



NOVEMBER 2009 VOLUME 38 NUMBER 11

# Cardiology

A MEMBER PUBLICATION OF THE AMERICAN COLLEGE OF CARDIOLOGY

After the **Final Payment Rule** – **WHAT'S NEXT?**

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*New*  **MULTAQ**<sup>®</sup>  
(dronedarone) **400**mg  
Tablets

*Now Approved!*  
*Now Available!*

Please see brief summary of Prescribing Information,  
including **boxed WARNING**, on adjacent page.

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**sanofi aventis**

Because health matters

**MULTAQ**  
(dronedaron) Tablets

Rx Only

Brief Summary of Prescribing Information

**WARNING: HEART FAILURE**

**MULTAQ is contraindicated in patients with NYHA Class IV heart failure, or NYHA Class II – III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic [see Contraindications (4)].**

**In a placebo-controlled study in patients with severe heart failure requiring recent hospitalization or referral to a specialized heart failure clinic for worsening symptoms (the ANDROMEDA Study), patients given dronedarone had a greater than two-fold increase in mortality. Such patients should not be given dronedarone [see Clinical Studies (14.3) in the full prescribing information].**

**1 INDICATIONS AND USAGE**

MULTAQ® is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF] <40%), who are in sinus rhythm or who will be cardioverted [see Clinical Studies (14) in the full prescribing information].

**2 DOSAGE AND ADMINISTRATION**

The only recommended dosage of MULTAQ is 400 mg twice daily in adults. MULTAQ should be taken as one tablet with the morning meal and one tablet with the evening meal.

Treatment with Class I or III antiarrhythmics (e.g., amiodarone, flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol) or drugs that are strong inhibitors of CYP3A (e.g., ketoconazole) must be stopped before starting MULTAQ [see Contraindications (4)].

**4 CONTRAINDICATIONS**

MULTAQ is contraindicated in patients with:

- NYHA Class IV heart failure or NYHA Class II – III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic [see Boxed Warning and Clinical Studies (14.3) in the full prescribing information]
- Second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker)
- Bradycardia <50 bpm
- Concomitant use of strong CYP 3A inhibitors, such as ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, and ritonavir [see Drug Interactions (7.2)]
- Concomitant use of drugs or herbal products that prolong the QT interval and might increase the risk of Torsade de Pointes, such as phenothiazine antipsychotics, tricyclic antidepressants, certain oral macrolide antibiotics, and Class I and III antiarrhythmics
- QTc Bazett interval ≥500 ms or PR interval >280 ms
- Severe hepatic impairment
- Pregnancy (Category X): MULTAQ may cause fetal harm when administered to a pregnant woman. MULTAQ is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus [see Use in Specific Populations (8.1)].
- Nursing mothers [see Use in Specific Populations (8.3)]

**5 WARNINGS AND PRECAUTIONS**

**5.1 Patients with New or Worsening Heart Failure during Treatment**

Advise patients to consult a physician if they develop signs or symptoms of heart failure, such as weight gain, dependent edema, or increasing shortness of breath. There are limited data available for AF/AFL patients who develop worsening heart failure during treatment with MULTAQ. If heart failure develops or worsens, consider the suspension or discontinuation of MULTAQ.

**5.2 Hypokalemia and Hypomagnesemia with Potassium-Depleting Diuretics**

Hypokalemia or hypomagnesemia may occur with concomitant administration of potassium-depleting diuretics. Potassium levels should be within the normal range prior to administration of MULTAQ and maintained in the normal range during administration of MULTAQ.

**5.3 QT Interval Prolongation**

Dronedaron induces a moderate (average of about 10 ms but much greater effects have been observed) QTc (Bazett) prolongation [see Clinical Pharmacology (12.2) in the full prescribing information and Clinical Studies (14.1) in the full prescribing information]. If the QTc Bazett interval is ≥500 ms, MULTAQ should be stopped [see Contraindications (4)].

**5.4 Increase in Creatinine after Treatment Initiation**

Serum creatinine levels increase by about 0.1 mg/dL following dronedaron treatment initiation.

The elevation has a rapid onset, reaches a plateau after 7 days and is reversible after discontinuation. If an increase in serum creatinine occurs and plateaus, this increased value should be used as the patient's new baseline. The change in creatinine levels has been shown to be the result of an inhibition of creatinine's tubular secretion, with no effect upon the glomerular filtration rate.

**5.5 Women of Childbearing Potential**

Premenopausal women who have not undergone a hysterectomy or oophorectomy must use effective contraception while using MULTAQ. Dronedaron caused fetal harm in animal studies at doses equivalent to recommended human doses. Women of childbearing potential should be counseled regarding appropriate contraceptive

choices taking into consideration their underlying medical conditions and lifestyle preferences [see Use in Specific Populations (8.1)].

**6 ADVERSE REACTIONS**

The following safety concerns are described elsewhere in the label:

- New or worsening heart failure [see Warnings and Precautions (5.1)]
- Hypokalemia and hypomagnesemia with potassium-depleting diuretics [see Warnings and Precautions (5.2)]
- QT prolongation [see Warnings and Precautions (5.3)]

The safety evaluation of dronedaron 400 mg twice daily in patients with AF or AFL is based on 5 placebo controlled studies. ATHENA, EURIDIS, ADONIS, ERATO and DAFNE. In these studies, a total of 6285 patients were randomized and treated, 3282 patients with MULTAQ 400 mg twice daily, and 2875 with placebo. The mean exposure across studies was 12 months. In ATHENA, the maximum follow-up was 30 months.

In clinical trials, premature discontinuation because of adverse reactions occurred in 11.8% of the dronedaron-treated patients and in 7.7% of the placebo-treated group. The most common reasons for discontinuation of therapy with MULTAQ were gastrointestinal disorders (3.2 % versus 1.8% in the placebo group) and QT prolongation (1.5% versus 0.5% in the placebo group).

The most frequent adverse reactions observed with MULTAQ 400 mg twice daily in the 5 studies were diarrhea, nausea, abdominal pain, vomiting, and asthenia.

Table 1 displays adverse reactions more common with dronedaron 400 mg twice daily than with placebo in AF or AFL patients, presented by system organ class and by decreasing order of frequency. Adverse laboratory and ECG effects are presented separately in Table 2.

**Table 1: Adverse Drug Reactions that Occurred in at Least 1% of Patients and Were More Frequent than Placebo**

	Placebo (N=2875)	Dronedaron 400 mg twice daily (N=3282)
<b>Gastrointestinal</b>		
Diarrhea	6%	9%
Nausea	3%	5%
Abdominal pain	3%	4%
Vomiting	1%	2%
Dyspeptic signs and symptoms	1%	2%
<b>General</b>		
Asthenic conditions	5%	7%
<b>Cardiac</b>		
Bradycardia	1%	3%
<b>Skin and subcutaneous tissue</b>		
Including rashes (generalized, macular, maculo-papular, erythematous), pruritus, eczema, dermatitis, dermatitis allergic	3%	5%

Photosensitivity reaction and dysgeusia have also been reported at an incidence less than 1% in patients treated with MULTAQ.

The following laboratory data/ECG parameters were reported with MULTAQ 400 mg twice daily.

**Table 2: Laboratory data/ECG parameters not necessarily reported as adverse events**

	Placebo (N=2875)	MULTAQ 400 mg twice daily (N=3282)
Serum creatinine increased ≥10% five days after treatment initiation	21%	51%
	(N=2237)	(N=2701)
QTc Bazett prolonged (>450 ms in males >470 ms in females)	19%	28%

Assessment of demographic factors such as gender or age on the incidence of treatment- emergent adverse events did not suggest an excess of adverse events in any particular sub-group.

**7 DRUG INTERACTIONS**

Dronedaron is metabolized primarily by CYP 3A and is a moderate inhibitor of CYP 3A and CYP 2D6 [see Clinical Pharmacology (12.3) in the full prescribing information]. Dronedaron's blood levels can therefore be affected by inhibitors and inducers of CYP 3A, and dronedaron can interact with drugs that are substrates of CYP 3A and CYP 2D6.

Dronedaron has no significant potential to inhibit CYP 1A2, CYP 2C9, CYP 2C19, CYP 2C8 and CYP 2B6. It has the potential to inhibit P-glycoprotein (P-gP) transport.

Pharmacodynamic interactions can be expected with beta-blockers; calcium antagonists and digoxin [see *Drug Interactions (7.1)*].

In clinical trials, patients treated with dronedarone received concomitant medications including beta-blockers, digoxin, calcium antagonists (including those with heart rate-lowering effects), statins and oral anticoagulants.

### 7.1 Pharmacodynamic Interactions

Drugs prolonging the QT interval (inducing Torsade de Pointes)

Co-administration of drugs prolonging the QT interval (such as certain phenothiazines, tricyclic antidepressants, certain macrolide antibiotics, and Class I and III antiarrhythmics) is contraindicated because of the potential risk of Torsade de Pointes-type ventricular tachycardia [see *Contraindications (4)*].

Digoxin

Digoxin can potentiate the electrophysiologic effects of dronedarone (such as decreased AV-node conduction). In clinical trials, increased levels of digoxin were observed when dronedarone was co-administered with digoxin. Gastrointestinal disorders were also increased.

Because of the pharmacokinetic interaction [see *Drug Interaction (7.3)*] and possible pharmacodynamic interaction, reconsider the need for digoxin therapy. If digoxin treatment is continued, halve the dose of digoxin, monitor serum levels closely, and observe for toxicity.

Calcium channel blockers

Calcium channel blockers with depressant effects on the sinus and AV nodes could potentiate dronedarone's effects on conduction.

Give low doses of calcium channel blockers initially and increase only after ECG verification of good tolerability [see *Drug Interactions (7.3)*].

Beta-blockers

In clinical trials, bradycardia was more frequently observed when dronedarone was given in combination with beta-blockers.

Give low dose of beta-blockers initially, and increase only after ECG verification of good tolerability [see *Drug Interactions (7.3)*].

### 7.2 Effects of Other Drugs on Dronedarone

Ketoconazole and other potent CYP 3A inhibitors

Repeated doses of ketoconazole, a strong CYP 3A inhibitor, resulted in a 17-fold increase in dronedarone exposure and a 9-fold increase in  $C_{max}$ . Concomitant use of ketoconazole as well as other potent CYP 3A inhibitors such as itraconazole, voriconazole, ritonavir, clarithromycin, and nefazodone is contraindicated [see *Contraindications (4)*].

Grapefruit juice

Grapefruit juice, a moderate inhibitor of CYP 3A, resulted in a 3-fold increase in dronedarone exposure and a 2.5-fold increase in  $C_{max}$ . Therefore, patients should avoid grapefruit juice beverages while taking MULTAQ.

Rifampin and other CYP 3A inducers

Rifampin decreased dronedarone exposure by 80%. Avoid rifampin or other CYP 3A inducers such as phenobarbital, carbamazepine, phenytoin, and St John's wort with dronedarone because they decrease its exposure significantly.

Calcium channel blockers

Verapamil and diltiazem are moderate CYP 3A inhibitors and increase dronedarone exposure by approximately 1.4- to 1.7-fold [see *Drug Interactions (7.1, 7.3)*].

Pantoprazole

Pantoprazole, a drug that increases gastric pH, did not have a significant effect on dronedarone pharmacokinetics.

### 7.3 Effects of Dronedarone on Other Drugs

Statins

Dronedarone increased simvastatin/simvastatin acid exposure by 4- and 2-fold, respectively.

Because of multiple mechanisms of interaction with statins (CYPs and transporters), follow statin label recommendations for use with CYP 3A and P-gP inhibitors such as dronedarone.

Calcium channel blockers

Dronedarone increases calcium channel blocker (verapamil, diltiazem or nifedipine) exposure by 1.4- to 1.5-fold [see *Drug Interactions (7.1)*].

Sirolimus, tacrolimus, and other CYP3A substrates with narrow therapeutic range  
Dronedarone can increase plasma concentrations of tacrolimus, sirolimus, and other CYP 3A substrates with a narrow therapeutic range when given orally. Monitor plasma concentrations and adjust dosage appropriately.

Beta-blockers and other CYP 2D6 substrates

Dronedarone increased propranolol exposure by approximately 1.3-fold following single dose administration. Dronedarone increased metoprolol exposure by 1.6-fold following multiple dose administration [see *Drug Interaction (7.1)*]. Other CYP 2D6 substrates, including other beta-blockers, tricyclic antidepressants, and selective serotonin reuptake inhibitors (SSRIs) may have increased exposure upon co-administration with dronedarone.

Digoxin and P-glycoprotein substrates

Dronedarone increased digoxin exposure by 2.5-fold by inhibiting the P-gP transporter [see *Drug Interactions (7.1)*]. Other P-gP substrates are expected to have increased exposure when coadministered with dronedarone.

