Protecting Your Patients and Your Practice:
Evolving Models of Practice Symposium Offers Guidance for Integration
Now Approved!
Now Available!

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

Visit www.MULTAQ.com
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].

1 INDICATIONS AND USAGE

MULTAQ® is indicated for the reduction of the risk of cardiovascular hospitalization in patients with paroxysmal or persistent AF or 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, and for prevention of stroke or systemic embolism in patients with AF or AFL with at least one risk factor for stroke or systemic embolism [see Clinical Studies (14) and Warnings and Precautions (5.1)].

2 DOSAGE AND ADMINISTRATION

The only recommended dosage of MULTAQ® is 400 mg twice daily in adults. MULTAQ should be taken once as a 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)].

3 CONTRAINDICATIONS

MULTAQ is contraindicated in patients with:

1. 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]

2. Second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker)

3. Bradycardia <50 bpm

4. Concomitant use of strong CYP 3A inhibitors, such as ketoconazole, itraconazole, voriconazole, telithromycin, clarithromycin, nefazodone, and ritonavir [see Drug Interactions (7.2)]

5. Concomitant use of drugs or herbal products that prolong the QT interval and might increase the risk of Torsade de Pointes, such as phenothiazine anti-psychotics, tricyclic antidepressants, certain oral macrolide antibiotics, and psychoactive or psychotomimetics.

6. QTc Bazett interval ≥500 ms or PR interval >280 ms

7. Severe hepatic impairment

8. 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 (8.3)]

9. Nursing mothers [see Use in Specific Populations (8.3)].

4 WARNINGS AND PRECAUTIONS

5.1 Patients with New or Worsening Heart Failure during Treatment

Advised prescription for patients if they develop signs or symptoms of heart failure, such as weight gain, 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

Dronedarone 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 dronedarone 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. An increased value should be used as the patient's new baseline. The change in serum 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. If the QTc Bazett interval is >500 ms, MULTAQ should be stopped [see Contraindications (4)].

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 (5.3)]

• QT prolongation [see Warnings and Precautions (5.3)]

The safety evaluation of dronedarone 400 mg twice daily in patients with AF or AFL is based on 5 placebo controlled studies, ATHENA, EUROLIS, ADONIS, ERAUTO and DAFNE. In these studies, a total of 6285 patients were randomized and treated, 3182 patients with MULTAQ 400 mg twice daily, and 2873 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 dronedarone-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 dronedarone 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

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

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo (N=2875)</th>
<th>MULTAQ 400 mg twice daily (N=3282)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine increased</td>
<td>21%</td>
<td>51%</td>
</tr>
<tr>
<td>five days after treatment initiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QTc Bazett prolonged (&gt;450 ms in males &gt;470 ms in females)</td>
<td>19%</td>
<td>28%</td>
</tr>
</tbody>
</table>

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

Dronedarone 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]. Dronedarone's blood levels can therefore be affected by inhibitors and inducers of CYP 3A, and dronedarone can interact with drugs that are substrates of CYP 3A and CYP 2D6. Dronedarone 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 channel blockers; digoxin; other antiarrhythmics (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 oral 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, rifabutin, clarithromycin, and efavirenz 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
Statin
Dronedarone increased simvastatin/simvastatin acid exposure by 4- to 2-fold, respectively. Because of multiple mechanisms of interaction with statines (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 coadministration 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/m2 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/m2 basis), fetuses had an increased rate of skeletal abnormalities (anomalous ribcage and vertebral, pelvic asymmetry) at doses ≥20 mg/kg (the lowest dose tested and approximately half the MRHD on a mg/m2 basis).

Actual animal doses: rat (≥80 mg/kg/day); rabbit (≥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.

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sanofi-aventis U.S. LLC Bridgewater, NJ 08807

DRO-BPLR-AS-JUL09 Revised: July 2009
The College continues to battle implementation of the Centers for Medicare and Medicaid Services’ 2010 Physician Fee Schedule. Our goal is to introduce legislation that would mitigate the effects of the practice expense cuts. We are working with potential congressional sponsors and supporters to determine the right legislative options.

Of course, a moratorium on the Rule would be the most attractive option for cardiology, but it’s not feasible. Potential congressional supporters have made it clear that they will not support a complete moratorium that keeps cardiology status quo but wipes out the increases included in the Rule for primary care and other specialties.

Once we introduce our legislation, we will need you to contact your representatives and ask them to be co-sponsors of the legislation. We will need thousands of letters, calls and visits to key lawmakers urging their support for the legislation. Go to acc.org and click on the Campaign for Patient Access, or go directly to www.campaignforpatientaccess.org to find out more about how you can take part in the battle to defend our patients’ access to high-quality care.

The odds are stacked against us, and we will need every member's involvement more than ever before. This is not the time to lose hope or momentum. This is the time to raise your voices, to share your resources and to exhaust every opportunity.

This issue of Cardiology is all about opportunities and options. James Dove, M.D., M.A.C.C., George Rodgers, M.D., F.A.C.C., and Michael Valentine, M.D., F.A.C.C., share a report from the Evolving Models of Cardiovascular Practice symposium they developed to help physicians and practice managers consider all their options for survival in these trying times. Blair Erb Jr., M.D., F.A.C.C., tells you about our new Practice Survival Toolkit, loaded with tools and strategies to help you not only survive, but thrive. We also remind you of your options for Medicare enrollment.

Janet Wyman, M.S.N., A.P.R.N., B.C., R.N.-C.S., enumerates the many educational and professional options for cardiac care team members attending i2 Summit in March. We also tell you about changes to the 2010 schedule for Cardiology magazine that we hope will give us an opportunity to share more news with you in a more effective, efficient way. One of our international colleagues, Selina Kikkenborg Berg, R.N., M.S.N., shares a research opportunity to improve the way we care for patients with atrial fibrillation.

This year has not been an easy one, but it has been full of opportunity — opportunities to improve patient care, defend patient access and strengthen our cardiovascular community. I hope you will take time this holiday season to reflect on the many opportunities you have been given and delight in the possibilities for the new year ahead.

I wish you all a very safe and happy holiday season and look forward to working with you in 2010!

Alfred A. Bove, M.D., Ph.D., F.A.C.C.
ACC President
When the ACC Cardiovascular Leadership Institute began planning “Evolving Models of Cardiovascular Practice: Surviving and Thriving in Times of Change,” we knew it was a relevant and important program for our members. We had no idea just how critical it would become in the wake of the Centers for Medicare and Medicaid Services’ (CMS) release of the 2010 Physician Fee Schedule.

