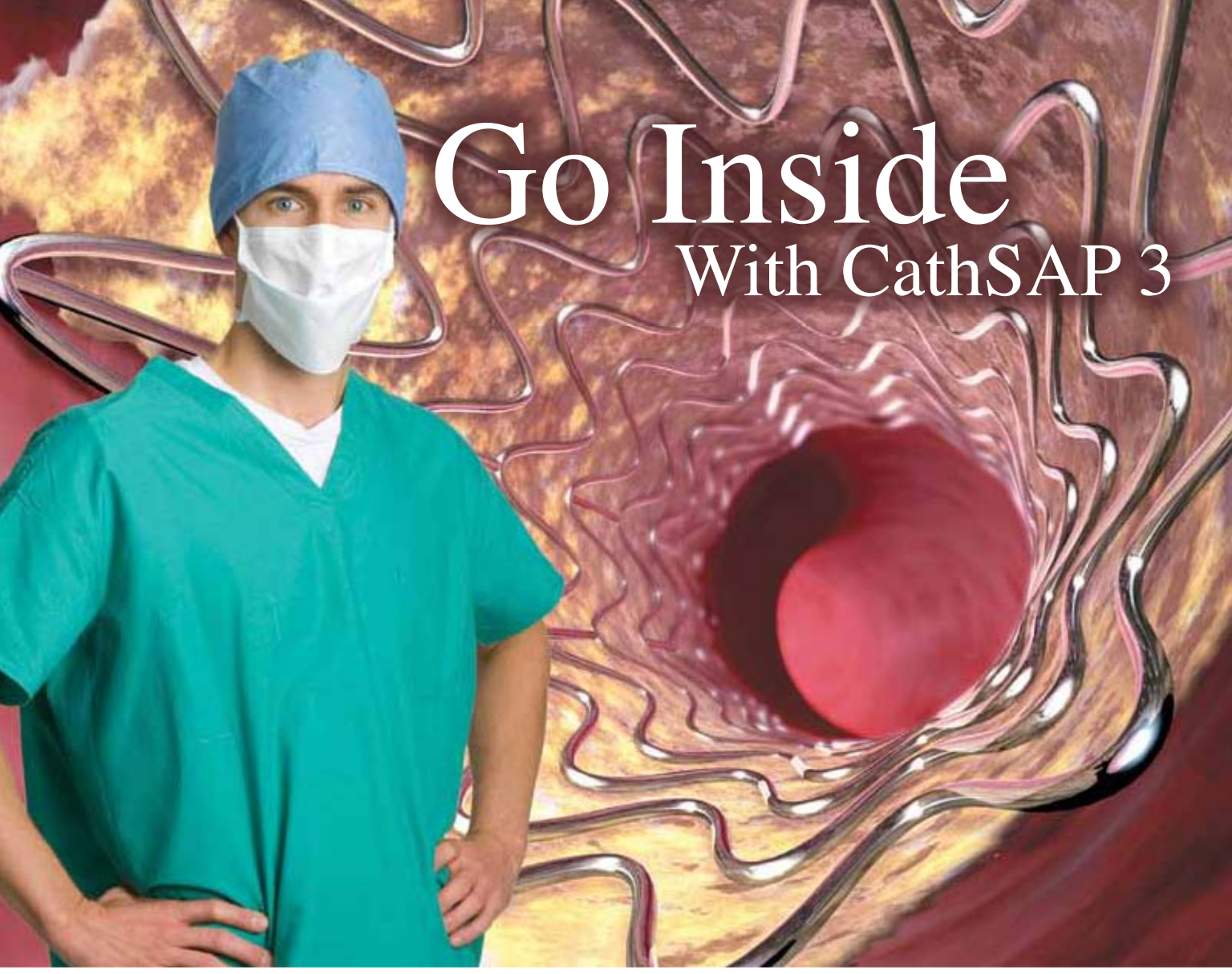
The Chinese Cardiovascular Community turns out to launch the "ACC Education Centers."

The ACC was well represented by leaders and staff at the World Congress of Cardiology in Beijing.

The relationship between the ACC and its Chinese counterparts continues to grow in the form of a new China Chapter as well. The inauguration of the ACC China Chapter occurred in Beijing in June during the World Congress of Cardiology. Working with the Chinese Medical Association, the new Chapter will focus on registry-related quality improvement and research, increased educational cooperation and improving the CV health of citizens in both the U.S. and China.