Warfarin and losartan (CYP 2C9 substrates)

In healthy subjects, dronedarone at a dose of 600 mg twice daily increased S-warfarin exposure by 1.2-fold with no change in R-warfarin and with no clinically significant increase in INR. In clinical trials in patients with AF/AFL, there was no observed excess risk of bleeding compared to placebo when dronedarone was co-administered with oral anticoagulants. Monitor INR per the warfarin label. No interaction was observed between dronedarone and losartan.

Theophylline (CYP 1A2 substrate)

Dronedarone does not increase steady state theophylline exposure.

Oral contraceptives

No decreases in ethinylestradiol and levonorgestrel concentrations were observed in healthy subjects receiving dronedarone concomitantly with oral contraceptives.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Pregnancy Category X [see *Contraindications (4)*]

MULTAQ may cause fetal harm when administered to a pregnant woman. In animal studies, dronedarone was teratogenic in rats at the maximum recommended human dose (MRHD), and in rabbits at half the MRHD. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

When pregnant rats received dronedarone at oral doses greater than or equal to the MRHD (on a  $mg/m^2$  basis), fetuses had increased rates of external, visceral and skeletal malformations (cranioschisis, cleft palate, incomplete evagination of pineal body, brachygnathia, partially fused carotid arteries, truncus arteriosus, abnormal lobation of the liver, partially duplicated inferior vena cava, brachydactyly, ectrodactyly, syndactyly, and anterior and/or posterior club feet). When pregnant rabbits received dronedarone, at a dose approximately half the MRHD (on a  $mg/m^2$  basis), fetuses had an increased rate of skeletal abnormalities (anomalous ribcage and vertebrae, pelvic asymmetry) at doses  $\geq 20$  mg/kg (the lowest dose tested and approximately half the MRHD on a  $mg/m^2$  basis).

Actual animal doses: rat ( $\geq 80$  mg/kg/day); rabbit ( $\geq 20$  mg/kg)

### 8.3 Nursing Mothers

It is not known whether MULTAQ is excreted in human milk. Dronedarone and its metabolites are excreted in rat milk. During a pre- and post-natal study in rats, maternal dronedarone administration was associated with minor reduced body-weight gain in the offspring. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from MULTAQ, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother [see *Contraindications (4)*].

### 8.4 Pediatric Use

Safety and efficacy in children below the age of 18 years have not been established.

### 8.5 Geriatric Use

More than 4500 patients with AF or AFL aged 65 years or above were included in the MULTAQ clinical program (of whom more than 2000 patients were 75 years or older). Efficacy and safety were similar in elderly and younger patients.

### 8.6 Renal Impairment

Patients with renal impairment were included in clinical studies. Because renal excretion of dronedarone is minimal [see *Clinical Pharmacology (12.3) in the full prescribing information*], no dosing alteration is needed.

### 8.7 Hepatic Impairment

Dronedarone is extensively metabolized by the liver. There is little clinical experience with moderate hepatic impairment and none with severe impairment. No dosage adjustment is recommended for moderate hepatic impairment [see *Contraindications (4) and Clinical Pharmacology (12.3) in the full prescribing information*].

## 10 OVERDOSAGE

In the event of overdosage, monitor the patient's cardiac rhythm and blood pressure. Treatment should be supportive and based on symptoms.

It is not known whether dronedarone or its metabolites can be removed by dialysis (hemodialysis, peritoneal dialysis or hemofiltration).

There is no specific antidote available.

Manufactured by Sanofi Winthrop Industrie

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DRO-BPLR-AS-JUL09

Revised: July 2009



## Cardiology Will Prevail Over Payment Cuts

November marks the 60th anniversary of the founding of our College. I doubt the 14 founders would recognize the dynamic, complex, international organization that is today's American College of Cardiology. I do believe, however, that they would recognize their vision in our mission to advocate for quality cardiovascular care and would take pride in the outstanding education and practical guidance we offer our members. I believe they would support our efforts to shape health care policy that benefits cardiovascular practitioners and patients.

Six decades after our founding, the College faces challenges it has never encountered before. On Oct. 31, the Centers for Medicare and Medicaid Services (CMS) released its Final 2010 Medicare Physician Fee Schedule. As we feared, the rule includes significant cuts to cardiovascular services. Nearly all services that cardiologists perform will see cuts ranging from 10 to more than 40 percent over four years. SPECT imaging is hit the hardest with a 36 percent cut in 2010 alone. The largest cuts are related to practice expense. CMS chose to use the AMA's flawed Physician Practice Information Survey data to inform the cuts.

The many calls, letters, e-mails and meetings between ACC members and their legislators were *not* wasted, however. **We are being heard.** ACC's unprecedented advocacy efforts in the past months resulted in the CMS decision to phase in the cuts over four years. Of course, cuts of this magnitude cannot be absorbed in 2010 or over the next four years. But the phase-in period gives us time to fight the implementation of the cuts until the data can be reviewed and validated.

The ACC understands the impact these cuts will have on your practices and your patients, and we're preparing a massive and coordinated response (see more on p. 4).

This issue looks toward the future of cardiovascular medicine, with advice on navigating short-term challenges, as well as visionary reflections on what may lie ahead.

**William T. "Mike" Carlson Jr.** completes his series on physician-hospital integration with an article on perhaps the most important element of these relationships: governance. As we enter a new era in which many private practices likely will look toward integration with hospitals, I encourage you to consider his sage guidance for building a physician-centric governance structure that works best for you and your patients.

**John Byrne, M.D., F.A.C.C.,** shares his vision for the future of collaborative cardiology, a vision that brings together surgeons, general cardiologists, interventionalists and imaging specialists for the benefit of the patient. His ideas are fascinating, challenging and a little provocative — as the future of cardiovascular medicine surely will be.

Sixty years have elapsed since the snowy Monday when our founders met to form an exciting new organization, dedicated to educating the practicing cardiologist. In those 60 years, our College has met change with our founders' bold determination and unrelenting focus on the wellbeing of the patient. I look forward to working with you as we embark on another remarkable 60 years.

**Alfred A. Bove, M.D., Ph.D., F.A.C.C.**  
ACC President

November 2009



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**T**he Centers for Medicare and Medicaid Services (CMS) has released its 2010 Medicare Physician Fee Schedule final rule, which includes policies that significantly reduce payments for cardiovascular-related services.

These cuts are very bad public policy and present a grave threat to cardiology practices and patient access. Many cardiology practices will be unable to continue performing some services in the office when Medicare's payments stop covering the cost of providing care, and patients will have to receive services from hospitals. The consequent shift from the physician office to the outpatient hospital setting will, in many cases, more than double the costs of services. Medicare patients will feel an immediate impact from higher co-payments and another impact in the near future as Medicare Part B premiums increase to cover the increased expenditures.

The ACC understands the very real threat these cuts pose to practices and patients. The College is pursuing all options to stop the implementation of the cuts and preserve patient access to quality care. What follows is a high-level summary of the policy proposals included in the rule, as well as an overview of ACC's next steps.

After the **Final Payment Rule**

**WHAT'S NEXT?**

**Final Rule  
Includes Phased-In  
Cuts for Cardiology**

## Rule Highlights

**Practice Expense:** The biggest cuts are related to practice expense. CMS chose to incorporate the results of the American Medical Association's (AMA) Physician Practice Information Survey into its formula for calculating practice expense relative value units (RVUs). Because of your efforts, the agency did attempt to mitigate the impact of these cuts by phasing in the changes over a four-year period. However, the bottom line is that CMS did not review or validate the data used to determine the practice expense portion of the cuts. Cardiology cannot absorb cuts of this magnitude — whether enacted this year or spread over four.

With the exception of evaluation and management services, nearly all services that cardiologists perform will see cuts ranging from 10 percent to more than 40 percent for individual services phased in over four years. SPECT imaging is hit the hardest with a 36 percent cut in 2010 alone. A few other key examples:

- Transthoracic echo with spectral and color flow Doppler (93306): 10 percent cut
- Coronary stent (92980): 4 percent cut
- EKG: (93000): 5 percent cut
- Level 4 established patient office visit (99214): 7 percent increase

As mentioned above, the ACC is exploring several options for stopping the implementation of this survey data. Although CMS did not withdraw the proposal to use the AMA survey data, as the ACC had recommended, the decision to implement a transition period is a response to the concerns raised by the cardiology community.

**Coding Changes:** There are three important changes to CPT for cardiologists in 2010 — the first affects myocardial perfusion/SPECT imaging, the second affects coronary CT angiography, and the third affects cardiac MRI (see page 16 for specifics on the new codes).

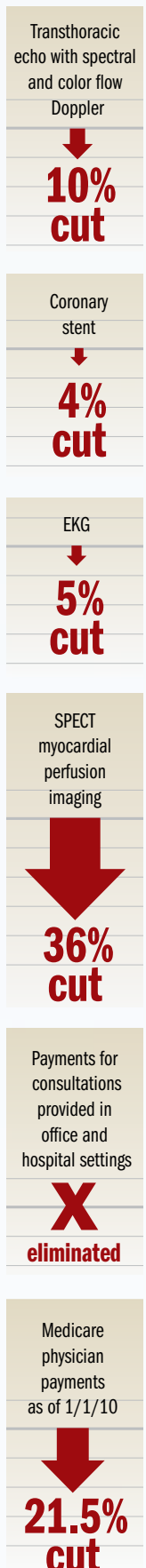
Interim RVUs published for the new bundled code for SPECT myocardial

perfusion imaging show a 36 percent payment cut for this core cardiology service, partially as a result of the bundling of two add-on codes and partially because CMS did not apply the four-year phase in of the AMA practice expense data to this newly numbered code. The ACC and the Heart Rhythm Society successfully challenged interim RVUs assigned to several cardiac device monitoring services. New, modestly higher RVUs will be implemented for 2010.

**Consultations:** CMS eliminated payments for consultations provided in office and hospital settings under the final rule. The RVUs assigned to these codes will be redistributed to office and hospital visits, and services now billed as consultations will be billed as hospital or office visits. This will reduce payments to varying degrees for consultation services. Physicians will report initial hospital visits for services that are currently coded as inpatient consultations but will be required to report a modifier if serving as the admitting physician.

**Malpractice:** CMS has chosen to update the malpractice RVUs with data from a new survey of specialty-level malpractice premiums. In addition, CMS has proposed a new method for determining malpractice RVUs for technical component services. The proposed new malpractice RVUs would reduce cardiology payments by 1 percent; however, the impact will vary depending on the mix of services provided.

**Equipment utilization:** CMS has finalized its proposal to change the agency's formula for calculating the per-procedure cost of medical equipment worth more than \$1 million. The proposal would assume that all equipment with an acquisition cost greater than \$1 million is used 90 percent of the time an office is open, thus driving down the practice expense RVUs for services using that equipment. This assumption affects cardiac MR, cardiac CT and non-hospital cardiac catheterization services.



*continued on next page*

### Hospital Outpatient Prospective Payment System (HOPPS) vs. Physician Fee Schedule (PFS) Payment

		Physician Office Total Cost	Hospital Total Cost
Rest echo (93306)	2009	\$183.94	\$ 431.37
	2010	\$ 168.07	\$ 450.97
Stress test (93017)	2009	\$ 59.51	\$ 170.99
	2010	\$ 53.02	\$ 176.17

**SGR:** As required by current law, the final rule includes a 21.5 percent reduction in Medicare physician payment as of Jan. 1, 2010. This cut is in addition to the payment reductions that result from the proposed policy changes described above. In short, there could be as high as a 30 percent cut in Medicare payments for cardiology. However, as in previous years, we expect Congress to pass a one- to two-year fix this fall.

**PQRI/E-Prescribing:** New measures groups, which require physicians to report on only 30 patients instead of 80 percent of eligible patients to qualify for a 2 percent bonus,

## This fight has just begun, and we will prevail. But we need your involvement now more than ever.

have been added for coronary artery disease and heart failure. Most cardiology measures, along with the new measures groups, can only be reported through a registry. In addition, CMS made it much easier for physicians who use e-prescribing to receive a 2 percent bonus requiring reporting of e-prescribing for only 25 eligible patient encounters to qualify. More information on the Physician Quality Reporting Initiative and e-prescribing is available at [www.acc.org/healthit](http://www.acc.org/healthit).

### What's Next

This fight has just begun, and we will prevail. But we need your involvement now more than ever. The ACC has developed a four-pronged strategy to help ensure your practice viability and patient access to quality cardiovascular care. The College is:

1. Developing legislation to prevent implementation of the rule and ensure practice viability and access are part of health care reform;
2. Exploring both legal and regulatory action with the goal of protecting access to care and practice viability;
3. Organizing an unprecedented public awareness campaign; and
4. Mobilizing members to help fund and succeed in this most critical challenge.