If implemented, the planned cuts in Medicare reimbursement over the next four years will devastate the private practice of cardiology. The ACC Market Intelligence team surveyed our membership and found two-thirds of cardiologists already have integrated their practices with a hospital or larger practice or anticipate doing so at some point in the next three years. MedAxiom conducted similar research for our symposium and found two-thirds of respondents have integrated or are in the process of doing so, with another 32 percent saying integration is not in their immediate plans but is a possibility for the future. Declining physician reimbursement was a leading reason for integration among those already integrated and those considering it.

For a specialty like cardiology, known for its autonomy and free thinking, this is astounding. Unfortunately, the government and payers have prioritized cost above quality and access to care. Our practices, small businesses that employ skilled staff, face an unprecedented threat. The College designed the “Evolving Models” symposium to offer concrete advice to help private practitioners survive this changing business climate.

We obviously hit a nerve. In November, more than 100 cardiologists and practice managers gathered at Heart House for this standing-room-only program. So many more expressed interest that we are offering the program as an online Meeting on Demand. (Call the ACC Resource Center at 800-253-4636, ext. 5603, to learn more.)

Although it’s disappointing that so many private practices likely will be forced to find a new model for providing cardiovascular care, the symposium was a great success in giving ACC members the business guidance they’ll need in 2010 and beyond.
Survival Strategies

Pat White, president of MedAxiom, presented the MedAxiom survey data, which examined 136 practices. Among those already fully integrated, the survey reported reasons for integrating, use of integration consultants, compensation models and valuation. Fully integrated practices also reported changes in cost and performance post-integration. One hundred percent would recommend integration to other practices, with 86 percent saying physician satisfaction has increased since the integration.

“'For a specialty like cardiology, known for its autonomy and free thinking, this is astounding. Unfortunately, government and payers have prioritized cost above quality and access to care.'”

Former ACC President James T. Dove

William T. “Mike” Carlson Jr., counsel for Maynard, Cooper & Gale (and frequent columnist in the Practice Management section of this magazine), covered the various options for cardiologists: stick with the status quo, seek out other business relationships, integrate with other physician groups, or integrate with a hospital. Carlson also reviewed the potential pitfalls in the process. He advised participants to hire a valuation firm and do their research.

Eighty-one percent of the integrated practices in MedAxiom’s survey worked with a consultant or other outside counsel to negotiate the integration. Practice prices are declining, particularly as related to intangibles (reputation of the practice, health records on file, etc.). Compensation numbers for physicians also are dropping, so it’s worth working with a professional who has experience in negotiating these deals.

continued on next page

CMS Payment Cuts May Lead to Increased Private Practice Migration

Nearly half of private cardiology practices are considering integration, according to a recent survey from the American College of Cardiology. The survey, conducted by the College's Market Intelligence team, reveals a strong trend toward hospital migration, particularly in light of the cuts included in the 2010 Medicare Physician Fee Schedule final rule. Private practice cardiologists, who account for 59 percent of the total cardiovascular physician workforce in the U.S., are more likely to consider integration into a hospital system than a merger with another practice. Only one-third of practices surveyed do not expect to integrate at all.

Physicians in private practice confirm that the rule threatens the viability of private practice. Sixty-one percent of private practices report they will be forced to reduce their staff as a result of the rule, 46 percent will eliminate services lines, and nearly one in five will be forced to reduce office hours and limit Medicare payment. Larger private practices are not immune to the threats the rule imposes, but solo practitioners and smaller practices will feel the greatest effect, with anticipated cuts across the board in staff, service lines, Medicare payment and office hours.

Practitioners report they have strong concerns not only about the impact these changes will have on the economic viability of their practices, but more fundamentally about how these changes in cardiology practice will affect patients. “ACC has been good at promoting quality of cardiology care,” says one cardiologist. “If we don’t figure out the economic survival of private practice, quality may take a back seat to survival.” Another practitioner agrees: “I am worried about the future of the private practice of cardiology. I have built a group of 11 private practitioners and had we not been bought out by our hospital 16 months ago, we likely would not be together today. We service close to 100,000 patients.”

The survey was conducted between Oct. 31 and Nov. 17 among 801 domestic ACC members. For more information on the data, please contact Neal Kovach at nkovach@acc.org.
On the bright side, according to Carlson, governance models are improving. Hospitals are giving physicians more autonomy, which is a very good thing from our perspective.

Hospital execs agreed. Michele Molden, CEO of Piedmont Heart Institute in Atlanta, underscored that working cooperatively with physicians is in the best interest of the hospital: “The only way hospitals will see an increase on the profit side will be to work with physicians.” Skip Meador, vice president of cardiovascular services and neurosciences at Centra Health in Lynchburg, Va., said, “I don’t have anything without physicians.” Molden and Meador advised paying close attention to the governance structure to build a model that works and develop trusting relationships.

Throughout the symposium, we conducted breakout sessions on various employment models, sessions on legal concerns, governance, valuation, negotiating and more. We also offered a session on how to be successful if you choose to remain independent. You can review all 15 hours of important presentations and advice — and save yourself hours with legal counsel — with the Evolving Models of Cardiovascular Leadership Institute Work Group.

The ACC will continue to oppose the implementation of the fee cuts with every tool at its disposal, and the four-year phase-in will allow us to continue to fight the threats to cardiovascular patients in 2010 and beyond. In the likely event that at least some of these cuts go into effect, however, the College is ready with strategic tools like the Evolving Models symposium to help members survive — and thrive — in a new economic reality.

Dove is a past president of the ACC and chair of the Cardiovascular Leadership Institute Work Group. He founded Prairie Cardiovascular Consultants, Ltd., in Springfield, Ill., and served as director of the Evolving Models of Cardiovascular Practice symposium. Rodgers is with Biophysical Corp. He is a member of the Cardiovascular Leadership Institute Work Group. Valentine is with The Cardiovascular Group Centra/Stroobants Heart Center in Lynchburg, Va. He is co-chair of the Cardiovascular Leadership Institute Work Group.
**XIENCE V® is Superior* to TAXUS® Liberté® in COMPARE**

**Primary Endpoint**
1-Year MACE

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- TAXUS Liberté®: 9.1%

Reduction: 31%

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

- XIENCE V®: 0.7%
- TAXUS Liberté®: 2.6%

Reduction: 74%

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

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

*XIENCE V® 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 Express™ was the control in SPIRIT IV. Source: SPIRIT IV, one year results, TCT 2009 and XIENCE V® 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.

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

1,800 Patient Real-World, Complex Population

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*Risks and benefits should be considered in patients with severe contrast agent allergies.

**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:

- Are unable to receive antithrombotic and/or antiplatelet therapy
- Have lesions that prevent complete angioplasty balloon inflation or proper placement of the stent or stent delivery system
- Have 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.

**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 dilation of the arterial segment containing the stent. Long-term outcomes following repeat dilation 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.

**Potential adverse events**
Adverse events (in alphabetical order) which may be associated with coronary stent use are:

- 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 agents.