Also during the World Congress of Cardiology, ACC leaders and staff held a special session focused on the role of registries in measuring and improving performance. ACC CEO **Jack Lewin, M.D.,** discussed how to effectively engage physicians in quality improvement, and ACC President **Ralph Brindis, M.D., M.P.H., F.A.C.C.,** tied in comparative effectiveness and the NCDR®. **Janet Wright, M.D., F.A.C.C.,** explored appropriate use criteria implementation, and **Henry Solomon, M.D., F.A.C.C.,** addressed the critical role of observational data.

For more information about the ACC Education Center initiative, go to: *www.emd-asia.com/ACC_Center/Index.html.*



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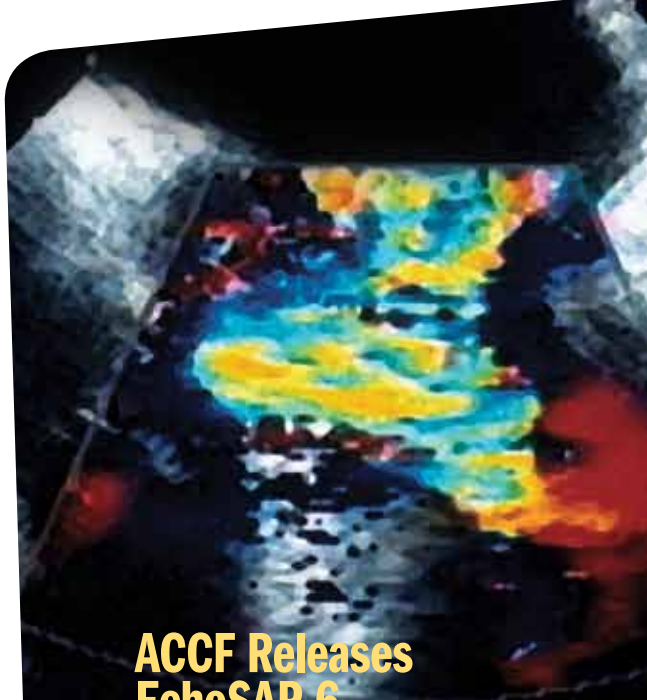
Take Advantage of the ACCF's Maintenance of Certification Tools

The American College of Cardiology Foundation (ACCF) is working with ABIM to help cardiovascular professionals navigate their way through the Maintenance of Certification (MOC) process. Providers with time-limited Board Certificates in Cardiovascular Disease, Interventional Cardiology or Clinical Cardiac Electrophysiology are required by ABIM to participate in MOC. The ACCF has a number of regional conferences, self-assessment tools and initiatives designed specifically to make the MOC process easier. For additional details access ACCF's MOC Toolkit at *CardioSource.org/moc*.

Registration Now Open for NY Cardiovascular Symposium

Join health care professionals from around the world for the 43rd Annual New York Cardiovascular Symposium, Dec. 10-12 at the Hilton New York. The information-packed, three-day conference chaired by **Valentin Fuster, M.D., Ph.D., M.A.C.C.,** provides unique opportunities to discuss and debate cutting-edge issues that impact both the cardiovascular profession and practice. Highlighted topics include such essentials as coronary artery and valvular heart diseases, cardiac and electrical failure and atrial fibrillation. Additionally, participants will benefit from comparing clinical strategies with fellow attendees from a wide spectrum of countries. For more information go to *CardioSource.org/*nycsymposium.



ACCF Releases EchoSAP 6

The American College of Cardiology Foundation has released the new EchoSAP 6, which is designed to help professionals hone their skills in this evolving imaging modality. EchoSAP 6 lets users experience a comprehensive overview of the field in ways that appeal to different learning styles, with two primary educational formats:

1. A "didactic" syllabus that provides an overview of echocardiography, including brand new sections on advanced and emerging technologies in the field, such as tissue-Doppler, strain, and 3-D echo.
2. 80+ image-rich cases studies that allow users to apply what they have learned. These case studies are organized by disease category and address varying levels of expertise, including basic and advanced.

In addition, EchoSAP6 includes larger, higher-resolution videos in response to feedback from purchasers of previous EchoSAP products. The user interface is also greatly improved. For more information, go to: *www.cardiosource.org/EchoSAPHD*

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California CHAPTER

Twinning Program Proves Successful in Building Relationships Abroad

Collaboration, sharing and the drive to positively impact the field of cardiology have resulted in a successful partnership between the American College of Cardiology's (ACC) California Chapter and the British Cardiovascular Society (BCS).

Last year, BCS and the California Chapter announced the launch of the first-ever "Twinning Program." While the two groups may be more than 5,000 miles apart, the program has afforded many unique opportunities to collaborate on educational programs and resources, as well as participate in institutional visits, lecture tours and mini-preceptorships.