Stay tuned to *Cardiology* magazine, ACC Advocate and ACC News for more on these efforts and ways you can get involved. Your feedback on the tools and resources you'd like to see in the coming months also is appreciated. Please e-mail [advocate@acc.org](mailto:advocate@acc.org) with your thoughts.

# Cardiology

November 2009  
Vol. 38, No. 11

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

**Telephone:** (800) 992-7224  
or (202) 375-6000

**Fax:** (202) 375-7000

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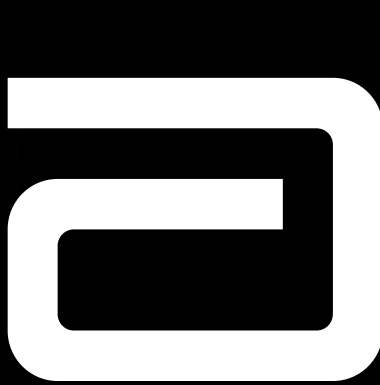
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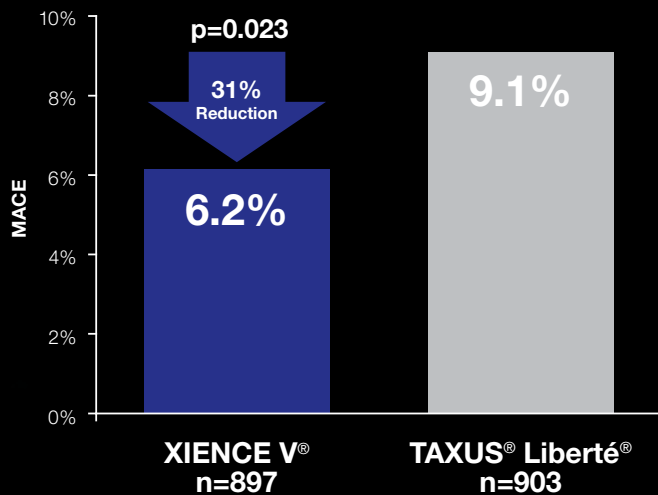
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Everolimus Eluting Coronary Stent System

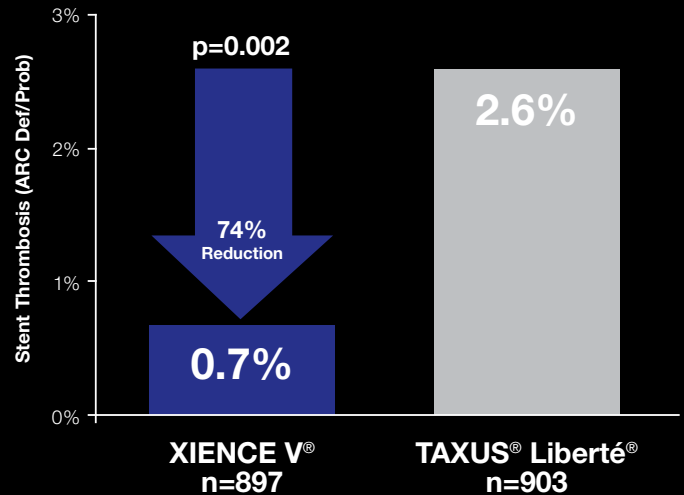
## COMPARE Trial

### XIENCE V<sup>®</sup> is Superior\* to TAXUS<sup>®</sup> Liberté<sup>®</sup> in COMPARE

Primary Endpoint  
1-Year MACE



Secondary Endpoint  
1-Year Stent Thrombosis (ARC Def/Prob)



**COMPARE is an investigator-initiated, single-center, prospective RCT testing XIENCE V<sup>®</sup> vs. TAXUS<sup>®</sup> Liberté<sup>®</sup> in 1,800 all-comer, real-world patients.**

**Indications:** The XIENCE V Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

**For Important Safety Information, see page XX.**

\*XIENCE V<sup>®</sup> has demonstrated statistical superiority in the primary endpoints of SPIRIT IV, SPIRIT III and SPIRIT II in target lesion failure (TLF), in-segment late loss and in-stent late loss respectively. TAXUS<sup>®</sup> Express2<sup>™</sup> was the control in SPIRIT IV. Source: SPIRIT IV, one year results, TCT 2009 and XIENCE V<sup>®</sup> IFU.

MACE = All Death, Non-Fatal MI and TVR. MACE was prespecified for superiority testing.

All data from Kaplan-Meier Curves. Source: Dr. Peter Smits, COMPARE Trial, 1-Year Results Presentation, TCT 2009.

**Please contact your Abbott Vascular representative to learn more or visit our web site at [www.XienceV.com](http://www.XienceV.com)**

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Xience V<sup>®</sup> |  **Abbott Vascular**

**XIENCE V® is Superior\* to TAXUS® Liberté® in COMPARE**

**1,800 Patient Real-World, Complex Population**

Multistenting	62%	Ostial	19%
Calcification	34%	Diabetes	18%
Direct Stenting	34%	Bifurcation	10%
Multivessel	27%	CTO	4%
AMI	25%	Chronic Renal Failure	3%
Thrombus	24%	Left Main	2%
NSTEMI	23%	Saphenous Graft	2%

**R ONLY** **The XIENCE™ V Everolimus Eluting Coronary Stent on the MULTI-LINK MINI-VISION® or MULTI-LINK VISION® Delivery System**

**INDICATIONS**

The XIENCE V Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

**CONTRAINDICATIONS**

The XIENCE V stent is contraindicated for use in patients:

- Who cannot receive antiplatelet and/or anti-coagulant therapy
- With lesions that prevent complete angioplasty balloon inflation or proper placement of the stent or stent delivery system
- With hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, and fluoropolymers.

**WARNINGS**

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Judicious patient selection is necessary because device use has been associated with stent thrombosis, vascular complications, and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

**PRECAUTIONS**

- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent is presently unknown.
- Risks and benefits should be considered in patients with severe contrast agent allergies.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Use fluoroscopy to avoid arterial damage.
- Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize.

Stent thrombosis is frequently associated with myocardial infarction (MI) or death.

- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the XIENCE V SPIRIT family of trials.
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.
- A patient's exposure to drug and polymer is proportional to the number of and total length of implanted stents. See *Instructions for Use* for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE V stent have not been established for subject populations with the following clinical settings:
  - Patients with prior target lesion or in-stent restenosis related brachytherapy, patients in whom mechanical atherectomy devices or laser angioplasty devices are used simultaneously, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.5 mm or > 4.25 mm or lesion lengths > 28 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, chronic total occlusions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent acute myocardial infarction (AMI) or evidence of thrombus in target vessel, moderate or severe lesion calcification, multivessel disease, in-stent restenosis, and patients with longer than 24 months follow-up
- Everolimus has been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE V stent because of limited systemic exposure to everolimus eluted from XIENCE V.
- Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant patients was associated with increased serum cholesterol and triglycerides that in some cases required treatment.
- Non-clinical testing has demonstrated that the

XIENCE V stent, in single and in overlapped configurations up to 68 mm in length, is MR Conditional. It can be scanned safely under the conditions in the *Instructions for Use*.

- The XIENCE V stent should be handled, placed, implanted, and removed according to the *Instructions for Use*.

**POTENTIAL ADVERSE EVENTS**

Adverse events (in alphabetical order) which may be associated with coronary stent use in native coronary arteries include but are not limited to:

- Abrupt closure, Access site pain, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobalt, chromium, nickel, tungsten, acrylic and fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriovenous fistula, Arrhythmias, atrial and ventricular, Bleeding complications, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Distal emboli (air, tissue or thrombotic), Emergent or non-emergent coronary artery bypass graft surgery, Fever, Hypotension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, Ischemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia (due to vascular injury), Pseudoaneurysm, Renal Failure, Restenosis of the stented segment of the artery, Shock/pulmonary edema, Stroke / cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular complications including at the entry site which may require vessel repair, Vessel dissection

Adverse events associated with daily oral administration of everolimus to organ transplant patients include but are not limited to:

- Abdominal pain, Acne, Anemia, Coagulopathy, Diarrhea, Edema, Hemolysis, Hypercholesterolemia, Hyperlipidemia, Hypertension, Hypertriglyceridemia, Hypogonadism male, Infections: wound infection, urinary tract infection, pneumonia, pyelonephritis, sepsis and other viral, bacterial and fungal infections, Leukopenia, Liver function test abnormality, Lymphocele, Myalgia, Nausea, Pain, Rash, Renal tubular necrosis, Surgical wound complication, Thrombocytopenia, Venous thromboembolism, Vomiting

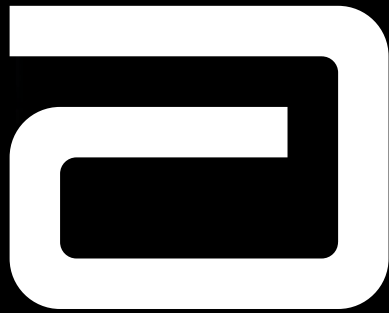
Prior to use, please reference the *Instructions for Use* at [www.abbottvascular.com/ifu](http://www.abbottvascular.com/ifu) for more information on indications, contraindications, warnings, precautions, and adverse events.

<sup>1</sup>Based on Q2 2009 market share. Data on file at Abbott Vascular.

All drawings are artist's representations only and should not be considered as engineering drawings or photographs.

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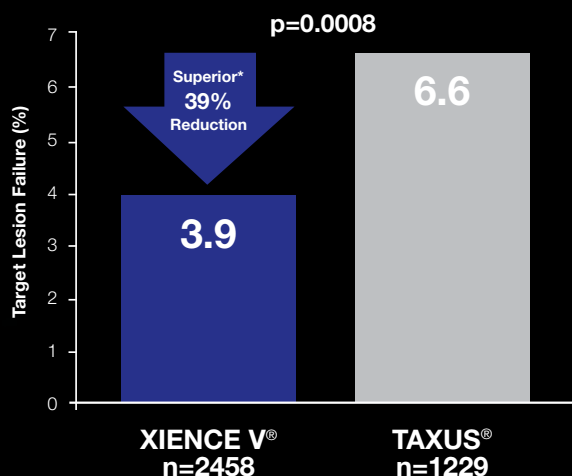
# Xience V<sup>®</sup>

Everolimus Eluting Coronary Stent System

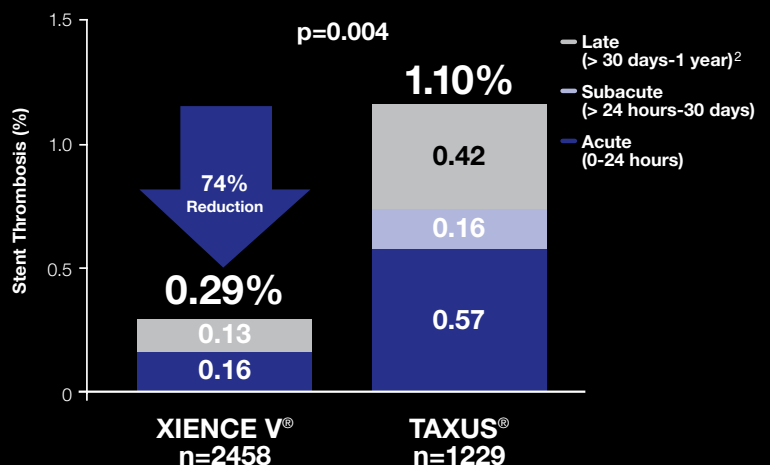
## SPIRIT IV

### XIENCE V<sup>®</sup> Delivers Low 0.29% Stent Thrombosis in 2,458 Patients in SPIRIT IV

**Clinically-Driven TLF: Primary Endpoint**  
(TLF = Cardiac death, target vessel MI and ID-TLR)



**1-Year Stent Thrombosis (ARC Def/Prob)<sup>1</sup>**



**Indications:** The XIENCE V Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

**For Important Safety Information, see adjacent page.**

\*XIENCE V<sup>®</sup> has demonstrated statistical superiority in the primary endpoints of SPIRIT IV, SPIRIT III and SPIRIT II in target lesion failure (TLF), in-segment late loss and in-stent late loss respectively.

TAXUS<sup>®</sup> Express<sup>2™</sup> was the control in SPIRIT IV. Source: SPIRIT IV, one year results, TCT 2009 and XIENCE V<sup>®</sup> IFU.

<sup>1</sup> P-values based on Fisher's exact test.

<sup>2</sup> Categorical data, 365 ± 28 days.

Please contact your Abbott Vascular representative to learn more or visit our web site at [www.XienceV.com](http://www.XienceV.com)

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# ACC Develops Principles for Comparative Effectiveness Research

By Joseph P. Drozda Jr., M.D., F.A.C.C.