**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.
XIENCE V® Delivers Low 0.29% Stent Thrombosis in 2,458 Patients in SPIRIT IV

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® 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® Express® was the control in SPIRIT IV. Source: SPIRIT IV, one year results, TCT 2009 and XIENCE V® IFU.

1 P-values based on Fisher's exact test.

2 Categorical data, 365 ± 28 days.

Please contact your Abbott Vascular representative to learn more or visit our web site at www.XienceV.com

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Commentary

How the Rule Will Affect My Practice

By Susan J. Alexander, M.D., F.A.C.C.

The cuts included in the Medicare Physician Fee Schedule will have a devastating effect, not only on physicians, but on our patients and our employees. At my practice in Spokane, Wash., we’re making tough decisions in the wake of the Rule — and ultimately we’ll have to decide if remaining in private practice is a viable option.

The Impact on Patients

We are likely going to have to cut back our remote clinics in Washington and northern Idaho, leaving scores of elderly without cardiac care. In an effort to increase the number of patients we see in our main office, we will overbook by 10 percent each day on each physician’s schedule. A patient who is late will have to wait to be fit into the schedule later in the day.

Nurses will no longer be able to spend time on the phone when a patient calls in for advice; patients will have to make an appointment for help. Letters to patients with test results, etc., will be replaced with a secure site or phone recording for them to access their results.

In short, the lucky patients who still have access to our services will not benefit from the level of personal contact and feedback they have learned to expect. In order to attempt to keep our practice financially viable, we’ll have to abandon much of the time we spend with our patients answering questions and offering advice — and quality of care will suffer.

The Impact on Employees

I write this in the wake of a meeting during which my practice made the decision to cut disability insurance and paid time off for our employees, and to freeze salaries and hiring. In the future, staff members will have to purchase their own coverage — if they are able to afford it. One can imagine the devastating impact if they become disabled without it.

We also face the terrible possibility of laying off more employees. The staff we can keep will be responsible for helping us manage the vastly larger case load — with no increase in pay.

The Impact on Physicians

Let’s not forget that we, as physicians, are employees of the practice, as well, and depend on the practice for our livelihood. We have reassigned office space to create more exam rooms in order to accommodate the increase in patient load. In an effort to minimize our use of transcription services, we will be typing our own notes. This will require time previously spent in discussion with patients. We have reduced our own benefits and time off significantly, impacting the time we have to spend with our families, and thus our quality of life. Our workload is growing (and our pay is shrinking), and given our frenetic daily clinical schedules, we’ll have to take an enormous amount of work home to tackle after hours. It’s an increased burden for physicians who already are stretched thin.

I find it difficult to stomach the cuts included in the Physician Fee Schedule as I watch our legislators in Washington working on health care reform legislation that does not adequately address the billions we all witness daily being wasted on defensive medicine and medical fraud. We don’t need to cut physician pay. We need to spend what we have more wisely. Our livelihoods — and our patients’ lives — depend on it.

Alexander is with Spokane Cardiology in Spokane, Wash.
Saving Time Saves Lives

This month the Journal of the American College of Cardiology published results from ACC’s national campaign to reduce door-to-balloon time for ST-segment elevation myocardial infarction (STEMI) patients. The ACC’s Door-to-Balloon (D2B) Alliance achieved its goal of lowering D2B times to within the guideline-recommended 90 minutes for 75 percent of patients by 2008, according to a new study from the December 15 – 22 issue of JACC.

In 2005, approximately one half of patients with STEMI who received a primary percutaneous coronary intervention (PCI) met the recommended 90-minute D2B time. The D2B Alliance launched in November 2006 to help participating hospitals lower their D2B times. By March 2008, over 75 percent of patients in those hospitals had D2B times of less than 90 minutes.

“This ambitious effort to improve timeliness of heart attack care has reported marked improvements,” says Elizabeth H. Bradley, Ph.D., professor at Yale School of Public Health, and lead author of the study. “The improvement was across the nation, not just in a few hospitals or states. The movement changed the way heart attack care is delivered — for the benefit of patients.”

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The authors conducted an evaluation of D2B times in 831 hospitals participating in the ACC’s National Cardiovascular Data Registry (NCDR®) CathPCI® Registry from April 1, 2005, to March 31, 2008, to examine the use of D2B Alliance-recommended strategies, changes in D2B times before and after the launch of the program, and differences in D2B times for patients treated in D2B Alliance hospitals and hospitals not enrolled in the program. The prevalence of each strategy recommended by the D2B Alliance improved significantly during the time period measured, as did the three-year trend in patient D2B times within 90 minutes, from 52.5 percent in 2005 to 76.4 percent in 2008.

More recent data collected by the CathPCI Registry indicate that hospital performance has continued to improve beyond the end of the study period. The most recent available data, from June 30, 2009, show that 81.7 percent of eligible patients receiving primary PCI had D2B times of less than 90 minutes. The average D2B time has dropped significantly as well, from an average of 121 minutes at the end of 2005, to an average of 80 minutes as of June 30.

“This effort shows what is possible when health care professionals work together to quickly improve care through the use of strategies developed from rigorous research,” says Harlan M. Krumholz, M.D., F.A.C.C., Harold H. Hines Jr. Professor of Medicine at Yale School of Medicine, and co-author of the study. “We think of breakthroughs as something that happens in the laboratory, but this research shows how we can generate knowledge by studying how top performers work and then transform the national care of patients with heart attacks.”

NCDR® Presents 14 Abstracts at AHA

The ACC’s National Cardiovascular Data Registry (NCDR®) is on a roll! The American Heart Association accepted 14 NCDR abstracts for presentation at its Annual Scientific Sessions last month, including five abstracts from the CathPCI Registry®, four from the ICD Registry™, one from the CARE Registry®, two from ACTION®-GWTG™ and two from the IC³ Program® (the new PINNACLE Registry™).

This is a testament to the rich evidence coming from these groundbreaking registries.

Of particular excitement were the abstracts from the College’s first outpatient registry, the IC³ Program. The first was an oral presentation by Paul S. Chan, M.D., M.P.H., A Report of the First 10,000+ Patients. The study found nearly three in five patients enrolled in the IC³ Program had coronary artery disease. Equally important, the study also demonstrated that participants reliably could assess outpatient performance measures, and that opportunity for improving the quality of outpatient cardiovascular care exists.