Dr. Ralph Brindis, ACC President; Dr. George Smith, ACC Governor Northern California; Dr. Dipti Itchhaporia, ACC Governor Southern, California; Dr. John G. Harold, Past Chair ACC Board of Governors; Dr. Jack Lewin, CEO ACC

Most recently, the partnership resulted in the creation of an ACC-BCS Fellowship in Cardiovascular Imaging. The fellowship is designed as a cooperative training experience between California's Cedars-Sinai Medical Center and London's Royal Brompton Hospital. In addition, ACC leaders recently traveled to Manchester to discuss policy and care delivery at a BCS meeting in June for National Health Service (NHS) commissioners and medical managers. ACC CEO **Jack Lewin, M.D.,** spoke on U.S. health reform and its implications on cardiology, touching on uneven quality, variations in care, poor care coordination and other critical health care issues. ACC President **Ralph Brindis, M.D., Ph.D., F.A.C.C.,** used his presentation to pose the question "Quality vs. Service Delivery – An International Conundrum?"

"We have enjoyed the opportunity to interact with our British colleagues through the twinning pilot and to share experiences that may lead to greater cross-pollination of ideas and concepts and ultimately to improved care of our patients," said former California Chapter Governor **John G. Harold, M.D., M.A.C.C.**

Dr. Harold encourages other ACC chapters to develop similar relationships. The ACC International Council is in the process of analyzing the BCS-CAACC pilot with an eye toward growth opportunities. For BCS and the California Chapter, he notes, that this pilot is not the end of the unique relationship.

"We are excited about the prospects for the future and for building an enduring partnership," he said. "Working together to benefit patients around the globe overcomes geographic boundaries."

Idaho CHAPTER

Idaho Chapter Making Inroads with State Lawmakers

Established in October 2009, the Idaho Chapter of the ACC is one of the newest chapters. However, it is quickly making a name for itself at the state and national level with key lawmakers.

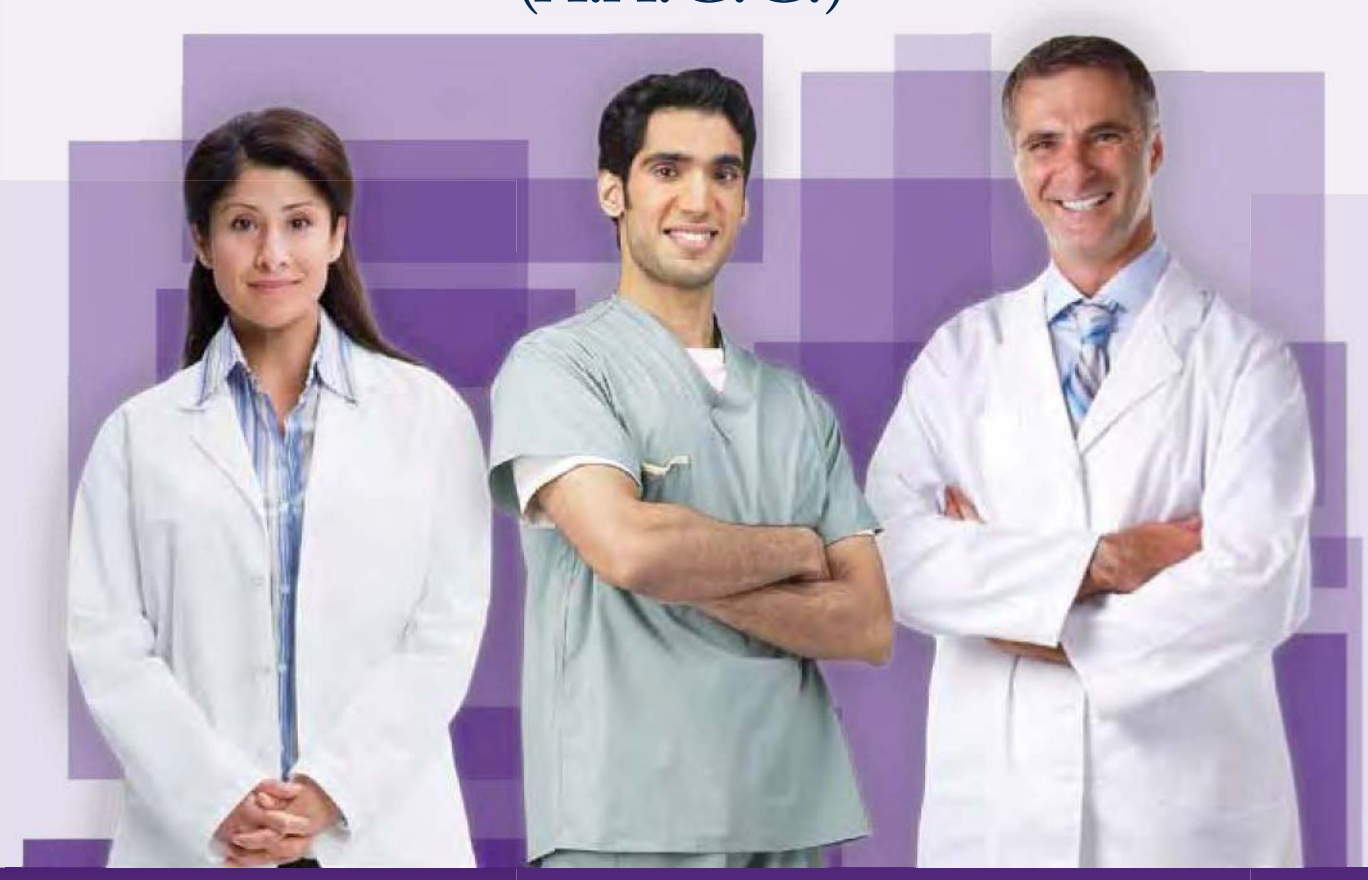
The Idaho-ACC held its first Lobby Day in February 2010. Participants met with the chairs of the state House and Senate health committees, as well as Idaho Lt. Governor Brad Little and Tammy Perkins, the senior special assistant for health and social service to Gov. Butch Otter. Patient access, cardiovascular disease prevention, Medicare payment and tort reform were among the major topics discussed.