The ACC strongly supports investment in comparative effectiveness research (CER). Given the high prevalence of cardiovascular illnesses, along with the documented variability in the use of procedures to diagnose and treat it, CER could yield high returns in terms of its potential to inform practice, improve care and influence costs.

To this end, the ACC has developed a set of CER principles intended to preserve the essential elements of good health care:

- Sound scientific foundation;
- Effective communication among clinicians, patients and their families;
- Freedom from inappropriate influence on provider and patient decisions and from worsening disparities in access or treatment; and
- A commitment to continuous quality improvement.

In short, the principles stress ACC's strong support for CER as a way of supporting informed decision-making, while also recognizing that CER will require substantial and long-term financial support. The principles also recognize that the research on comparative effectiveness is "only the first step in improving the quality, equity and efficiency of medical care," and stress that improving quality must be the primary aim of CER.

CER is an essential building block to understanding the populations that may benefit from the many treatment options for cardiovascular disease, including medical therapy, stents, surgery and defibrillators. Understanding the comparative effectiveness of both diagnostic and treatment strategies in different patient populations, including the elderly, women and multiple ethnicities, is also very important. In order to better target the best candidates for various imaging and diagnostic procedures, we need to understand the comparative effectiveness of these beneficial technologies — and under what conditions the technologies have the greatest impact on care and outcomes. CER on these technologies would also help inform policy decisions related to their use.

Expanding the pool of available data used to determine comparative effectiveness will help clarify the "grey areas" of medical research. Randomized trials are important, but large observational trials and registries, like the ACC's National

Cardiovascular Data Registry (NCDR®), will be important in helping us understand the role of imaging and other diagnostic tests not only in diagnosis but also in their impact on downstream treatment and outcomes. Facilitating linkages of clinical and administrative databases is crucial to developing this research agenda. Inpatient and outpatient registries could help track key elements of comparative effectiveness, including laboratory results, medication adherence and diagnostic decisions. Translation of the results of CER will require transparency in order to enable users to determine the strength of the evidence, the trade-offs of risks and benefits, and the implications when two or more strategies appear equally effective.

The ACC also supports cost-effectiveness analyses that are based on high-quality comparative clinical effectiveness research. Since cost-effectiveness analyses vary depending on the assumptions used, and since such assumptions vary depending on the payer, multiple analyses for any technology or procedure may, in fact, be carried out. The ACC also believes that CER priorities should be set by a multi-stakeholder group to ensure that the research agenda reflects the needs of the country. The research agenda should be based on the burden of the disease being considered, mainly morbidity and mortality. In addition, CER should be directed by organizations distinct from entities that create coverage and benefit programs, and requires close monitoring to avoid adverse consequences on access, quality and safety.

CER, when conducted correctly, is a useful tool to make it much easier for patients and their doctors to choose the best treatment and avoid unnecessary treatment not only for heart disease, but other diseases as well.

To read the complete health policy statement, visit [www.acc.org](http://www.acc.org). To learn more, watch a CVN video at [www.cardiosource.com/cvn/index.asp?videoid=1315](http://www.cardiosource.com/cvn/index.asp?videoid=1315).

**Drozda is chair of the ACC's Clinical Quality Committee.**



### ACC Medical Directors' Institute Focuses on Comparative Effectiveness

The ACC held a successful Medical Directors' Institute last month that brought together ACC leaders and health plan representatives for thoughtful discussions around comparative effectiveness. Attendees heard from a number of thought leaders who provided a wide range of perspectives on the issue. Among the speakers and panelists: **Michael McGinnis** of the Institute of Medicine, **Myrl Weinberg** of the National Health Council and **Carolyn Clancy** of the Agency for Healthcare Research and Quality. Participants also heard from ACC leaders on College-wide quality improvement initiatives like the IC<sup>3</sup>® Program (currently the PINNACLE Registry™) and FOCUS, the College's newest effort to encourage the use of appropriate use criteria at the point of care. Participants came away with an understanding of ways the cardiovascular community can play a role in the comparative effectiveness arena.



McGinnis



Weinberg



Clancy

## ACC Launches Nation's First Registry-Based Cardiovascular Practice Network

Cardiovascular practices face myriad challenges in today's health care environment — legislative and regulatory threats to payment, demands to demonstrate performance and justify clinical decisions, the emergence of reimbursement models based on efficiency or value, and the rise of new and untested business arrangements.

To address these challenges, the ACC last month launched the PINNACLE Network™. PINNACLE, an acronym for Practice Innovation and Clinical Excellence, is the first-ever, registry-based network of practices that care for patients with heart disease. Its goal: to provide doctors and nurses with the tools they need to deliver effective and efficient care to every patient, every time.

The PINNACLE Network immediately addresses the rapidly shifting business environment that private cardiovascular practices face with a wealth of practice management and financial management tools. It offers a centralized, one-stop shop for practice management tools, workflow and workforce solutions, educational resources, health IT tools and risk management strategies for lowering medical liability costs.

The PINNACLE Network also builds a foundation for innovative, registry-based systems to reward practices for the high-quality care that they provide. Members of the network



can tap ACC's experience and leadership in the development of data registries, built for quality improvement and powered to inform decision-making. Known for its first two years as the IC<sup>3</sup> Program, The PINNACLE Registry™ is the nation's first office-based, cardiologist-designed program that puts credible data in the hands of the professionals at the point of care.

The ACC believes that the systematic practice of quality care is the foundation for practice success — clinically, financially and professionally. The PINNACLE Network is the community and the pathway to help practices achieve that success.

For more information on the PINNACLE Network and the PINNACLE Registry, visit [www.pinnacle-network.org](http://www.pinnacle-network.org).

## FTC Delays Red Flags Rules Again

The Federal Trade Commission (FTC) has even further delayed implementation of new rules aimed at preventing identity theft, this time until June 1, 2010. The ACC, the American Medical Association (AMA), Medical Group Management Association (MGMA) and other medical associations have challenged the rules' inclusion of physicians as "creditors" because they regularly defer payment for goods and services. The FTC released rules in November 2007 requiring all financial institutions and "creditors" to develop and implement a written program to protect consumers by identifying potentially suspicious "red flags" that may signal identity theft. The ACC is taking advantage of this newest reprieve to continue efforts to have physicians removed from the creditor definition.

In the meantime, the ACC recommends that practices begin preparing a written identity theft detection and prevention program that complies with the new rules as a contingency plan. The AMA and MGMA have developed Red Flags Rule guidance documents and sample policies that can be modified, available at [www.ama-assn.org/ama/no-index/physician-resources/red-flags-rule.shtml](http://www.ama-assn.org/ama/no-index/physician-resources/red-flags-rule.shtml) and [www.mgma.com](http://www.mgma.com). The FTC also has developed a template that groups at low risk can use to develop their programs, available at [www.ftc.gov/redflagrule](http://www.ftc.gov/redflagrule).

## Using Medicare's Incident-To Rules Correctly

Under Medicare Part B rules, practices can bill Medicare at 100 percent of the physician fee schedule for certain “integral, although incidental” services performed by non-physicians with physician supervision. This is called incident-to billing.

Incident-to billing provides higher reimbursement for non-physician — such as nurse practitioner, technician and physician assistant — services. Professional services provided by non-physicians under the Medicare fee schedule not performed under incident-to rules are paid at 85 percent of the fee schedule. By meeting the requirements of incident-to billing (see box), practices are able to earn 15 percent more for services provided.

**Of the services performed by non-physicians for cardiology, which accounted for 10 percent of the claims examined by the OIG, 85 percent of the non-physicians were qualified and 15 percent were unqualified to perform the services billed.**

### OIG Report

The Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) recently released a report examining the use of the incident-to provisions. The OIG report examined a small sample of claims for incident-to services for compliance with the current rules, stemming from concerns that the services “may be vulnerable to overutilization and may put beneficiaries at risk of receiving services that do not meet professionally recognized standards of care.”<sup>1</sup>

The report found that many practices, including cardiology practices, are not following the requirements for billing incident-to services. Specifically, the OIG found that 21 percent of incident-to services were performed by non-physicians whom the OIG determined to be unqualified. The OIG determined non-physicians to be unqualified if they did not possess necessary licenses or certifications, had no verifiable credentials or lacked training to perform the services billed.

Of the services performed by non-physicians for cardiology, which accounted for 10 percent of the claims examined by the OIG, 85 percent of the non-physicians were qualified and 15 percent were unqualified to perform the services billed. Given the results of the report, cardiology practices should review

the Medicare incident-to guidelines, as well as the state laws governing scope of practice for non-physicians, to ensure compliance with the requirements.

### OIG Recommendations

The OIG issued several recommendations to the Centers for Medicare and Medicaid Services (CMS) as a result of this analysis to better ensure that services performed under incident-to rules are performed by properly qualified non-physicians. These include revising incident-to rules to require services performed by non-physicians be identified with a modifier; taking steps to ensure that non-physicians performing services are appropriately qualified; and taking action to address claims inappropriately billed under incident-to.

In its response, included in the report, CMS offers its support for OIG's overall objectives, but articulates its concerns about using a modifier to identify services performed by a non-physician because of potential overlap between physicians and staff as they relate to incidental services.

CMS' response to OIG's findings indicates an interest in both making changes to the incident-to requirements and increasing review of claims for incident-to services. CMS said it will continue to examine this issue.

To view the report, visit: [oig.hhs.gov/oei/reports/oei-09-06-00430.pdf](http://oig.hhs.gov/oei/reports/oei-09-06-00430.pdf)

### References

1. Office of the Inspector General, Department of Health and Human Services. “Office of the Inspector General Work Plan Fiscal Year 2009.” Available: [www.oig.hhs.gov/publications/docs/workplan/2009/WorkPlanFY2009.pdf](http://www.oig.hhs.gov/publications/docs/workplan/2009/WorkPlanFY2009.pdf)

## How Incident-To Works

Several qualifications must be met for a service to be eligible as performed incident-to a physician's service. To start, the service must be performed on a patient who first has seen a physician, and the physician must have established a treatment plan. The non-physicians, operating within their scope of practice as set forth by state law, can carry out the terms of that treatment plan under the supervision of the physician and bill Medicare for 100 percent of the physician fee schedule. The physician must remain involved in the patient's care. Non-physicians also can bill incident-to a qualified, enrolled non-physician and receive 85 percent of the Medicare physician fee schedule for that service.

During the course of treatment, if the patient develops new problems or symptoms not anticipated in the original treatment plan, the patient again must see a physician for the practice to bill Medicare for 100 percent of the physician fee schedule for the treatment of the new problems or symptoms. For more information on the incident-to billing rules, view the Medicare Internet-Only Benefits Policy Manual (Pub. 100-02), Chap. 15, Sec. 60 at: [www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf](http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf).

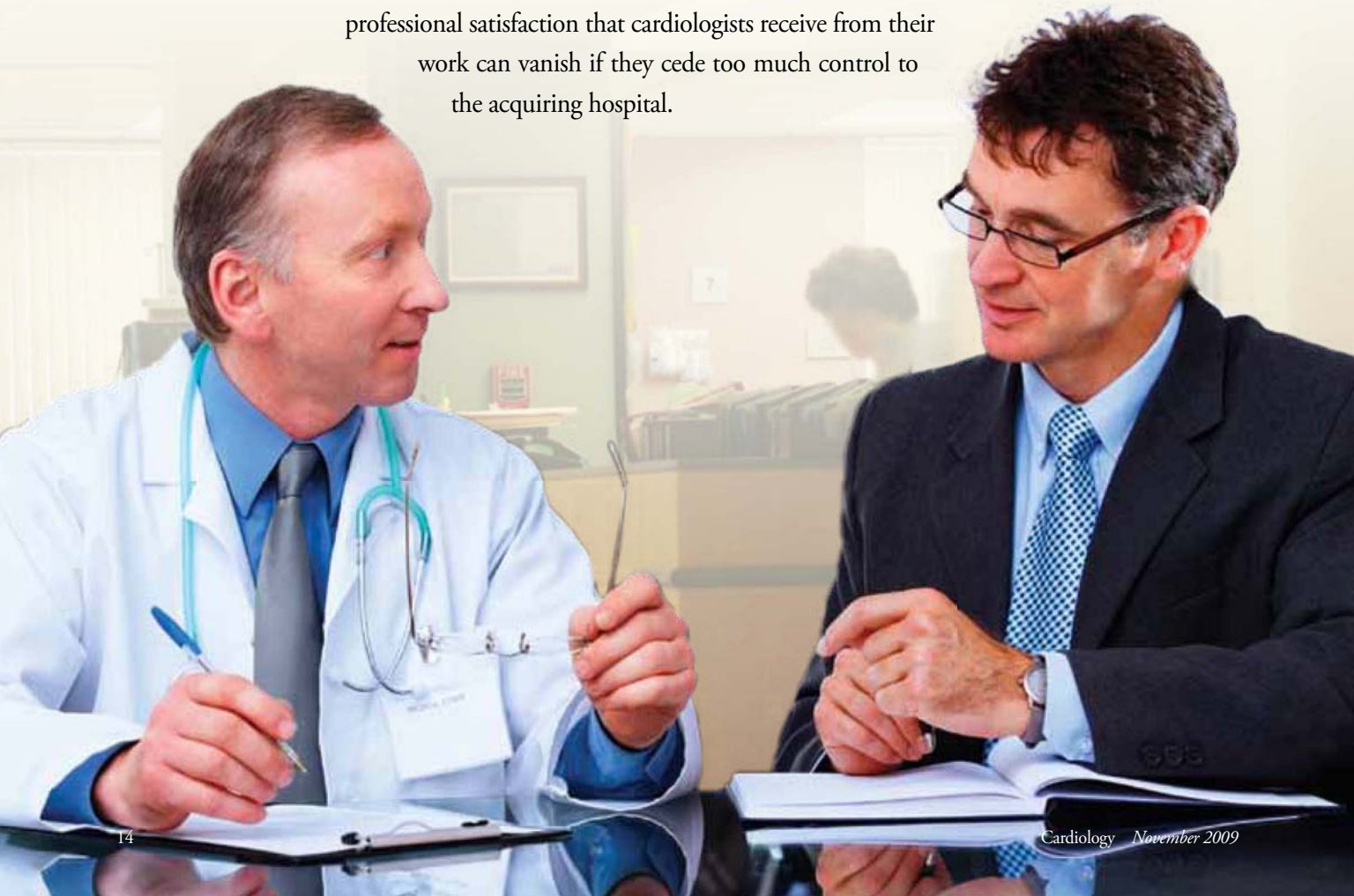
# Governance: The Centerpiece of Physician-Hospital Integration