The second abstract (a poster presentation by ACC staff member Kristi Mitchell, M.P.H., and Sunil Gupte, Ph.D.) was Electronic Medical Record Adoption in Cardiology Practices: A 2009 Snapshot. This study found electronic medical record (EMR) adoption within the IC³ Program is slightly greater than that reported in the literature and may be due to the greater number of large practices enrolled. The IC³ Program provides a foundation to analyze EMR adoption and implementation rates in U.S. cardiology practices and to observe trends associated with reducing some of the financial barriers due to the recent provision of federal funding. As such, the IC³ program will be positioned to determine the impact of EMR usage on clinical quality and patient outcomes.
While the 2009 recession slowed many ambitious plans at the state level, it still was a busy year for health care in the state legislatures. Fortunately, thanks to the cooperation and hard work from ACC chapters, no legislation negatively affecting cardiologists passed, and, in several cases, state legislatures approved positive legislation for cardiology. The following is an overview of the key issues ACC members faced in the states in 2009:

Imaging/Self-Referral

Despite several attempts by various radiology groups to pass state legislation restricting physician access to medical imaging, Maryland remains the only state in which radiology-exclusive groups and individual solo practitioner radiologists may perform in-office CT and MR. While bills modeled on the Maryland law were introduced in several states, they failed to pass.

In addition, states like Arkansas, Connecticut, Montana and Texas fended off their own legislative challenges to imaging access. In Washington, an imaging law taking physician ownership and self-referral issues off the table and substituting quality assessment passed with support from nearly all specialty societies that provide imaging services. While it’s unclear if payers will adopt the Washington recommendations, ACC’s appropriate use criteria received a better rating than the American College of Radiology’s appropriateness criteria for cardiac nuclear medicine procedures.

Tobacco

Attempts to pass or enhance smoke-free laws had mixed results in states across the country. Efforts proved unsuccessful in states like Alabama, Indiana and Louisiana. In Michigan, smoke-free legislation advanced further than in years past but stalled in the end. However, several states, counties and cities were able to pass smoke-free laws, including South Dakota.

Become an Advocacy ‘Wiz’

The College and its chapters have a powerful new advocacy tool at their disposal. CapWiz is an easy-to-use, online system that allows you to find and contact your local, state and national legislators. Go to capwiz.com/acc to learn the issues, locate elected officials by ZIP code and send a message advocating for issues important to your practice and patients.
North Carolina, Wisconsin, Mississippi and St. Louis County, Missouri. Other states, such as Ohio, turned back efforts to weaken existing laws, and Arkansas, Kentucky and Rhode Island were able to pass increases in tobacco excise taxes.

Many states already have indicated they will continue to push smoke-free laws in 2010, including Kansas, where Gov. Mark Parkinson (D) recently said he will push the legislature to pass a statewide smoke-free indoor air law when it reconvenes in January.

Medical Liability Reform

Unfortunately, 2009 saw states attempting to overturn medical liability laws that already were on the books. For example, in Nevada, the ACC Nevada Chapter successfully fended off a bill that would have overturned parts of Nevada’s malpractice law, which has a hard cap of $350,000. Other states, such as Mississippi and Missouri, saw their state supreme courts challenge existing laws.

On the plus side, Oklahoma passed landmark medical liability reform legislation capping non-economic damages at $400,000 outside of exceptional circumstances, and Montana passed a bill limiting the liability of health care professionals during a disaster. The New Mexico House of Representatives introduced similar legislation, but unfortunately it did not pass.

Other Issues

This year saw several states introduce legislation designed to increase revenues — but at a profound cost to patients. Many of these proposals — such as a 3 percent tax on physicians in Michigan — got further than we would have thought, but ultimately were shot down. We also saw wins in other areas, such as a New York health department decision to adopt a statewide standard that allows nuclear techs to perform radionuclide injections.

In addition to working closely with individual legislators, the ACC greatly expanded its relationship with the National Conference of State Legislatures, as well as the National Lieutenant Governors Association (NLGA). The ACC is working with NLGA to spearhead the “Your Heart is in Your Hands” campaign, a cardiovascular health education program designed to lower mortality in more than 20 participating states.

A clear priority for state legislatures in 2010 will be implementing (or attempting NOT to implement) health care reform legislation passed by Congress. States also saw their Medicaid enrollments increase by 5.4 percent across the country, the biggest jump in six years. In 2010, they will have to devise plans to pay for the increased pressure on Medicaid.

The ACC will continue to act as a resource to state officials as they pursue the best health care policies for their states. We also will continue to monitor and report on legislation that would limit physician access to in-office medical imaging; push for stronger smoke-free laws and increased tobacco taxes; support efforts to speed health information technology adoption and implement the use of electronic medical records; and improve STEMI systems of care throughout the country.

It’s a significant agenda. I encourage you to get involved in your state by working closely with your chapter to help defend our right to practice and our patients’ best interests.

Harold is with Cedars-Sinai Medical Center in Los Angeles. He is Chair of the Board of Governors.
Physician Fee Schedule cuts . . . health care reform legislation . . . health information technology (IT) . . . The practice of cardiology faces significant change in 2010 and beyond. What do you need to succeed?

The ACC.10 Practice Management program is designed to answer that question, showing you how to survive — and thrive — in a new era of medicine. We understand the challenges you’re facing, and we have planned Practice Management sessions with both practice administrators and private practice cardiologists in mind.

Over the course of ACC.10, we’ll explore new and emerging models of care and offer concrete strategies from physicians and administrators who have integrated their practices with hospitals. We’ll investigate the controversial Medicare payment cuts and provide the latest news on Medicare reimbursement demonstration projects. We will offer insight into health IT, cost controls, quality improvement, variation in care and comparative effectiveness research.

Our goal is for these Practice Management sessions to help you deal with the many external challenges facing your cardiology practices as efficiently and effectively as possible — so you can maintain your focus on quality and patient-centered care.

Although our profession faces many challenges, our dynamic and innovative approach to medicine will help us prevail. You’ll find that vibrant spirit alive and well in Atlanta, March 14 – 16.

Here are a few of the highlights of our ACC.10 Practice Management line-up:

• Health IT Spotlight Session The ACC and Healthcare Information and Management Systems Society (HIMSS) will host a day-long spotlight session on Sunday, March 14, featuring the hottest topics in health IT and key opinion leaders in the field. Topics will include health IT policy, the future of health IT and more. Plus, attendees will enjoy a tour of the Electronic Health Records Pavilion at the ACC Exposition.

• ACC/MedAxiom/MGMA Practice Administrator Program: What’s Happening to My Profession? On Sunday, March 14, from 10 a.m. to 2 p.m., the ACC will partner with MedAxiom and the Medical Group Management Association to offer a symposium covering everything from “meaningful use” of health IT to the ACC’s Hospital to Home Initiative to emerging models of cardiovascular practice.

• Evolving Models of Cardiovascular Practice — What To Do After A Merger On Sunday, from 12:15 p.m. to 1:45 p.m., The Croes Oliva medical group management consulting firm will partner with the ACC to cover profitable, beneficial post-merger relationships for physicians and their new practice or hospital employer.