Since then, legislation for a tobacco excise tax is expected to be introduced in 2011 and Dr. Gould is working with Chapter leaders and other cardiovascular professionals in the state to encourage greater involvement in educating Idaho lawmakers about key cardiovascular issues. The Chapter is also planning for its next Lobby Day.

"It's not that taxing to spend a day getting to know your local representation," says Chapter President and Idaho Governor **Lee Gould, M.D., F.A.C.C.** "In fact, chances are, in smaller communities, you likely already have a connection. Health care is a local issue and taking initiative early affects more appropriate change."

Taryn Gold of ACC Chapter Affairs says it's significant that Dr. Gould is laying the initial groundwork so future leaders of the chapter won't have to start from scratch. "Member involvement is the biggest challenge we face in organizing Lobby Days," says Gold. "The Idaho Chapter is proof that one of the best things you can do as a new chapter is to just jump in."

Associate of the American College *of* Cardiology (A.A.C.C.)



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Comparing Effectively with NCDR

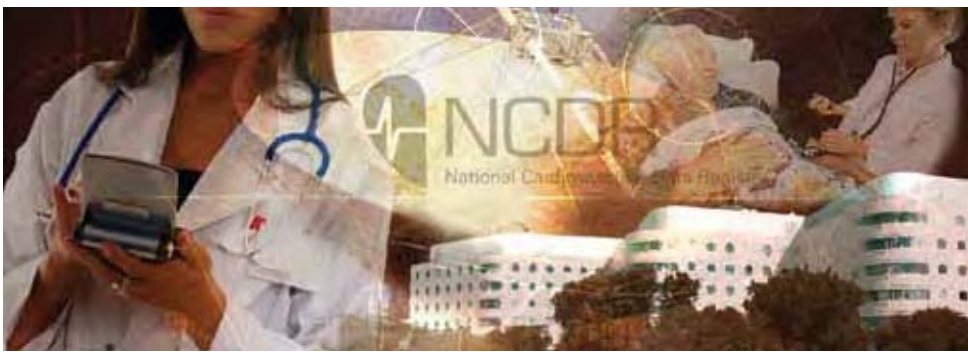
By Colleen Balius, B.S.N., R.N.

My day was winding down and as I entered the elevator to head home, I couldn't help but overhear a conversation between several fellow elevator passengers about where to eat dinner. "Anyone interested in Mexican," one said. The other responded, "Let me check my GPS" and then mentioned the name of a restaurant I knew well. It had great fish tacos, enormous burritos and was ideal for a post-surfing meal. I wondered what the GPS application said. Did it provide information on cost? What about quality, taste and/or food freshness?

These days we seem to thrive off of knowing who is good, who is better, and who is best. We set our calendars for TV shows like "American Idol" and "Dancing with the Stars." And we're OK with the decisions of three or four judges. When it comes to people's medical care processes, how do we find better comparative analysis? Can we compare our own performance at a national level? How about performance and process in the Cath Lab? What about ICDs, their lead success and patient outcomes?