By William T. "Mike" Carlson Jr.

Often, cardiologists who begin integration talks with one or more local hospitals tend to focus on the valuation of the practice and their compensation for the coming years. However, as many of those doctors are willing to testify, the governance discussions will play a larger role in physician satisfaction after the integration documents are signed.

The reason is simple. Whatever value the cardiologists receive for their practice, those funds are quickly deposited and forgotten. Similarly, cardiologists quickly adjust to their new compensation arrangements and tend to forget how many tens of thousands of dollars less they would be making if they had remained independent. Governance, on the other hand, affects a cardiologist's work assignments, locations, staffing and even vacation scheduling.

The professional satisfaction that cardiologists receive from their work can vanish if they cede too much control to the acquiring hospital.





**Principle #1:**  
**Aim for a physician-centric governance structure.**

A typical governance structure will have a joint council with equal physician and hospital representation. This council should be a decision-making body (rather than merely advisory) that has responsibility for high-level decision-making. The most common responsibilities for these councils are development of the annual capital and operating budgets and the cardiology/cardiovascular strategic plan, monitoring of the service line's quality and financial performance and oversight of the service line's operations.

Anecdotal evidence suggests that some of the most successful councils are those with more physician representatives than hospital representatives. The idea of successful physician-centric governing bodies is not new at the health system level (Mayo Clinic and Geisinger Health System are just two examples). However, here I am referring to a governing council dedicated to integrating and leading both inpatient and outpatient cardiovascular services.

Probably the best known of these cardiology-specific governing councils is at the Minneapolis Heart Institute (MHI), part of the Allina Health System. The MHI council has seven members, five of whom are cardiologists. As a demonstration of their success, despite the reimbursement challenges of the last three years, this council has managed the service line so as to produce more than \$10 million in additional contribution margin for the system while achieving quantifiable quality of care improvements as well.

An important aspect of the physician-centric governance structure is having a CEO who is a cardiologist. This should be a person who is equally comfortable in a meeting with fellow physicians or the hospital's senior management team. It will take such a person, working with a capable non-physician administrator, to achieve the integrated model's financial and quality goals.

**Principle #2:**  
**Do not relinquish control of day-to-day operations.**

In visiting with dozens of cardiology groups, one of the two greatest concerns I've noted among cardiologists considering hospital integration relates to the hospital running their practice. The good news is that most hospitals do not want to run your practice.

Cardiologists instinctively understand that, if a hospital pays millions of dollars for their practice, the hospital will expect a "seat at the table." However, that seat is typically reserved for meetings where budgets, strategic plans, and performance related to those budgets and plans are discussed. As long as the group operates their practice consistent with the governing council's decisions, most hospitals are willing to allow the cardiologists to make the day-to-day scheduling, staffing and other operational

decisions. Since the cardiologists typically have at least equal representation on the governing council, that is not a difficult standard.

**Principle #3:**  
**Beware of the multi-specialty approach.**

Many of this country's largest hospitals already employ physicians. Those that do not realize that their discussions with the cardiologists are merely the beginning in terms of physician integration. The bureaucratic nature of hospitals leads their administrators to believe they need a distinct organization to employ and manage the physicians.

Even where these distinct organizations have a physician governing body, this hospital initiative feeds the second greatest concern of cardiologists: non-cardiology physicians making decisions about cardiology services. The reason, of course, is that the cardiologists rarely have a majority of the governing body's seats. Even worse, many hospitals make clear that the physician governing body is merely advisory and the real decision-making will be by hospital administration.

This problem is exacerbated where cardiologists are in negotiations with a hospital where a distinct physician organization already exists. However, there are two approaches that can assist cardiologists in overcoming the disadvantages that result from a distinct physician organization.

First, you can argue for a distinct "cardiology silo." What this means is that the physician governing board will make decisions that are equally applicable to all employed physicians (e.g., choosing the malpractice carrier, determining what employee benefits will be available to non-physician personnel, etc.). However, cardiology-specific decisions will be made by a council of cardiologists and hospital representatives that is separate from the employing physician entity.

Second, you can make an argument for a complete break from the separate physician organization. In most hospitals, the cardiology service line is the most profitable. As such, the decisions about the cardiology service line's case mix index, contribution margin, new sites of service and plans for physician recruitment have a greater impact on the hospital's bottom line than that of any other physician specialty. Do not forget that, while hospital administrators are evaluated on a complex goal matrix, they are aware of that old adage: "No Margin, No Mission."

**Carlson is with Maynard Cooper & Gale, P.C., Birmingham, Ala. Stay tuned for the next installment in our ongoing series about the ACC Foundation white paper "Practice Opportunities: Practice Integration, Management Contracts, Hospital Integration." In January, the series will consider antitrust concerns. For more, see the full white paper at [www.acc.org/practicemgt/practiceintegration081209.pdf](http://www.acc.org/practicemgt/practiceintegration081209.pdf).**



## ACC Overview of Upcoming Coding Changes in 2010

**2009** was a seminal year for cardiology coding and payment. Not only were there revisions to echocardiography codes, there also were significant changes in cardiac device monitoring coding and payment processing. Recently announced changes for 2010 will be more modest, but still will affect three commonly used services — myocardial perfusion/SPECT imaging; coronary CT angiography (CTA); and cardiac MRI.

The ACC has prepared the following overview to help ease the transition to the new codes and better enable physicians and coders to prepare and comply with the new coding structures.

### Multiple Study SPECT Imaging

Multiple study SPECT imaging is one of the most commonly provided cardiology services. To date, this service has typically been reported using three codes: 78465 to report heart imaging, and two add-on codes, 78478 for wall motion study and 78480 for ejection fraction. However, given the recent trend by policy-makers to create one “bundled” code for services performed together, a new code (78452) has been created to report all three of these services.

Similarly, codes for a single SPECT study and planar studies have been created that bundle wall motion and ejection fraction codes. Even if a SPECT or planar study is performed without these additional studies, they should still be reported with these new codes, as the old codes have been deleted.

Medicare has reduced the payment for these services by 36 percent with the release of the final 2010 Medicare Physician Fee Schedule. Other services that require the reporting of multiple codes for a single service may be subject to similar review and potential payment reductions in the future. The ACC is fighting to prevent cuts of this magnitude from being implemented.

### Coronary CTA

Coronary CTA is a rapidly developing technology that has been reported using eight different Category III codes since 2005. While Category III codes are used to track emerging technology and often are not paid services, the Category III codes for coronary CTA have been paid services under Medicare and by some private payers for a number of years.

Beginning in 2010, four new Category I CPT codes are being added for coronary CTA, replacing the eight Category III codes. Since the codes have changed — shifting from eight codes to four — it is important to review the service provided to determine which code is most appropriate.

### Cardiac MRI

While new cardiac MRI codes were created in 2008, the reporting structure for the codes will change slightly in 2010. As a result of the reporting change, four codes will be deleted and a new add-on code created. Services previously reported with 75558, 75560, 75556 and 75564, which all included velocity flow mapping, now should be reported with the appropriate code from 75557-75563 with an add-on code, 75565, to report the velocity flow mapping.

The tables to the right list the nine new cardiology CPT codes for 2010. Table 1 lists the revised SPECT codes. Table 2 lists the new codes from the eight existing Category III tracking codes.

**Table 1**  
Revised SPECT Codes

<b>78451</b>	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
<b>78452</b>	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
<b>78453</b>	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
<b>78454</b>	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

**Table 2**  
New Codes from Eight Existing Category III Tracking Codes

<b>75571</b>	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
<b>75572</b>	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
<b>75573</b>	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)
<b>75574</b>	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed) Cardiac MRI
<b>75565</b>	Cardiac Magnetic Resonance Imaging for velocity flow mapping (list separately)

**Tips for Transitioning With Your Health Plans** The ACC recommends working now with your health plans to accurately implement and crosswalk current codes to the new codes so there is no delay in processing beginning in 2010. The ACC is working with local chapters and cardiovascular specialty societies to assist carriers in updating their coverage policies and is asking health plans to maintain reimbursement rates at 2009 levels. Practices should consider negotiating any 2010 contracts now and asking for 2009 reimbursement levels. For information on your local carrier, negotiating contracts or issues with implementation of new coverage policies, please contact Saiza Elayda at [selayda@acc.org](mailto:selayda@acc.org).

# Shaping the Future of Cardiology Today

By Steve Simpson, M.D.

Concerns about access to care, health care expenditures and quality of care in the United States are resulting in major policy changes. Most of these changes will take effect just as we become practicing cardiologists. Participation during training in our political action committee (PAC) and the legislative process is important — these changes will affect our practice. Although most fellows feel compelled to become involved, it is difficult to find the best place to start.

The first step to approaching the issue of health care reform is knowledge. Staying up to date can be a time-consuming but fun process. The ACC Quality First and advocacy pages are an excellent place to start. Find them at [qualityfirst.acc.org](http://qualityfirst.acc.org) and [www.acc.org/advocacy/advocacy.htm](http://www.acc.org/advocacy/advocacy.htm). They provide up-to-date information and editorials on what is going on in the U.S. health care debate.

If you're anything like me, once you are engaged in the debate, I have no doubt you will form a strong opinion and feel compelled to make your opinion known. Here are a few ways to do so.

Contact your legislators and build relationships with them. Going to [writerep.house.gov](http://writerep.house.gov) and [www.senate.gov](http://www.senate.gov) is a good way to find your current representatives' contact information. Many of us have written letters or made phone calls to our representatives, but there are many other ways to contact a representative. Trying to develop a relationship with your representatives and their staff is the most effective way to make your voice heard. Often representatives hold office hours at local coffee shops or meetings at libraries to discuss current

issues when Congress is not in session. You may be surprised to find that our representatives are very accessible and willing to hear our point of view. Always be well prepared, concise and professional when you are interacting with your representative and their staff. The ACC CardioAdvocacy Network (CAN) Web site can help prepare you to hold a meeting, write a letter or make a phone call ([www.acc.org/advocacy/CAN\\_Network/can.htm](http://www.acc.org/advocacy/CAN_Network/can.htm)). You'll find sample letters, tips on interacting with your representative and current issues that deserve your attention.

Get involved with your chapter. At the local level, your ACC state chapter often has campaigns organized for local issues and concerns. To find more information about chapter news and events or contact information for your local group, go to [www.acc.org/about/chapters/chapters.htm](http://www.acc.org/about/chapters/chapters.htm). Chapters also are a starting point to becoming more involved in ACC's national efforts.

Finally, support the ACC PAC. Contributions from the PAC help influence policy. Without our support the PAC will not be able to provide data and education to representatives, propose legislation or support the election campaigns of those who support our cause. To contribute or learn more, visit [www.accpacweb.org](http://www.accpacweb.org). Fellows in training have the potential to make a very real difference in how we practice cardiovascular medicine in the decades to come — but only if we take action today.