• Lab Accreditation — What Practices Need to Know to Comply with the Centers for Medicare and Medicaid Services’ Rules Sunday, from 2:30 p.m. to 3:30 p.m., a representative from the Intersocietal Accreditation Commission will discuss the accreditation process and provide information on how a practice can apply
for accreditation. A practice CEO will discuss her own experience preparing for and undergoing the accreditation process.

- **Quality First Initiative Brown Bag Luncheon** On Tuesday, March 16, from 12:15 p.m. to 1:45 p.m., the College will offer this brown-bag session with an overview of the PINNACLE Network™. You’ll learn more about resources and support structures to help strengthen your practice and bring you through these turbulent times. The discussion also will cover the PINNACLE Registry™ (formerly the IC3 Registry), the ACC’s outpatient registry designed to help practices transition to an era of performance measurement through adherence to clinical guidelines and demonstration of quality. Finally, attendees will learn about the ACC Cardiovascular Recognition Program (CVRP), which the ACC will promote as a replacement for current quality-recognition programs being used by health plans.

- **And more …** Throughout the ACC.10 program, you will find featured sessions on health care reform, patient-centered care, racial and ethnic disparities in cardiovascular care and the Quality First initiative.

Although our profession faces many challenges, our dynamic and innovative approach to medicine will help us prevail. You’ll find that vibrant spirit alive and well in Atlanta, March 14 – 16. I encourage you to visit acc10.acc.org now to register for ACC.10 and i2 Summit and begin exploring the fantastic program, including the wide variety of Practice Management programming. I look forward to welcoming you to Atlanta!

O’Murchu is co-chair of the Annual Scientific Session Programming Committee. He is with Temple University Hospital Division of Cardiology in Philadelphia.

**ACC Launches Practice Survival Toolkit**

You’ll find a huge volume of practice management content at ACC.10 in March, but the ACC also is providing immediate tools for survival. The College has launched a new Practice Survival Toolkit in response to the unprecedented cuts planned by the Centers for Medicare and Medicaid Services (CMS) for Jan. 1, 2010.

The ACC recognized the profound impact the CMS rule for 2010 will have on practicing cardiologists and convened a work group comprised of current and former governors, practice administrators and ACC staff to quickly develop this set of tools and resources to help you prepare.

Our membership works in a variety of practice environments. In recognition of this, we have included an expansive array of information and resources in hopes that cardiologists from all types of practices will find it of benefit. Topics range from simple advice such as collecting co-pays at the time of service all the way to options for future business plans.

It is important for you to know that the ACC recognizes and respects the many practice arrangements now present in our country. Our objective is the survival of the practice of cardiology in the U.S. so that we can continue to reduce cardiovascular mortality and improve our patients’ quality of life.

To access the Practice Survival Toolkit, visit www.acc.org/practicemgt/pst_home.cfm.

**Blair Erb Jr., M.D. F.A.C.C.**
Medicare Enrollment Options

Physicians essentially have three options when it comes to Medicare enrollment:

1. They may **sign a participating (PAR) agreement** and accept Medicare’s allowed charge as payment in full for all of their Medicare patients.

2. They may **elect to be a non-participating (non-PAR) physician**, which allows them to make assignment decisions on a case-by-case basis and to bill patients for more than the Medicare allowance for unassigned claims.

3. They may **become private contracting physicians** and bill patients directly, foregoing any payments from Medicare to their patients or themselves.

Physicians who wish to change their Medicare status have the option to do so annually. This decision typically is binding until the next annual contracting cycle, except in cases where a practice situation has changed significantly, such as relocation to a different geographic area or to a different group practice. To become a private contractor, physicians must give 30 days notice before the first day of the quarter the contract takes effect.

Physicians considering a change in status should make sure they are not bound by any contractual arrangements with hospitals, health plans or other entities. In addition, they should make sure their state laws do not prohibit balance billing of patients.

**PAR Physicians**

PAR physicians must accept Medicare’s approved amount (80 percent paid by Medicare, plus a 20 percent patient co-pay) as payment in full for all covered services for the duration of the calendar year. A PAR physician cannot bill patients for amounts exceeding the Medicare allowance. While PAR physicians must accept assignment on all Medicare claims, Medicare participation agreements do not require physician practices to accept every Medicare patient who seeks treatment from them.

As incentive for participation, Medicare payments for PAR physicians are 5 percent higher than for non-PAR physicians. In addition, directories of PAR physicians are available to patients and groups that request them, and carriers tend to process PAR physician claims more quickly.

**Non-PAR Physicians**

Medicare approved amounts for services provided by non-PAR physicians are set at 95 percent of Medicare approved amounts for PAR physicians. However, non-PAR physicians are able to charge more than the Medicare approved amount. Limiting charges for non-PAR physicians are 115 percent.
When considering the non-PAR options, physicians must determine whether their total revenues from Medicare, patient co-pays and balance billing would exceed their total revenues as PAR physicians. They must also account for collection costs, bad debts and claims for which they do accept assignment. When non-PAR physicians accept assignment for low-income or other patients, Medicare approved amounts still are only 95 percent of the approved amounts paid to PAR physicians for the same service. Non-PAR physicians must collect the full limiting charge amount at the time of service in order to receive payment equal to that of PAR physicians for the same service. That being said, if the full limiting charge is collected for more than 35 percent of the services provided, Medicare revenues would exceed those of PAR physicians.

Medicare Enrollment Period Extended

Changes under the 2010 Medicare Physician Fee Schedule final rule affect the enrollment period for participation in the Medicare program. The Centers for Medicare and Medicaid Services (CMS) has extended the 2010 Annual Participation Enrollment Program end date from Dec. 31 to Jan. 31, 2010. The effective date for any participation status change will remain Jan. 1, 2010, and stay in effect for the year. The Participation Agreement (CMS-Form 460) is available on the CD-ROM that is sent out annually by Medicare contractors during the annual participation enrollment period. The agreements also should appear on the Web sites of Medicare contractors.

Private Contractors

Provisions in the Balanced Budget Act of 1997 give physicians and their Medicare patients the freedom to privately contract to provide health care services outside the Medicare system. However, private contracting decisions may not be made on a case-by-case or patient-by-patient basis. To opt out, a physician must file an affidavit that meets the necessary criteria and is received by the carrier at least 30 days before the first day of the next calendar quarter. There is a 90-day period after the effective date of the first opt-out affidavit during which physicians may revoke the opt-out and return to Medicare as if they had never opted out. Once physicians have opted out of Medicare, they cannot submit claims to Medicare for any of their patients for two years.

A physician who has not been excluded under sections 1128, 1156 or 1892 of the Social Security Act may, however, order, certify the need for, or refer a beneficiary for Medicare-covered items and services, provided the physician is not paid, directly or indirectly, for such services (except for emergency and urgent care services). For example, if a physician who has opted out of Medicare refers a beneficiary for medically necessary services, such as laboratory or inpatient hospitalization, those services would be covered by Medicare.