Benchmarking, as defined by Wikipedia, is the process used in management in which organizations evaluate various aspects of their processes in relation to the best practice, usually within their own sector. The ACC's National Cardiovascular Data Registry (NCDR®) has been doing just that for the last 14 years. Each of the six NCDR registries is set up to receive data and aggregate it on a quarterly basis, allowing hospitals – and most recently practices – to benchmark their performance against similar institutions as well as nationally.

Each registry receives data via a secure web-based process. The facility-vetted-data can be directly submitted via the NCDR website or through a third party vendor tool. The NCDR allows facilities to see how they stack up against their peers and gauge where there may be room for quality improvement. Participation in NCDR registries is also recognized by numerous states, private payers, the Centers for Medicare and Medicaid Services (CMS) and quality groups for demonstrating quality for both reporting and pay-for-performance purposes.



NCDR offers an opportunity for all of us to better understand what we're doing and how we can do it better.

What this means for CCAs

As a CCA who works with CathPCI Registry® data, I can say the supreme benefit of submitting data to the NCDR is the ability to review and analyze comparative performance nationwide knowing my goal is to improve quality.

The quarterly "Outcomes Report" each participating hospital or practice receives displays individual measure element aggregation and composite scores. This allows each specific institution or practice to immediately compare their numbers with that of the national average. All CCAs should review these reports.

The NCDR website also provides a portal to a wealth of helpful information, including data definitions, "Frequently Asked Questions," guides to interpreting the quarterly reports and explanations of risk-adjusted algorithms.

As I come across some nuance of performance percentile that differs from my own calculations, I don't hesitate to call the NCDR staff (800- 257-4737) to log in my concern or question. I know that I will receive an e-mail response within 24 hours. Further, I've even requested a custom drill down on patients in the numerator population and have received it, usually within two weeks. I've had the utmost positive experience with the NCDR, even when their figures were justified over my own.

I highly encourage CCAs to learn more about the NCDR registries. In the current environment where being the best – or among the best – is critical, the NCDR offers an opportunity for all of us to better understand a) what we're doing and b) how we can do it better. For more information on the NCDR visit *www.ncdr.com*.

Balius is Clinical Data Coordinator, Heart & Vascular Institute, Hoag Memorial Hospital Presbyterian, Newport Beach, Calif.

Reducing Racial and Ethnic Disparities: credo Advances into Year Two

In 2009, the American College of Cardiology (ACC) launched credo, the Coalition to Reduce Racial & Ethnic Disparities in CV Outcomes, to provide cardiovascular (CV) professionals with evidence-based tools that would help them serve their diverse patient populations better and improve patient satisfaction and outcomes. During the first year of credo, leaders in CV disease research began the development and implementation of evidence-based education to help achieve this goal.

The ACC 2010 Annual Scientific Session provided the launch for credo activities with a symposium focused on the need for reducing racial-, ethnic-, gender- and age-based disparities. A free CME activity is now available online as well. The activity highlights the facts supporting the existence of disparities and points to resources and approaches that will help CV professionals serve their diverse patient populations better. All ACC members and health care providers caring for patients with CV disease may access this free educational opportunity at: *CardioSource.org/credo*.

Education to Improve Data Collection

Evidence of disparities and the impact of educational programs targeting such differences are only as strong as the data on which they are built. To ensure optimal data concerning race and ethnicity in the registries, credo has also worked closely with NCDR® participating hospitals and cardiology practices. The Health Research and Education Trust (HRET) and credo have collaborated to provide an online training program this summer that assists admissions and registry staffs in understanding the importance of collecting the data and offers tips and tools for systematic data collection. For more information on collecting race and ethnicity data go to: *www.hretdisparities.org*.

Performance Improvement Education

As part of the new Keeping PACE: Patient-centered ACS Care Education initiative, physicians and nurses review data from the ACTION Registry®-GWTG™ that concerns hospital care for acute coronary syndrome patients. They then focus their education on specific metrics that show a gap between performance and recommended care. To assist them, credo is developing live educational programs for Keeping PACE that will provide hospitals and practices with the opportunity to examine their data broken down by race, ethnicity, gender and age. This information will help hospitals and practices develop approaches that reduce any disparities in care. Other plans include developing patient education tools that will assist diverse patient populations in understanding their health care needs. Patient education is a key factor for reducing disparities in care. To learn more about Keeping PACE go to: *www.cardiosource.org/Certified-Education/eLearning-and-Products/PI-ACS-Home.aspx*

Moving Forward

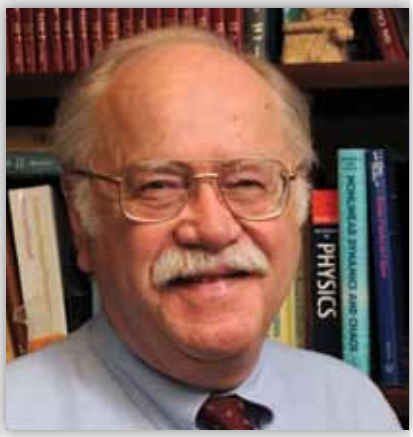
Additional activities and resources are planned for credo's second year, including an increased Web presence, as well as more educational activities to help clinicians translate information and data into improved care and outcomes for all of their patients, regardless of race, ethnicity, gender or age. The hope is that all ACC members and other health care providers who treat patients with CV disease will join credo in a continuing effort to improve care for all patients. To learn more, contact Laura Lee Hall at *lhall@acc.org*.