**Simpson is Chief Cardiology Fellow, Henry Ford Heart & Vascular Institute, Detroit.**



Nov. 28, 1949 Franz Groedel hosts the first meeting of the "American College of Cardiologists" at his office on Park Avenue. The 14 attendees draft a constitution, and on Dec. 2, the American College of Cardiology receives a corporate charter in Washington, D.C. Today, their College counts 37,000 cardiovascular specialists among its members and advocates for quality cardiovascular care worldwide.

The 60 years that have ensued since Groedel held his meeting have witnessed much growth and many changes, but our commitment to the remarkable vision of our 14 founders is unyielding. As we mark the 60th anniversary of the ACC, we celebrate the thousands of members, supporters and friends who have made the College the extraordinary institution it is today.



## Head to the Park and Walk with a Doc

By David Sabgir, M.D., F.A.C.C.

Saturday mornings in Ohio are not meant for sleeping in anymore. Rain or shine, Highbanks Metropolitan Park stirs with activity in preparation for the weekly “Walk with a Doc” before many across the state have taken their first sip of coffee. The program encourages area residents to meet at the local park and go on a walk together, making friends and exercising to promote heart health along the way.

I founded the program in 2005 after realizing that what I thought were helpful talks for my patients were turning out to be ineffective methods of motivation to get out and exercise. Feeling as if I was failing to convey the importance of heart healthy habits to patients while in the office, I did something completely different. I decided to go out to the park with my patients each week and exercise alongside them.

The “Walk with a Doc” mission is simple. We seek to encourage healthy physical activity in people of all ages and reverse the nationwide epidemic of obesity in order to improve the health and wellbeing of the country.

The program comes at no cost to participants and provides free blood pressure checks, pedometers, healthy snacks, recipes and information to make better lifestyle choices. The event also offers the opportunity to get answers to their questions from doctors and health care professionals. We walk in the opposite direction of the group to ensure everyone has a chance to be heard.



According to surveys about the walk, participants are pleased. They particularly like that it is a free event that provides no wait for access to physicians. Participants also responded positively to the routine aspect of the walk — we’re there each week for them, and they appreciate that.

It is our intention to keep the program a grassroots-oriented, local event. Outside of Columbus, the event has already sprung up in Louisiana, North Carolina and Colorado, and we hope it doesn’t stop there. We hope to branch out to other offshoots — maybe one day there will be “Walk with a

Nurse” or “Walk with a Pharmacist” events around the country.

Our greatest hope is to eventually see millions of citizens participating in these walks to lead to more

fully-engaged, better educated patients and enhance their wellbeing through the cardiovascular benefits that exercise provides.

Our strategic vision offers a broader perspective. As Walk with a Doc expands, we will be developing a new patient perspective on physicians and health care in general. By disrupting the physician/patient barriers, we are adding a new dimension to being a physician. Ultimately, we look to transform medicine by drastically improving self-management of our patients and in doing so, improve the health and wellbeing of our country.

Looking to start your own walk? We are fortunate to be in a position where we can offer you everything you need to start up your own Walk with a Doc. For more information or to get involved, visit us online at [www.walkwithadoc.org](http://www.walkwithadoc.org), e-mail [contact@walkwithadoc.org](mailto:contact@walkwithadoc.org), or give us a call at (614) 357-3054.

**Sabgir is a cardiologist with Mount Carmel Health Specialists in Columbus, Ohio.**



## Improving Quality from Hospital to Home

By Pat Lucken, F.N.P.-C., C.P.H.Q.

**By taking the time to recognize barriers to patient understanding and ensuring that we have met the three steps in the H2H process, we can reap the benefits of improved patient satisfaction, better outcomes and huge cost-savings.**

The ACC and the Institute for Healthcare Improvement (IHI) launched a new program last month designed to enhance quality and reduce costs by limiting unnecessary readmissions. The Hospital to Home (H2H) initiative aims to reduce 30-day readmissions for both acute myocardial infarction (AMI) and congestive heart failure (CHF) by 20 percent by December 2012.

The focus of H2H will be to create excellence in care transitions between inpatient and outpatient settings. The post-discharge period is a vulnerable period, a gap during which patients are at highest risk of readmission.

The H2H Steering Team envisions a three-step process starting prior to discharge. The process is one in which we as cardiac care team members can have a significant impact through open communication with the patient:

1. The first priority is to ensure patients understand the medications prescribed, and to be sure they have the ability to access them.
2. The next step is to ensure a follow-up appointment is scheduled, along with reliable transportation to the appointment. The appointment should be within a week of the hospital discharge.
3. Finally, the patient should be able to recognize symptoms to report and know how and when to access that care.

### Barriers to Learning

I know from personal experience working with heart failure

patients that there can be multiple barriers to effective learning that lead to avoidable readmissions. Some barriers are cultural: A Saudi-Arabian gentleman told me he was drinking two gallons of water a day because

he was a "desert man." Some patients are hesitant to question a doctor's orders or "pester" a health care professional to be sure they understand the orders. One patient was taking an NSAID three times daily for the past five years but could not tell me why. His response was, "My doctor told me to take it."

Other issues include socio-economic factors. We wonder why a patient doesn't weigh herself as instructed only to discover she cannot afford the luxury purchase of a scale.

Often there are literacy issues. I once asked a bachelor who had been readmitted for heart failure to create a food diary. Every night he would consume a can of chili. That can of chili had a full day's worth of sodium in it. Another gentleman insisted he never consumes salt, then told me, "My family eats TV dinners."

And finally there is the sodium indiscretion, as in the case of a patient who held his diuretic to attend a wedding and then indulged in a few margaritas ... with the salty rim.

Reducing avoidable readmissions by 20 percent by 2012 is an attainable goal. By taking the time to recognize barriers to patient understanding and ensuring that we have met the three steps in the H2H process, we can reap the benefits of improved patient satisfaction, better outcomes and huge cost-savings. If your facility is not already participating, I hope you will consider joining. To learn more and enroll, go to [www.h2hquality.org](http://www.h2hquality.org).

**Lucken is director of the Cardiac Service Line at St. Mary Medical Center, Apple Valley, Calif. (St. Joseph Health System of Orange, Calif.).**



### ACC Launches Readmissions Initiative with Webinar

The ACC, in partnership with the Institute for Healthcare Improvement (IHI), on Oct. 22 launched a new national quality improvement initiative to reduce the rate of preventable readmissions for patients discharged with a diagnosis of acute myocardial infarction (AMI) or heart failure (HF), called Hospital to Home (H2H). More than 2,000 attendees participated in the launch Webinar that featured H2H Steering Committee Co-Chair **Harlan Krumholz, M.D., F.A.C.C.**, and **Donald Goldmann, M.D.**, of IHI. The Webinar familiarized participants with the design and goals of the initiative and also

included an update on readmissions in the health care reform bills.

Currently, about 20 - 25 percent of patients hospitalized with AMI or HF are readmitted to the hospital within 30 days. Many of these admissions are preventable through improvements in the transition from inpatient to outpatient status. H2H will assist providers in overcoming the systemic barriers to improving readmission rates, with the goal of reducing 30-day all-cause, risk-adjusted readmission rates for HF and AMI patients by 20 percent nationally by 2012. H2H

will catalyze action by harnessing the collective knowledge of its key strategic partners and participants in a rapid learning community.

Since the launch, more than 350 facilities have enrolled in the program. More information, including the archived Webinar, a CVN video, and information on how to enroll, is available at: [www.h2hquality.org](http://www.h2hquality.org) or by e-mailing [hospital2home@acc.org](mailto:hospital2home@acc.org). Also, H2H Steering Committee Co-Chair Harlan Krumholz, M.D., F.A.C.C., discusses the initiative in greater detail on ACC's blog, available at: [lewinreport.acc.org](http://lewinreport.acc.org).



## Team Ball: Building a Winning Cardiovascular Care Delivery System

By John G. Byrne, M.D., F.A.C.C.

When you get right down to it, general cardiologists, interventional cardiologists, cardiac surgeons, vascular surgeons and cardiovascular imaging specialists aren't all that different. We're all treating the same set of patients, just with different sets of tools. So in my view, the idea that we should find ways to coordinate and align care, ideally in one practice — linked financially, geographically and programmatically — follows the same logic and business model around which great championship sports teams are built. Just as activities on an NFL football field are highly coordinated, cardiovascular physicians will need to become coordinated in order to win. As health care reform comes, as it should and will, highly competitive and resource-intense activities such as cardiovascular care will need to be coordinated in "accountable care delivery systems."\* Integrated groups that demonstrate effective teamwork and together deliver superior patient value will likely be the most successful models.

This is one of the central ideas we see emerging in the discussions around health care reform in Washington, D.C., and of course it's at the core of ACC's approach to health reform. From a functional standpoint, this will mean groups of cardiovascular physicians (surgeons, general cardiologists, interventionalists, imaging specialists) becoming financially linked. If a group is not financially linked, it will never be truly coordinated or aligned. Similarly, this model could be envisioned for gastroenterological specialists, neurological specialists and so on. From firsthand

experience, I believe this financially integrated model is the most effective method of coordinating and aligning activities. It offers not only highly effective communication and continuity of care among the CV subspecialists, it also provides a platform for new ways of thinking about our patients' problems. It also is perhaps the most professionally fulfilling model.

Naturally, building a successful collaborative team practice comes with its challenges. Like so many mergers and acquisitions, the largest challenge can be creating a unified culture in which all the players share a common goal, a common purpose, where no one person, role or subgroup is greater than the team. Achieving that shared culture, it turns out, is the greatest victory of all. And of course our patients benefit directly.

### Surgeon/Cardiologist Collaboration at ACC.10

ACC.10 and i2 Summit take a patient-centric approach to the latest science and cutting-edge education. "One of the things we're trying to showcase," says **Jim McClurken, M.D., F.A.C.C.**,

ACC.10 chair, "is collaborative input into patient treatment options that are ideally suited for the individual patient."



McClurken

The Beltway and the house of medicine alike are abuzz with talk of comparative effectiveness — what's proven to work best for patients. Accordingly, ACC.10 and i2 Summit feature a variety of sessions designed to share multispecialty input on basic science and clinical care. There will be stimulating point-counterpoint debates from various specialists who treat the same disease process, as well as collaborative presentations in which diverse specialists from around the world participate in the discussion.

For example, the ACC-European Society of Cardiology joint session, Transcatheter Aortic Valve and Stem Cells, Monday, March 15, 10:30 a.m. – noon, will be a "hybrid" session, which will include clinical and basic science presented by two surgeons and two cardiologists at the same session," says McClurken. A surgeon and ventricular assist device specialist will offer a perspective on stem cell research, followed by a cardiologist's medical perspective on the same topic. To find more collaborative sessions, go to [acc10.acc.org/edu/Pages/PlanningTools.aspx](http://acc10.acc.org/edu/Pages/PlanningTools.aspx) to access the ACC.10 and i2 Summit Program Planner.

## Hybrid Cath Lab/OR Suite

The integrated Heart Institute at Vanderbilt features a hybrid cath lab/operating room (OR), what Byrne describes as the “embodiment of the team’s collaborative model.” Don’t miss an exciting new feature at ACC.10 — the Hybrid Cath Lab/OR Suite and 3D CV Theater. Interventionalists, cardiac surgeons and general cardiologists will want to plan to spend time in this multi-modality room designed to allow a variety of integrated surgical and endovascular procedures. Located on the Expo floor in Hall B4, this interactive, multi-vendor exhibit will allow attendees a firsthand look at cutting-edge technologies, while the adjacent 3D CV Theater features video presentations of cases and discussions with physicians currently performing procedures in hybrid suites around the country.



## Building the Team

The ACC is helping surgeons and cardiologists nationwide move towards collaboration. In February, the College held a standing-room-only event, “Surgeon-Cardiologist Collaboration: A Patient-Centered Approach to Emerging Technologies and Appropriate Use Criteria.” We presented on topics like the appropriateness of PCI vs. surgery vs. various “hybrid” procedures. The conference was a magnificent start in opening channels of communication between groups that traditionally have operated separately, often competitively, and offering education targeted to collaborative groups.

I believe that as organizations like the ACC continue to encourage this collaborative, patient-centric approach to cardiovascular diseases, eventually we may see something like an American Board of Cardiovascular Sciences. The idea would be to take bright, young, energetic people right out of medical school and train them not in “medicine” or “surgery” but rather as cardiovascular specialists. Along this training road a cardiovascular physician may become a basic scientist, a general cardiologist, an interventional cardiologist, a structural heart disease specialist, a CV imaging specialist, a CV epidemiologist, a vascular surgeon or a cardiac surgeon. As health care reform approaches, perhaps now is the ideal time to consider breaking down the artificial and archaic barriers of “medicine” vs. “surgery.” Perhaps it’s time to realize we are all cardiovascular physicians, with different tools.