Physicians who have opted-out of Medicare under the Medicare private contract provisions also can furnish emergency care services or urgent care services to a Medicare beneficiary with whom the physician has previously entered into a private contract so long as the physician and beneficiary entered into the private contract before the onset of the emergency or urgent medical condition. These services would be furnished under the terms of the private contract.

In addition, physicians who have opted-out of Medicare may continue to furnish emergency or urgent care services to a Medicare beneficiary with whom the physician has not previously entered into a private contract, provided the physician:

• Submits a claim to Medicare in accordance with both 42 CFR part 424 (relating to conditions for Medicare payment) and Medicare instructions (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted out of Medicare).

• Collects no more than the Medicare limiting charge, in the case of a physician (or the deductible and coinsurance, in the case of a practitioner).

Physicians who choose to “opt out” of Medicare under a private contract are strongly urged to consult with an attorney to develop a valid contract.

CMS Delays PECOS Policy Change

You recently may have noticed some strange messages on your Explanation of Benefits. That’s because CMS added a new remark code in preparation for a change in policy. Once this change in policy goes into effect, CMS will no longer pay for services ordered or referred by practitioners not enrolled in the Medicare program. Those practitioners who furnish services to patients referred by others who are either not in the Medicare provider enrollment system, PECOS, or are not in the contractor’s master file when this new policy is implemented will not be paid for those services. The good news is that, as a result of efforts by the ACC and others, CMS has agreed to delay full implementation of this policy until April 5, 2010.

This new policy creates numerous problems, both legal and practical. The provider community, including the ACC, recently sent a letter to CMS opposing this new policy. Additionally, the ACC has been working directly with CMS to mitigate the effects of this policy on practitioners who receive referrals and will continue to do so.
EHR Case Study: EHR Use in an Integrated Ambulatory Setting

With the federal government authorized to give away $17.2 billion to assist providers who use health information technology (IT), the time has never been better to adopt an electronic health record (EHR) into your practice.

Below is the story of one cardiologist’s efforts to implement an EHR at seven CV practices affiliated with the University of Pennsylvania health system. Lee Goldberg, M.D., M.P.H., F.A.C.C., led the implementation process for the practices, which range in size from two physicians to as many as 25 including nurse practitioners. His full interview can be found at acc.org/healthIT in the EHR adoption toolkit.

Q: What challenges did you face in implementing the EHR? Have you successfully overcome them?
A: Some of the workload was shifted to the physicians, who now — rather than send out to a transcription service — have to do more of the letter generation themselves. But I would say most physicians at this point feel that the benefits have outweighed the challenges.

Q: What advice do you have to offer to a practice looking to choose and implement an EHR?
A: Practices need to look at not just the EHR but the workflow and the roles of staff behind it. You need to be open to the human factors involved.

Q: What goals did you set for the EHR? Did you meet them?
A: Our goals were to improve quality, patient safety and the ability to share data among practices efficiently. We feel that we’re better because of the EHR. We are capturing all kinds of information that was not well-captured in paper, following up on tests and orders, and tracking patient phone calls. We also now have drug-drug interaction and other drug safety warnings. We have immediate access to quality tools during the encounter.

Visit acc.org/healthIT for more health IT resources, including additional member interviews, an EHR toolkit and more.

ACC Helps Health IT Committees Define ‘Meaningful Use’

The ACC in October testified to the Office of the National Coordinator (ONC) for Health Information Technology (IT) to assist the office in its work defining “meaningful use” of certified health IT. The Centers for Medicare & Medicaid Services (CMS) is required to release proposed rules defining the term by Dec. 31. The proposed rule will address complicated health IT issues, such as data standards, data interoperability and health information exchange; information privacy and security; and system certification, among others. The meaningful use provisions are intended to incentivize the adoption of health IT.

During their testimony to the Health IT Policy and Standards Committees, ACC members presented the challenges they faced integrating health IT into their practices, and profiled lessons learned from the evolution of the IC3 Program® to the PINNACLE Network™. The ACC message, which has been presented multiple times to ONC, is clear: Proving meaningful use must not be overly burdensome, and must focus on real quality improvement. The College will carefully review the proposed rules when released in January 2010. For more about federal health IT efforts, visit: healthit.hhs.gov.

This Month in JACC

December 8

- The Emerging Role of Exercise Testing and Stress Echocardiography in Valvular Heart Disease
- A randomized, double-blind, placebo-controlled, dose-escalation study of intravenous adult human mesenchymal stem cells (Prochymal™) following acute myocardial infarction
- Field Triage Reduces Treatment Delay and Improves Long-Term Clinical Outcome in Patients with Acute ST-Segment Elevation Myocardial Infarction Treated with Primary Percutaneous Coronary Intervention

December 15/December 22

- Total Cardiovascular Disease Burden: Comparing Intensive With Moderate Statin Therapy - Insights From the IDEAL Trial
- Are Changes in Cardiovascular Disease Risk Factors in Midlife Women due to Chronological Aging or to the Menopausal Transition?
- Effect of Moderate Diet-induced Weight Loss and Weight Regain on Cardiovascular Structure and Function
- Smoking Status and Long-Term Survival After First Acute Myocardial Infarction: A Population-Based Cohort Study

December 29/January 5

- Cardiovascular Magnetic Resonance in Patients With Myocardial Infarction - Current and Emerging Applications
- The Year in Hypertension 2009
- NTproBNP guided treatment for chronic heart failure: results from the “BATTLESCARRED” trial

JACC Imaging

- Impact of Cardiac Contractility Modulation on Left Ventricular Global and Regional Function and Remodeling
- Bridging the Gap - Intraplaque Hemorrhage Identified as a Stimulator of Episodic Growth of Advanced, but Non-symptomatic Atherosclerotic Lesions
- Ultra-Low Dose Intra-arterial Contrast Injection for Iliofemoral Computed Tomographic Angiography

JACC Interventions

- Three Year Clinical Follow up of the XIENCE V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Coronary Artery Lesions. The SPIRIT II Trial
- Long-Term Clinical and Economic Analysis of the Endeavor Zotarolimus-Eluting Stent vs. the Cypher Sirolimus-Eluting Stent: Three-Year Results from the ENDEAVOR III Trial
- Clinical Outcomes Following Unrestricted Implantation of Everolimus-eluting Stents
Discussions of comparative effectiveness and cost effectiveness have loomed large in the medical community recently. My investigation of nurse-managed atrial fibrillation suggests this is an area of promise for increasing value to patients and decreasing costs, but there is a paucity of valid data.