Note: credo has received sponsorship support from Medtronic, Inc. Additional independent grant support has been provided by AstraZeneca, Daiichi Sankyo Lilly and Novartis.

In Memoriam

Morton F. Arnsdorf, M.D., M.A.C.C.

Morton F. Arnsdorf, M.D., M.A.C.C., a past ACC Secretary, member of the ACC Board of Governors and Board of Trustees, as well as past ACC Illinois Chapter President, passed away June 9 as the result of a motor vehicle accident in Indiana. He was 69 years old.



Arnsdorf earned his bachelor's degree from Harvard University and went on to receive his medical degree from Columbia University's College of Physicians and Surgeons. Following his residency training and a cardiology fellowship, Arnsdorf served in the U.S. Air Force as a major and chief of cardiology at the Air Force hospital in Elmendorf, Alaska. After his service, Arnsdorf then joined the University of Chicago as an assistant professor and worked his way to become the chief of cardiology. It was during this time that he met his future wife, Rosemary, who worked as a social worker and hospice director at the same medical center. He then took on the roles of professor emeritus, associate vice chairman of medicine and vice chairman for appointments and promotions, highlighting Arnsdorf's passion for mentorship and training future leaders.

Arnsdorf was best known for his research on abnormal heart rhythms and the molecular structure of drugs used in their treatment. Arnsdorf and colleagues pioneered the application of nanotechnology to the study of biomedical problems and were the first to report "nanodissection" to study the inner workings of ion channels in a cell wall. Arnsdorf authored or co-authored more than 100 articles and was known as a co-editor of the widely consulted publication UptoDate in Cardiology.

While described as humble and unassuming, Arnsdorf was well decorated with honors in the field. Included in the list of his numerous leadership positions and awards, Arnsdorf was recognized by the College with the ACC's Distinguished Fellow Award and he was elected by his peers to be a Master of the American College of Cardiology, an honor bestowed on fewer than 60 cardiologists in the United States.

Arnsdorf is survived by his wife of 24 years, her four children and their five grandchildren.

Annual Fund Donations Support ACC's Mission

Donations to the American College of Cardiology Foundation (ACCF) enhance the College's ability to continue serving its membership along with the cardiovascular community as a whole. Giving to the Annual Fund provides much-needed support for mission-related activities.

Individuals who donate will have the option of receiving one of the following gifts from the ACCF.

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Enjoy morning coffee or tea with this 16oz ceramic midnight blue duo tone bistro mug.

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An eco-friendly alternative to plastic water bottles, these BPA free aluminum 20oz water bottles come with a screw top lid, split key ring and a carabiner.

$100 and above

Enjoy this multifunctional zippered tote bag, with royal blue accents and fashionable leatherette detailing.

$250 and above

Stay protected from the elements with this royal blue/white golf umbrella. The vented, 62" arc umbrella is windproof and has an oversized wood handle for a comfortable grip.

$500 and above

Keep warm with this comfortable 58" x 58" royal blue jersey sweatshirt fleece blanket.

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New Relationships with Industry Principles Developed for Clinical Documents

The American College of Cardiology has developed new principles related to the development of clinical documents like guidelines, scientific advisories and appropriate use criteria in order to eliminate the possibility of undue bias.

Under the new principles, all clinical document authors, including organizational representatives of ACC Foundation (ACCF) document writing committees, must annually disclose *all* relationships with industry (RWI) and other entities using ACC's Electronic Disclosure Database. In addition, all ACCF Writing Committees must have a chair without relationships that are relevant to the document under development. The respective ACCF Document Oversight Committee will review and approve all writing committee appointments and adjudicate questions or concerns relating to RWI.

When it comes to Writing Committees, each committee must have 50 percent of the members (excluding the chair) without relevant RWI. This means that the responsibility for identifying members without relevant relationships will be distributed to all organizations. Partners or collaborating organizations will be asked to recommend several alternate representatives to facilitate the implementation of this policy. If there is difficulty in reaching the 50/50 distribution of members with and without relationships, organizations will be asked for alternative names until even distribution is reached.