In the end, we’re all fighting the same battle for the same patients. As President Kennedy once said: “We all breathe the same air, we all cherish our children’s future and we are all mortal.” It’s time to look to new models that help us achieve true collaboration and alignment for the benefit of our patients.



**Byrne is a member of the ACC’s Surgeon Scientific Council and The William S. Stoney Professor and Chairman of the Department of Cardiac Surgery and Co-Director and Surgeon-in-Chief of the Vanderbilt Heart and Vascular Institute at Vanderbilt University, Nashville, Tenn.**

\* Andrews, M. (2009). “Making Health Care Accountable.” *New York Times Prescriptions Blog*. [prescriptions.blogs.nytimes.com/2009/10/09/making-health-care-accountable/?hp&scp=1-b&sq=accountable+care+delivery+systems&st=nyt](http://prescriptions.blogs.nytimes.com/2009/10/09/making-health-care-accountable/?hp&scp=1-b&sq=accountable+care+delivery+systems&st=nyt). Accessed Oct. 30, 2009.

## ACC News

### ACC Joins Yale to Learn about Top Performance in AMI

The ACC will participate in a study to identify key factors associated with exemplary performance by hospitals that care for patients with acute myocardial infarction. The study, led by **Elizabeth Bradley, Ph.D.**, and **Harlan Krumholz, M.D., F.A.C.C.**, both of Yale University School of Medicine, and a large team of investigators, is a mixed-methods approach to focus specifically on hospital performance as reflected by the Centers for Medicare and Medicaid Services’ 30-day mortality measure. The alignment of the ACC with Yale will strengthen the study, and ACC members will have the opportunity to participate in generating knowledge-enhancing care that is directly relevant to their practice.



Krumholz

### Vote Now: Board of Governors Elections

Vote today for your ACC leadership at [www.acc.org/vote](http://www.acc.org/vote). Elections are being held for ACC governors and chapter presidents in British Columbia, Connecticut, Delaware, Florida, Iowa, Kansas, Michigan, Mississippi, New Hampshire, New Mexico, North Carolina, Oklahoma, Quebec, South Dakota, Vermont, Washington and Wisconsin.

All ACC members in these states and regions are eligible to vote and have received ballots by e-mail and postal mail. The deadline for voting is Nov. 24 at 5 p.m. (ET). If you are a member in one of the above states, please go to [www.acc.org/vote](http://www.acc.org/vote) to cast your vote.

### eHealth Initiative to Hold Annual Conference

The eHealth Initiative will host its sixth annual conference, *Delivering on the Promise of eHealth*, Jan. 25 – 26 with the support of the ACC. The conference will highlight specific examples of how eHealth programs are being pursued across the country, as well as address challenging questions about the ability of the U.S. to move towards universal, meaningful use of health information technology (IT) to improve health. The eHealth Initiative’s conference will critically examine meaningful use and other policy options and help attendees understand how health IT can improve the quality, safety and efficiency of health care. Policymakers, industry leaders, clinicians and patients will participate in engaging panel discussions and adversarial debates revolving around eHealth issues that affect the U.S. health care system. Exclusive early bird registration rates are available until Nov. 25. To register, visit: [www.ehealthinitiative.org/announcing-ehealth-initiatives-annual-conference-2010.html](http://www.ehealthinitiative.org/announcing-ehealth-initiatives-annual-conference-2010.html).

# Diabetes Initiative Addresses Gaps in Knowledge, Practice

By Roger S. Blumenthal, M.D., F.A.C.C.



**November is American Diabetes Month, and the ACC continues to add to its foremost educational initiative designed to help members combat this leading contributor to cardiovascular disease.**

The initiative, Convergence of Type 2 Diabetes and Cardiovascular Disease, encompasses a variety of educational opportunities — from those designed to address the needs of Fellows in Training to programs that help CV physicians and nurses assess and correct current practice gaps. The initiative incorporates a wide spectrum of learning formats including live programs and e-learning, developed by a distinguished panel of 14 cardiologists, endocrinologists, diabetologists and CV nursing professionals. The initiative already has conducted nine live regional symposia, and more are planned for 2010 throughout the country. Check out the upcoming programs on [cardiosource.com/diabetes](http://cardiosource.com/diabetes).

Visit [Cardiosource.com/diabetes](http://Cardiosource.com/diabetes) to earn CME and CE credits, access virtual clinics, case studies, expert opinions, meeting coverage, journal articles and clinical trial coverage.

Coming in spring 2010, the College will add Diabetes SAP, a new self-assessment program, to its array of diabetes education programs. Like the other educational activities included in this initiative, Diabetes SAP is designed so that every member of the cardiac care team may assess their knowledge and current practice strategies for diabetes management. Once they identify those gaps, Diabetes SAP will offer learner-centered education to fill those gaps in practice.

## Looking to the Future

Convergence of Type 2 Diabetes and Cardiovascular Disease has an eye to the future of diabetes and CV disease

management with tailored education designed for Fellows in Training. An ACCIS (ACC In-Service) online diabetes knowledge assessment module is

scheduled for launch in fall 2010. ACCIS modules assist trainees and training directors in identifying areas of strength and weakness through pre- and post-assessment.

Dec. 5 – 6, **Valentin Fuster, M.D., Ph.D., F.A.C.C.**, and **Robert Bonow, M.D., M.A.C.C.**, will offer their popular, no-cost “How to Become a Cardiovascular Investi-

## David vs. Goliath

In the first virtual case on [Cardiosource.com/DIABETES](http://Cardiosource.com/DIABETES), learners have the opportunity to work up and manage a virtual patient, David, who is battling Type 2 Diabetes and has other indications for a future cardiac event. During the initial virtual visit, learners will be able to assess their current knowledge, prioritize work-up options, review peer-to-peer evidence-based debate on specific management issues, and plan a course of action for future virtual visits with David. David returns to you five weeks later for his second, follow-up visit.

Practice virtually alongside leading clinical experts to work up/manage (first visit) and follow up/treat (second visit) David's coronary artery disease and type 2 diabetes mellitus.

gator” program. Fellows interested in investigating diabetes and CV diseases can learn more about their options for an academic career.

I encourage you to log on to [Cardiosource.com/diabetes](http://Cardiosource.com/diabetes) to learn more and ensure you continue to offer your patients the very best care for their Type 2 diabetes and cardiovascular disease.

**Blumenthal is chair of the Convergence of Type 2 Diabetes and Cardiovascular Disease Initiative and director of the Johns Hopkins Ciccarone Center for the Prevention of Heart Disease in Baltimore.**





## i2 Summit 2010 Reflects Rapid Growth of Interventional Field

By George Dangas, M.D., Ph.D., F.A.C.C. and David Holmes Jr., M.D., F.A.C.C.

Interventional cardiology continues its rapid and vibrant growth. New technologies, new strategies, new fields of less invasive treatment options, new challenges and new demands dominate the field. Keeping abreast of this rapid evolution is a constant challenge, and the flood of new information continues unabated.

The i2 Summit 2010 offers unique opportunities to help you overcome these challenges: informal interchange with interventional colleagues, the chance to strengthen ties with general cardiology, exposure to new approaches through live demonstrations, case studies and state-of-the-art lectures given by a superb faculty, small focused complications sections,

**This year's i2 Summit is particularly learner-centered. We aim to offer the most extensive maintenance of certification (recertification) program in interventional cardiology, but also in general cardiology with instruction in knowledge modules, simulations and practice-improvement modules (PIM).**

abstracts, late-breaking clinical trials that include the most up-to-date new data, updates on certification, simulation ... the list grows each year as we strive to build a meeting that meets the needs of the interventional community.

### Education with You in Mind

This year's i2 Summit is particularly learner-centered. We aim to offer the most extensive maintenance of certification (recertification) program in interventional cardiology, but also in general cardiology with instruction in knowledge modules, simulations and practice-improvement modules (PIM).

The program includes the latest science, as always. We have increased the sessions allocated to oral abstract presentations, and we have thematically placed them within program "tracks." We also have expanded the scope of the poster abstract presentations. This year we've distilled the science to its practical, clinical implications to an even greater extent than in the past. We will expand on the case-based discussions and presentations in order to reduce the clinical trial results into their applicable clinical messages. In addition, the academic panels will be targeted to address the shortcomings and advantages of recent trials and how they dictate the planning of further research projects. Attendees will be engaged in the continuous thought process of evidence-based medicine in the field of interventional cardiology.

### Making Connections

We're also bringing you unparalleled access to the experts — interaction that makes for an individualized learning environment. We are making a serious effort to increase the connection between attendees and faculty. For the first time, we are inviting any participant to submit a case to be discussed during the popular "Meet the Experts" sessions, in order to allow the experts to comment on cases sent in for their diagnostic or therapeutic dilemmas or technical challenges. We've also made a greater allowance for Q&A and discussion sessions.

You'll make connections with the experts, as well as with your colleagues in general cardiology and other subspecialties. The ACC's i2 Summit provides interaction with what is happening in the broader cardiology community

through a unified program with ACC.10. We're particularly excited to bring you jointly planned ACC and i2 sessions that will address very "hot" subjects with an all-inclusive approach: academic and clinical perspectives from a variety of cardiovascular sub-disciplines.

### Comprehensive Coverage

Our comprehensive approach also pertains to subject matter. Live cases, for example, will cover a wide spectrum. The curriculum covers everything from classic coronary intervention themes — multivessel disease, left main and chronically occluded vessels — to endovascular, valvular and adult congenital heart disease interventions.

Your program committee strives to make this an all-encompassing meeting aimed at the educational needs of the entire community of both interventional and general cardiovascular specialists. We look forward to your active participation, your questions, your learning, your growth. We'll see you in Atlanta, March 14 – 16!

**Dangas is chair of the i2 Summit Program Committee and program director for interventional cardiology at Columbia University Medical Center. Holmes, vice president of the ACC, is past chair of the Program Committee and a consultant in cardiovascular disease at the Mayo Clinic.**



Dangas



Holmes



ACCEL

## Under Pressure: Diagnosing Cardiac Abnormalities in Competitive Athletes

**B**ig careers, big records, big paychecks — big hearts? For some athletes, cardiomyopathies and other cardiac diseases can end their careers and even their lives. Names like Reggie Lewis and Hank Gathers remind us that athletes can be cut down by cardiac disease at any age, and sudden cardiac death can occur even on the courts where they reign.

Student athletes face similar risks and cardiologists should be aware that a number of cardiac conditions can affect even the most physically fit young people, including hypertrophic cardiomyopathies, unexplained left ventricular hypertrophy, myocarditis and coronary anomalies. In 2007, the American

families, their fans, even the alumni of the schools they played for.” Despite the pressure, he says, it is imperative that clinicians provide their best medical opinion.

The 12-point exam applies to all competitive athletes, student or professional. Besides electrocardiograms, these young people often benefit from echocardiography; if hypertrophy is an issue, echo may be helpful in assessing function and structure. Magnetic resonance imaging (MRI) can be valuable for evaluating heart structure, geometry, function and subendocardial scarring. However, MRI’s cost may put it out of reach for many athletes whose teams cannot provide financial support for the scan.



**“ There’s often great pressure to let an individual like that play, with pressure coming from the athletes themselves, their team, the team’s owners, their families, their fans, even the alumni of the schools they played for... it’s imperative that clinicians provide their best medical opinion. ”** Stephen Smith, M.D., F.A.C.C.

Heart Association updated its recommendations (endorsed by the American College of Cardiology Foundation) regarding pre-participation screening for cardiovascular abnormalities. The statement consists of 12 points for pre-participation cardiovascular screening of competitive athletes. A positive response or finding to one or more of these items (covering personal history, family history and physical examination) may be judged sufficient to trigger a referral for cardiovascular evaluation.

Not all referrals come from pre-participation screening. Professional athletes often are referred to a cardiologist after the detection of symptoms on incidental testing. According to **Stephen Smith, M.D., F.A.C.C.**, of the Henry Ford Health System in Detroit, “You have to look at those individuals a little more closely. There’s often great pressure to let an individual like that play, with pressure coming from the athletes themselves, their team, the team’s owners, their

If tests identify a likely or potential cardiac problem, Smith says, the recommendations from the 36th Bethesda Conference must be applied to determine whether the athlete is eligible to play. Unfortunately, unfavorable results usually send the athlete running for a more favorable second opinion.

Some of these athletes have implantable cardioverter defibrillators placed, but Smith cautions that we have no information on how these devices perform in the context of sports, particularly contact sports. He identifies this as one important area in which we need more data to guide us in sports medicine.

The fact is, Smith concludes, athletes don’t want to hear the results if they are bad. “These are young, healthy, athletic people who want to continue their sport. That’s their world. And as one of them once said to me, this is my life. So he didn’t want to give that up, despite the fact that he had a known diagnosis,” he says.