Most studies are small and underpowered. One study, for example, focused on nurse-led cardioversion but included only 300 patients.\(^1\)

Physicians evaluated patients and selected them for cardioversion, but after that, the nurse did all the pre-procedures, the blot-sampling, the sedation, the cardioversion and the follow up. Afterwards, the investigators asked the patients whether they were happy with the process, and 89 percent reported they would do it again. The cost decreased to one-third the original cost without the need for an anesthetist, and the authors noted there was no additional risk for patients.

Team-based follow-up care could also have a major impact on readmissions. As part of a larger study, there is a smaller study looking at patients with chronic atrial fibrillation who were assigned either to an extensive at-home follow-up program, in which they were managed by nurses, or to usual care.\(^2\) The home-based interventions group had fewer readmissions and days of associated hospital stay than the usual care group, but the results were not statistically significant because they were very underpowered: There were only 31 patients in each group.

We’ll have better data in the future about nurse-led programs to increase adherence to therapy. There is an ongoing study in Holland examining an Internet program, in which nurses specially trained to follow the European Society of Cardiology guidelines for the management of atrial fibrillation work with patients to increase their adherence to treatment programs.\(^3\) In a small pilot study, the researchers found this could really close the gap on adherence, readmissions and event rates.

The patient population with atrial fibrillation is growing, and the costs are huge. It appears that this is an area, like heart failure, cardiac rehabilitation and secondary prevention, in which a multidisciplinary team could reduce the morbidity of atrial fibrillation and be very cost-effective. But we need more investigations to examine this area in order to improve the care of atrial fibrillation patients.

Today’s heart failure patients receive their care from an increasingly complex array of practitioners — a cardiologist, a primary care physician, a nephrologist, a pulmonologist and so on. Add to the physicians a long list of highly skilled care team members: the nurse practitioner, specially trained registered nurses, chronic disease management nurses, dieticians, social workers, pharmacists and more.

The mass of literature continues to support the intrinsic value of multi-disciplinary management programs that serve to reduce hospitalizations and increase longevity and overall increased quality of life.

Within this framework, our clinic has embraced the philosophy of collaboration and team-based management, building a structure that takes maximum advantage of every member of the heart failure care team.

Our heart failure clinic is situated at the Royal Alexandra Hospital in Edmonton, Canada. What began as a research-funded project with one nurse practitioner and one registered nurse following a few heart failure patients has since exploded to include over 600 patients, a full-time nurse practitioner, four nurses, a social worker, dietician and pharmacist. Our team-based approach to heart failure management runs the gamut of patient care.

As with all models of care, our goals for the patient begin with stabilizing their clinical status, optimizing their medical management, controlling exacerbating risk factors and co-morbidities while considering device-related issues — all according to established practice guidelines.

What we add to the usual spectrum of care at our clinic is education, support and access to community resources. We emphasize self-management and early recognition of symptoms, as well as encourage active participation in the overall management. We assess and reinforce adherence to medical regimes while providing the necessary support and counseling for the patient and their family.

This comprehensive approach is only possible by making full use of our integrated, multi-disciplinary team. We schedule patients into regular clinic visits, during which they receive discipline-specific care from the cardiologist, nurse practitioner, registered nurse, dietician and social worker.

Patients derive additional benefits from follow-up telephone consultations with various members of our team between clinic visits. During these conversations we assess symptoms as well as response and adherence to recent changes in therapy. We also are able to reinforce key education and provide necessary emotional support.

Our team doesn’t end with our clinic. We maintain a strong partnership with the many other individuals who take part in the care of a patient: the primary care provider, chronic disease management nurses, home care services, palliative care, social workers, etc.

We reach out to this arm of the care team to provide credited educational sessions in the management of these increasingly complex patients. We conduct Grand Round talks and speak at multidisciplinary rounds to share specific patient education information. This allows for consistency of care and progress towards the best possible care for the heart failure patient. Translation: a significant reduction in emergency room visits and decrease in long, complicated admissions in acute care facilities.1

The team-based structure we have developed also affords us research opportunities that allow us to advance the value of the team-based approach and study new therapies.

Heart failure programs that adopt team-based strategies for the delivery of care optimize available resources for the benefit of the patient and the profession. We encourage you to take a team-based approach within your practice and develop strong working relationships with primary care providers and other members of your patients’ care team.


Holland, J. Batterby and I. Harvey et al., Systematic review of multidisciplinary interventions in heart failure, Heart 91 (2005), pp. 899–906
Cardiac care team members will find themselves at the summit of interventional cardiology in March in Atlanta. We have designed the i2 Summit 2010 with a wide variety of programming ideal for the care team, including the CCA Spotlight Session taking place on March 13. It’s a visionary agenda with very practical applications for every member of the team.

The Future, In Practical Terms

Our agenda also incorporates a variety of sessions that look to the future of cardiology and its practical implications. At many scientific meetings, programming focuses on research — new therapies and techniques that won’t be implemented for years, if at all. One of our most popular session themes from previous years, which we are bringing back in 2010, is “The Cath Lab of Tomorrow.” We’ll look at significant research results that have been published in the past year that will result in major protocol or procedure changes in the upcoming year. These include the left atrial appendage device for atrial fibrillation patients, the new thienopyridines that have been approved, percutaneous edge-to-edge repairs for mitral valve regurgitation. The goal is to learn how we can prepare our labs for new procedures and change our protocols and patient instructions.

A new topic for the CCA spotlight session will look at how comparative effectiveness helps us better work with patients and our physician colleagues to determine what therapies are appropriate for which patients and when. We’ll demonstrate to attendees how data from the NCDR® registries and the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC²) can help make better informed treatment decisions and more accurately define risk profiles considering an individual’s unique co-morbidities.

Keynote Themes

At ACC.09, Fred Bove, M.D., Ph.D., F.A.C.C., announced that the theme of his presidency would be the “Year of the Patient.” Accordingly, the College has focused on patient-centered care as a key initiative — and you will find that is very much the case at i2 Summit. One of our two keynote sessions on Saturday will encourage attendees to think from the patient’s perspective. We will examine health literacy and discuss informed consent tools that are personalized to a patient’s individual risk profile, describing the procedure in language they can comprehend. Our last patient-centered topic will examine the teachable moment in the cath lab. Too often when patients leave the cath lab with a recommendation for “medical management,” they believe there’s no need to change their lifestyle. We need to capture the moment to begin educating the patient to the contrary.

Our Saturday afternoon program begins with a second theme of paramount importance: comparative effectiveness research. This i2 Summit session will look at how comparative effectiveness helps us better work with patients and our physician colleagues to determine what therapies are appropriate for which patients and when. We’ll demonstrate to attendees how data from the NCDR® registries and the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC²) can help make better informed treatment decisions and more accurately define risk profiles considering an individual’s unique co-morbidities.