Finally, relevant RWI for all Writing Committees will be published with the document and "comprehensive" RWI will be available electronically. In addition, Writing Committees may not draft text or vote on recommendations where a relationship is applicable.

For more information on the College's relationship with industry principles go to *CardioSource.org*.

Patient Education Videos Now Available 'En Espanol'

The ACC's CardioSmart website now features a video-library designed specifically to reach Spanish-speaking patients and their care providers. The videos address basic information on preventing and managing heart disease. Topics range from managing hypertension and/or cholesterol to understanding various cardiovascular procedures like nuclear imaging or echocardiography. To access the videos go to *CardioSmart.org*.

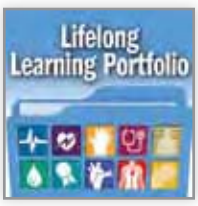
CardioSource Communities

New on *CardioSource.org*

CardioSource.org has more than a new look. Check out these exciting, new features —

Use **CardioSource Communities** to join groups, participate in forums, comment on articles, create a blog and more. Don't miss these great opportunities to discuss issues, collaborate and connect with your peers at ***www.cardiosource.org/My-CardioSource/My-Communities.aspx***

Customize your online experience with **My CardioSource**, where you can set your interests and preferences for getting news and information to fit your needs and even customize your "My CardioSource" home page. ***www.cardiosource.org/My-CardioSource.aspx***



ACC's Lifelong Learning Portfolio makes it easy to manage CME as it provides you with guidance for managing and tracking your education and Maintenance of Certification activities. ***llp.cardiosource.org/Default.aspx***

Looking for a colleague? Use **ACC's Member Center** to find colleagues by going to ***www.cardiosource.org/ACC/Member-Center.aspx***. Access the Member Center through My CardioSource, too.

Have questions about using the new site? Read the **CardioSource FAQs** (***www.cardiosource.org/ACC/About-ACC/CardioSource-FAQs.aspx***.) You may also contact the Resource Center at (800) 253-4636, x5603 or via e-mail at *resource@acc.org*.

What's New on CardioSource Communities

CardioSource Communities is off to a great start – check out what's happened in the last month and then visit *cardiosource.org/My-CardioSource/My-Communities.aspx* to get started!

Former ACC President Alfred Bove, M.D., M.P.H., M.A.C.C., blogs about "The Heart and Diving." Bove writes, "The biggest attention getter in the diving community related to the heart is the issue of Patent Foramen Ovale. Since a PFO is found in about 30% of people, testing for it will always have a one in three chance of finding one. There are no data to suggest that a PFO is a hazard in diving. Its presence is likely to slightly increase the risk for decompression sickness but the risk is miniscule. A PFO is not a contraindication to diving."

85 Cardiovascular Care Associates (CCA) join the CCA group. The Cardiac Care Associate group is a place for cardiovascular care team members, including nurses, physician assistants and clinical pharmacists, to network, have discussions on issues of interest to cardiac care team and access the actionable, timely and critical information needed to positively impact patient outcomes. So far, group members have had several discussions and uploaded photos from recent events.

25 Members of CardioSource Communities comment on "Case 1: A 78-year-old African American female with throat discomfort and left arm paresthesias," offering a host of potential solutions to this challenging case study. Is it ACS? Angina? Dissection? View the article and leave your answer.

Handheld Echo machines, are they any good? David E. Winchester, M.D., Michael J. Barrett, M.D., F.A.C.C., and Terry D. Bauch, M.D., F.A.C.C., discuss the value of new handheld echo machines. Winchester asks, "How do they work? I've seen them on the expo floor with models who have great echo windows, but do these hold up on the wards with 'real' patients?"

Fellows in Training (FIT) discuss board review, resources for job hunting, ACC travel awards and more in the FIT group. The FIT group is focused on providing educational opportunities and business information needed for advancing fellows' careers.

About
Writing for Cardiology

Cardiology magazine, which is written by, for and about ACC members, attempts to put research, science and clinical guidelines in the context of daily clinical practice and to keep you informed about ACC and professional news. We are always looking for new authors, ideas and contributions. Short articles or letters to the editor run 350 to 500 words. Longer articles run 500 to 800 words. Feel free to submit ideas or articles to *cardiologyeditor@acc.org*.