## Four Steps for Diagnosing Athletes

1. Use the 12-point AHA Recommendations for Screening for Cardiovascular Abnormalities in Competitive Athletes, available at [circ.ahajournals.org/cgi/content/full/115/12/1643](http://circ.ahajournals.org/cgi/content/full/115/12/1643) (See 12 Points)
2. An electrocardiogram can be helpful if you identify abnormalities based on the 12-point screening
3. Conduct more advanced testing in certain individuals based on what you believe you will find
4. Apply 36th Bethesda guidelines determining eligibility to play, available at [www.acc.org/qualityandscience/clinical/bethesda/beth36/index.pdf](http://www.acc.org/qualityandscience/clinical/bethesda/beth36/index.pdf)

## 12 Points

### Medical history\*

### Personal history

1. Exertional chest pain/discomfort
2. Unexplained syncope/near-syncope†
3. Excessive exertional and unexplained dyspnea/fatigue, associated with exercise
4. Prior recognition of a heart murmur
5. Elevated systemic blood pressure

### Family history

6. Premature death (sudden and unexpected, or otherwise) before age 50 years due to heart disease, in  $\geq 1$  relative
7. Disability from heart disease in a close relative < 50 years of age
8. Specific knowledge of certain cardiac conditions in family members: hypertrophic or dilated cardiomyopathy, long-QT syndrome or other ion channelopathies, Marfan syndrome, or clinically important arrhythmias

### Physical examination

9. Heart murmur‡
10. Femoral pulses to exclude aortic coarctation
11. Physical stigmata of Marfan syndrome
12. Brachial artery blood pressure (sitting position)§

\* Parental verification is recommended for high school and middle school athletes.

† Judged not to be neurocardiogenic (vasovagal); of particular concern when related to exertion.

‡ Auscultation should be performed in both supine and standing positions (or with Valsalva maneuver), specifically to identify murmurs of dynamic left ventricular outflow tract obstruction.

§ Preferably taken in both arms.

Source: Marron, B.J., et al (2007). Recommendations and considerations related to preparticipation screening for cardiovascular abnormalities in competitive athletes: 2007 update: A scientific statement from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism: Endorsed by the American College of Cardiology Foundation. *Circulation* 115: 1643 – 55.

## ACC.10 & i2 Summit Call for Science

Don't miss your chance to be part of the future of cardiology at ACC.10 and i2 Summit. The ACC is now accepting Late-Breaking Clinical Trial submissions. Submit trials in general and interventional cardiology from major randomized trials that will have significant impact on clinical practice. Go to [acc10.acc.org/CallForScience/Pages/default.aspx](http://acc10.acc.org/CallForScience/Pages/default.aspx) for more information.



## New This Year!

### Submit Your Most Challenging Case

The ACC invites you to submit your most challenging coronary or endovascular intervention or structural heart disease case for consideration at a Meet the Experts session during i2 Summit, March 14 – 16. For more information, or to submit your case, go to [acc10.acc.org/CallForScience/Pages/CallforCases.aspx](http://acc10.acc.org/CallForScience/Pages/CallforCases.aspx). The deadline to submit is Dec. 15 at 8 a.m. ET. Submitters will be notified by the end of January whether their case(s) will be presented.

## Coming Spring 2010 ...

Watch for the launch of CardioSource 3.0, the ACC's new and improved Web portal, this spring. Designed with you in mind, this new site will be your source for the latest clinical content as well as everything you need to know as a member of the College — all made easily accessible through the latest technology. Watch for more information in upcoming issues of *Cardiology*.



## ACC Receives Grant for Clinical Research Network

The ACC has received a two-year grant to form a National Cardiovascular Research Infrastructure (NCRI) in cooperation with the Duke Clinical Research Institute. This landmark partnership will create a clinical trials network that the federal government can use for comparative effectiveness research and post-approval observational studies. The NCRI will engage NCDR® participants in the pursuit of research, offering them necessary training to become principal investigators within their own hospitals and establish their own research teams. The initiative also will better allow the ACC to systematically identify clinical topics for guideline development outcomes-based initiatives.



Duke Clinical Research Institute  
DUKE UNIVERSITY MEDICAL CENTER

## FDA Awards Contract to ACCF for CHD Registry

The FDA recently awarded a contract to the American College of Cardiology Foundation for the development of a congenital heart disease registry. The intent of the contract is to develop a registry that will increase the scientific knowledge base for congenital heart disease. The contract will further assist in the development of NCDR's IMPACT Registry™, which tracks the prevalence, demographics, management and outcomes of pediatric and adult patients with congenital heart disease who are undergoing diagnostic catheterizations and catheter-based interventions. The IMPACT Registry is piloting 15 sites. For more information on the IMPACT Registry, visit: [impact.ncdr.com](http://impact.ncdr.com).

IMPACT Registry™



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Contact **Jamie Sitko**, Physician Recruiter for Aspirus at 800-792-8728 or fax CV to 715-847-2742 or email: [jamiesi@aspirus.org](mailto:jamiesi@aspirus.org)

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Please forward CV to:  
 Northwest Cardiovascular Institute LLP  
 Attn.: Sally Sparling, CEO  
 2222 NW Lovejoy, Suite 606  
 Portland, Oregon 97210  
[sallysparling@nw-ci.com](mailto:sallysparling@nw-ci.com)



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## Cardiology opening in Beautiful East Tennessee

Mercy Health Partners is seeking a BC/BE cardiologist to join a busy cardiology practice in Jefferson City, TN, 30 minutes from Knoxville TN. Practice currently has one invasive cardiologist and one nurse practitioner.

Physician will provide clinical outpatient services and inpatient consultations at St. Mary's Jefferson Memorial Hospital and provide invasive procedures at the St. Mary's Medical Center in Knoxville. A 64-Slice CT Scanner is available for CT angiography. Call is limited to 10 nights per month - for phone consultations only. Physician office management, marketing, credentialing and managed care contracting is provided by the group. Salaried position with incentive compensation, excellent benefits, malpractice, and CME allowance, and moving expenses provided.

Jefferson City sits in the foothills of the Great Smoky Mountains, where many people are retiring for its beauty and quality of life. With beautiful area lakes and parks, there are great recreational opportunities. Live on the lake, enjoy out door life and practice cardiology in a wonderful area of the country. You'll also be near the main campus of The University of Tennessee and have access to theatre, opera, and an excellent symphony orchestra.

**Contact: Karen McKinney, Physician Recruiter, Mercy Health Partners,  
Phone: (865) 549-4529 • Fax: (865) 549-4646  
Email: kmckinney@mercy.com**

## Assistant Professors in Cardiovascular Medicine

The Division of Cardiovascular Medicine at Stanford University is seeking two faculty members at the Assistant Professor level to join the Interventional Cardiology and Heart Transplant Sections. The positions are for full-time faculty members in the Medical Center Line. The individuals should have advanced clinical and research experience and be trained in cardiovascular interventions or in all aspects of cardiac transplantation. There will be a significant research component and candidates should be capable of conducting independent research in these respective areas. The major criteria for appointment, reappointment and promotion for faculty in the MCL shall be excellence in the overall mix of clinical care, clinical teaching, scholarly activity that advances clinical medicine, and institutional service-appropriate to the programmatic need the individual is expected to fulfill. Applicants must have an MD degree and be board certified in Cardiovascular Disease (or eligible). Advanced certification or training is highly desirable. Stanford University is an equal opportunity employer and is committed to increasing the diversity of its faculty. It welcomes nominations of and applications from women and minority groups, as well as others who would bring additional dimensions to the university's research, teaching, and clinical missions.

***Applicants should send a curriculum vitae and names of three potential referees to  
Faculty Affairs, Cardiovascular Medicine, Stanford University School of Medicine,  
300 Pasteur Drive, Stanford, CA 94305-5406.***

This Month in  
**JACC**

**November 3**

- The Sympathetic Nervous System In Heart Failure: Physiology, Pathophysiology, and Clinical Implications
- Angiotensin-Converting Enzyme Inhibitor Therapy at the Time of Coronary Artery Bypass Surgery: When a Friend Turns Mean-Spirited
- Triggering of Nocturnal Arrhythmias by Sleep-disordered Breathing Events

**November 10**

- The J Curve between Blood Pressure and Coronary Artery Disease or Essential Hypertension — Exactly How Essential?
- Is it Time to Expand the Use of Cardiac Resynchronization Therapy to Patients with Mildly Symptomatic Heart Failure?
- The Coronary Artery Calcium Score and Stress Myocardial Perfusion Imaging Provide Independent and Complementary Prediction of Cardiac Risk

**November 17**

- Adult Congenital Heart Disease: Importance of the Right Ventricle
- Incidence and Predictors of Drug Eluting Stent Fracture in Human Coronary Artery — Pathologic Analysis
- The Relative Efficacy and Safety of Clopidogrel in Women and Men

**November 24**

- Appropriate Evaluation and Treatment of Heart Failure Patients after an Implantable Cardiac Defibrillator Discharge: Time to Go Beyond the Initial Shock
- Women Have Lower Prevalence of Structural Heart Disease as a Precursor to Sudden Cardiac Arrest: The Oregon Sudden Unexpected Death Study
- Genotype-Phenotype relationship in the Long-QT Syndrome: Brimming with Knowledge but Thirsting for a Therapeutic Solution

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cardiovascular  
**Interventions**

- Intracoronary Optical Coherence Tomography: A Comprehensive Review — Clinical and Research Applications
- Cardiac Catheterization on the Road Less Traveled: Navigating the Radial vs. Femoral Debate
- Prognostic Impact of Periprocedural Bleeding and Myocardial Infarction after Percutaneous Coronary Intervention in Unselected Patients: Results from the EVENT Registry

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**Imaging**

- Quantification of Mitral Regurgitation by Real-time Three-dimensional Echocardiography: Head-to-Head Comparison with 3D Velocity-encoded Magnetic Resonance Imaging
- Assessment of Myocardial Ischemic Memory Using Persistence of Post-systolic Thickening after Recovery from Ischemia
- Assessment of Coronary Plaque Progression in Coronary CT Angiography Using a Semi-Quantitative Score

**Educational Programs Calendar**

	December 4 - 5, 2009 <b>How to Become a Cardiovascular Investigator</b> Valentin Fuster, M.D., Ph.D., F.A.C.C.	Washington, D.C. CME
	December 11 - 13, 2009 <b>42nd Annual New York Cardiovascular Symposium</b> Valentin Fuster, M.D., Ph.D., F.A.C.C.	New York CME CE
	January 11 - 15, 2010 <b>41st Annual Cardiovascular Conference at Snowmass</b> Spencer B. King III, M.D., M.A.C.C.	Snowmass, Colo. CME CE
	January 22 - 24, 2010 <b>29th Annual Perspectives on New Diagnostic and Therapeutic Techniques in Clinical Cardiology</b> C. Richard Conti, M.D., M.A.C.C.	Lake Buena Vista, Fla. CME CE
	February 5 - 6, 2010 <b>4th Annual Heart of Women's Health</b> JoAnne M. Foody, M.D., F.A.C.C. Suzanne Hughes, M.S.N., R.N.	Washington, D.C. CME CE
	February 12 - 14, 2010 <b>2nd Annual Clinical Practice of Peripheral Vascular Disease</b> Michael R. Jaff, D.O., F.A.C.C. Christopher J. White, M.D., F.A.C.C.	Phoenix CME CE
	February 15 - 19, 2010 <b>32nd Annual Cardiology at Big Sky Meeting</b> Kim A. Eagle, M.D., M.A.C.C. Sidney Goldstein, M.D., F.A.C.C.	Big Sky, Mont. CME
	March 13, 2010 <b>"Boot Camp" for Cardiology Fellowship Program Directors and Coordinators: Educating the Educators</b> Jeffrey Kuvin, M.D., F.A.C.C.	Atlanta CME
	May 6 - 8, 2010 <b>32nd Annual Recent Advances in Clinical Nuclear Cardiology and Cardiac CT Featuring Case Review with the Experts</b> Daniel S. Berman, M.D., F.A.C.C. Guido Germano, Ph.D., M.B.A., F.A.C.C. Jamshid Maddahi, M.D., F.A.C.C.	Washington, D.C. CME TECH
	May 21 - 22, 2010 <b>Emergency Cardiovascular Care 2010: Enhancing Regional STEMI Systems of Care</b> Christopher B. Granger, M.D., F.A.C.C. James G. Jollis, M.D., F.A.C.C. Mayme Lou Roettig, R.N., M.S.N.	Chicago CME CE

For a complete listing of upcoming events and to register online, go to [www.acc.org/education/programs/programs.htm](http://www.acc.org/education/programs/programs.htm)

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