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A new topic for the CCA spotlight session will look at adult congenital heart disease in the cath lab. As more and more congenital heart disease patients survive into adulthood, our cath labs are seeing patients with very unusual anatomy. This session will help you better understand these unique patients and what you’ll need to anticipate for their procedures. This session will start with one of the more common anomalies now presenting, Tetralogy of Fallot; followed by the latest in PFO closures; and finishing with the unique considerations in anomalous coronary interventions.

Return Favorites

The peripheral intervention topic this year will focus on carotid interventions. We will consider where we are in carotid treatment, patient selection and post-procedure care, and we’ll review some interesting cases.

Finally, in New Approaches to CAD Management in 2010, we have an exciting session planned starting with “In Situ Simulation: A Tool for Improving Teamwork and Communication in the Cath Lab and Beyond.”

Of course, the greatest benefit to cardiac care team members at i2 Summit will be the outstanding opportunities to interact with our colleagues. Interventional cardiology teams are doing creative things across the country, and the i2 Summit brings us all together. I hope you’ll be among the many colleagues I welcome to Atlanta! Register today for i2 Summit and begin planning your itinerary at i2Summit10.acc.org. Don’t forget — CCA programming takes place Saturday, March 13, so come a day early to take full advantage of the content designed for cardiac care team members.
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Program Directors:
Michael R. Jaff, D.O., F.A.C.C.
Christopher J. White, M.D., F.A.C.C.

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A ‘Taxing’ Win in Michigan

The ACC Michigan chapter and ACC State Advocacy Workgroup recently celebrated a win when the Michigan Senate killed legislation slated to tax physicians.

The Michigan House had earlier approved the legislation, which contained a three percent tax on gross receipts for doctors. Supporters argued the funds raised by the tax would raise more federal matching money for state-run health care programs, and doctors who see Medicaid patients would benefit from higher reimbursement rates generated by the tax.

The Michigan State Medical Society (MSMS) and Michigan ACC argued that the legislation unfairly singled out doctors. The percentage of Michigan physicians accepting Medicaid patients has been reduced from 88 percent to 55 percent in previous decades, meaning the 45 percent of physicians who don’t see Medicaid patients would have been forced to absorb this costly new tax or pass the cost on in the form of higher rates for their services.

In a prime example of the College’s commitment to state advocacy, efforts by the state chapter and the workgroup, along with ACC Advocacy staff, MSMS and specialty physicians, led to an important win for cardiologists in the Great Lakes State.

ACTION Registry®- GWTG™ Made Easier

The NCDDR’s ACTION Registry®-GWTG™ is making it easier for hospitals that have limited resources for data collection to participate in the nation’s only Acute Coronary Syndrome (ACS) registry program. The NCDDR has created a new option for participation: ACTION Registry-GWTG Limited. This new, pared down version will include data on the acute myocardial infarction performance measures, selected quality measures, and risk-standardized outcomes — but requires more than 50 percent less data collection than the traditional ACTION Registry-GWTG Premier. ACTION Registry-GWTG Limited will allow monitoring and performance improvement of AMI care, and allow hospitals to submit data for the American Heart Association’s Mission:Lifeline.

Sign up for ACTION Registry-GWTG Premier or Limited programs by Jan. 15, and you will receive one free registration for the NCDDR Annual meeting, March 11 -12, 2010. To receive more information on how to join, go to www.ncdr.com/action or call a registry specialist at (800) 257-4737.
Readership Survey Prompts Change in Delivery

This summer, the ACC conducted a survey among readers of Cardiology magazine to find out how useful Cardiology is to ACC members — and how we can make it better. We saw a significant increase — to 46 percent — in the number of readers who would like to read Cardiology content exclusively online or both in print and online. In response, we are changing the delivery of Cardiology magazine in 2010. You’ll receive print issues of Cardiology on a bimonthly basis, loaded with member content, editorials, clinical perspectives, Q&As and trend articles. In between print issues, you’ll be able to access news, cutting-edge science and practical clinical information on our redesigned Web site, CardioSource 3.0, coming in spring 2010. We hope this change will help us deliver the content you need in the most timely and convenient fashion for members.

Watch for your first bimonthly print issue in your mailbox in mid-January.

Our survey also found —

- The majority of ACC readers (76 percent) continue to rate Cardiology effective at providing a quick, easy read of relevant research, science and clinical guidelines.
- The number of cardiac care team readers who find the publication useful is up 16 percentage points from 2007, to a total of 70 percent.
- One-third of readers read 75 percent or more of every issue, and two-thirds of readers read at least half of each issue.
- Members are sharing their issue of Cardiology with staff and colleagues, and an average of 3.18 people read each distributed copy.
- Cardiology is an important forum for members to communicate with each other. Readers value that the magazine allows members to share ideas, information and opinions that are relevant to their practice.
- Practical application of clinical practice activities and news are the most valued type of content, followed by trend articles, op-eds, feature articles, Q&A and product reviews. Readers are most interested in content relevant to their practice such as clinical practice issues, guidelines, quality, research, imaging tools, medical devices and clinical news.
- Over half (58 percent) report that they are interested in contributing to or already have written for Cardiology. If you want to contribute to Cardiology magazine, please contact ptresky@acc.org.

We want to hear what you think. Share your comments, concerns and questions with the editorial staff of Cardiology at any time by e-mailing ptresky@acc.org.

N=375, survey live July 24 – Sept. 3. For more information on the survey data, contact Neal Kovach, nkovach@acc.org.
Career Opportunities

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Please forward CV to:
Northwest Cardiovascular Institute LLP
Attn.: Sally Sparling, CEO
2222 NW Lovejoy, Suite 606
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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.

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

The University of Texas Health Science Center in Houston is accepting applications for its Clinical Cardiac Electrophysiology Fellowship program for July 2010. This opportunity provides comprehensive training in all areas of clinical electrophysiology that includes ablation of Atrial Fibrillation, ventricular tachycardia and other complex arrhythmias, implantation of ICDs and Bi-Ventricular devices, at the Heart & Valve Institute in Memorial Hermann Hospital, a high-volume center with state of the art EP laboratories equipped with bi-plane fluoroscopy, CARTO and ESI mapping systems, intracardiac echocardiography and cryoablation.

Please submit cover letter and C.V. to Bharat K. Kantharia, MD, FRCP, FAHA, FACC, FESC, CCEP Program Director P.O. Box 20708, Houston, Texas 77225-0708, Phone: (713)500-6590, Fax: (713)500-6556.

University of Texas Health Science Center at Houston is an EO/AA employer. M/F/D/V. This is a security sensitive position and thereby subject to Texas Education Code § 51.215. A background check will be required for the final candidate. Hiring is contingent upon eligibility to work in the United States and upon appropriate credentialing and Texas State licensing. Women and Minority candidates are encouraged to apply.
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