This Month in JACC

August 3

- Randomized Comparison of Eptifibatide Versus Abciximab in Primary Percutaneous Coronary Intervention in Patients With Acute ST-Segment Elevation Myocardial Infarction: Results of the EVA-AMI Trial
- Minimally-Invasive Implantation of Living Tissue Engineered Heart Valves: A Comprehensive Approach From Autologous Vascular Cells to Stem Cells

August 10

- Effectiveness of In-lab High Dose Clopidogrel Loading vs Routine Preload in Patients Undergoing Percutaneous Coronary Intervention. Results of the ARMYDA-5 PRELOAD (Antiplatelet therapy for Reduction of MYocardial Damage during Angioplasty) Randomized Trial
- Assessment of Advanced Coronary Artery Disease: Advantages of Quantitative Magnetic Resonance Perfusion Analysis

August 17

- Modest Visceral Fat Gain Causes Endothelial Dysfunction In Healthy Humans

August 24

- Safety and Efficacy of Sertraline for Depression in Patients With Heart Failure: Results of the SADHART-CHF Trial

August 31

- Prevalence and Predictors of "Off-label" use of Cardiac Resynchronization Therapy in Patients Enrolled in the NCDR ICD Registry
- Optimal Left Ventricular Endocardial Pacing Sites for Cardiac Resynchronization Therapy in Patients with Ischemic Cardiomyopathy

JACC cardiovascular Imaging

August

- Intravascular and Extravascular Microvessel Formation in Chronic Total Occlusions: Potential Insights on Pathogenesis Based on MicroCT Imaging
- Stress and Rest Dynamic Myocardial Perfusion Imaging by Evaluation of Complete Time-Attenuation Curves with Dual-Source CT
- Prevalence of myocardial scar in patients with cryptogenic cerebral ischemic events and patent foramen ovale

JACC cardiovascular Interventions

August

- Impact of Bivalirudin Therapy in High-Risk Patients with Acute Myocardial Infarction: One-Year Results from the HORIZONS-AMI Trial
- Angiographic and Clinical Outcomes Among Patients with Acute Coronary Syndromes Presenting with Isolated Anterior ST-Segment Depression: A TRITON-TIMI 38 Substudy
- Outcomes of Percutaneous Coronary Intervention in Intermediate Coronary Artery Disease: Fractional Flow Reserve-Guided versus Intravascular Ultrasound-Guided Outcomes of Patients for Same-Day Discharge after Percutaneous Coronary Intervention: A Five-Year Experience

Educational Programs Calendar

August 19, 2010 — *Dallas* — CME MOC
ACCF Study Session for ABIM Maintenance of Certification: Interventional Cardiology Updates 2009 and 2010
Joseph D. Babb, M.D., F.S.C.A.I., F.A.C.C.
James E. Tcheng, M.D., F.A.C.C., F.S.C.A.I., F.E.S.C.

August 20 - 22, 2010 — *Dallas* — CME
ACCF/SCAI Premier Interventional Cardiology Overview and Board Preparatory Course
Joseph D. Babb, M.D., F.S.C.A.I., F.A.C.C.
James E. Tcheng, M.D., F.A.C.C., F.S.C.A.I., F.E.S.C.

August 31 - September 4, 2010 — *Chicago* — CME
The ACCF Cardiovascular Board Review for Certification and Recertification
Kim A. Eagle, M.D., M.A.C.C.
Patrick T. O'Gara, M.D., F.A.C.C.

September 4, 2010 — *Chicago* — CME MOC
ACCF Study Session for ABIM Maintenance of Certification: Cardiovascular Disease Updates 2009 and 2010
Rick A. Nishimura, M.D., F.A.C.C.
Patrick T. O'Gara, M.D., F.A.C.C.

September 9 - 11, 2010 — *Washington, D.C.* — CME
2010 ACCF/SCCT Coronary CTA Practicum
Allen J. Taylor, M.D., F.A.C.C., F.A.H.A.

September 23 - 25, 2010 — *Washington, D.C.* — CME CE
Arrhythmias in the Real World 2010
Peter N. Smith, M.D., F.A.C.C.
Arthur J. Moss, M.D., F.A.C.C.
Kelley P. Anderson, M.D., F.A.C.C.

October 7 - 9, 2010 — *Chicago* — CME CE
2010 Heart Valve Summit: Medical, Surgical and Interventional Decision-Making
David H. Adams, M.D., F.A.C.C.
Steven F. Bolling, M.D., F.A.C.C.
Robert O. Bonow, M.D., F.A.C.C.
Howard C. Herrmann, M.D., F.A.C.C., F.S.C.A.I.

October 14 - 16, 2010 — *Washington, D.C.* — CME
2010 ACCF/SCCT Coronary CTA Practicum
Wilfred Mamuya, M.D., Ph.D., F.A.C.C.

For a complete listing of upcoming events and to register online, go to *CardioSource.org/certified-education.aspx* and click on Courses and Conferences

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