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Cardiology

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Indication

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

IMPORTANT SAFETY INFORMATION

Contraindications

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

Warnings and Precautions

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

Please see brief summary of prescribing information on adjacent page.

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

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

Redefine your treatment landscape

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

Adverse Reactions

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

Dosage and Administration

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

Drug Interactions

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

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

GILEAD

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

Brief Summary of Prescribing Information

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

Ranexa (ranolazine) extended-release tablets

1. INDICATIONS AND USAGE

Ranexa is indicated for the treatment of chronic angina.

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

2. DOSAGE AND ADMINISTRATION

2.1 Dosing Information

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

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

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

2.2 Dose Modification

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

3. DOSAGE FORMS AND STRENGTHS

Ranexa is supplied as film-coated, oblong-shaped, extended-release tablets in the following strengths:

- 500 mg tablets are light orange, with GSI500 on one side
- 1000 mg tablets are pale yellow, with GSI1000 on one side

4. CONTRAINDICATIONS

Ranexa is contraindicated in patients:

- Taking strong inhibitors of CYP3A *[see Drug Interactions (7.1)]*
- Taking inducers of CYP3A *[see Drug Interactions (7.1)]*
- With clinically significant hepatic impairment *[see Use in Specific Populations (8.6)]*

5. WARNINGS AND PRECAUTIONS

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

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

6. ADVERSE REACTIONS

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

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

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

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

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

Cardiac Disorders – bradycardia, palpitations

Ear and Labyrinth Disorders – tinnitus, vertigo

Gastrointestinal Disorders – abdominal pain, dry mouth, vomiting

General Disorders and Administrative Site Adverse Events – peripheral edema

Respiratory, Thoracic, and Mediastinal Disorders – dyspnea

Vascular Disorders – hypotension, orthostatic hypotension

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

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

Laboratory Abnormalities

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

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

7. DRUG INTERACTIONS

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

CYP3A Inhibitors

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

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

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

P-gp Inhibitors

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

CYP3A and P-gp Inducers

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

CYP2D6 Inhibitors

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

Digoxin

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

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

Drugs Metabolized by CYP3A

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

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

Drugs Transported by P-gp

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

Drugs Metabolized by CYP2D6

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

8. USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

10. OVERDOSAGE

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

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

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

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

Rx only

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

Ranexa Prescribing Information, September 2009

21-526-GS-007 09SEP09

Cardiovascular Professionals Lead the Way in Patient-Centered Care

According to the Institute of Medicine, patient-centered care is one of the six principles necessary for the improvement of health care delivery. While on its face patient-centered care sounds simple enough, in reality empowering patients to become active participants in their own health presents some challenges given the current health care structure. This issue of *Cardiology* takes a look at not only the American College of Cardiology's (ACC) ongoing efforts to develop comprehensive resources and tools that facilitate and sustain patient-centered care, it also addresses some of the recent hot-button topics like shared decision-making and the patient-centered medical home that are fueling debate and discussion among health care providers, policymakers and others.

Also in this issue, we pay respect to our friend and colleague, **James Dove, M.D., M.A.C.C.,** who passed away on Nov. 7. His contributions both to cardiology as a whole and to the ACC, are unparalleled. Jim had a longstanding interest in improving patient access to quality cardiovascular care and facilitating care delivery between subspecialty physicians and primary care physicians. He was also a recognized leader when it comes to the use of health IT. I think the photos of him at work and with his family provide a glimpse of just how much he was respected and loved, and just how much he will be missed.

Finally, this issue provides a high-level overview of the recently released 2011 Medicare Physician Fee Schedule and what cardiovascular professionals need to know in advance of Jan. 1. The rule includes the second year phase-in of the 2010 practice expense cuts, as well as wholesale coding changes for diagnostic cardiac catheterization and lower extremity revascularization. It also begins to address provisions that were included in the new health reform law. We also hear from **Gerard Martin, M.D., F.A.A.P., F.A.C.C.,** about the great strides the Adult Congenital and Pediatric Cardiology section has made in addressing the numerous legislative, medical, workforce and training issues pediatric and congenital cardiologists and surgeons face daily. In addition, this issue features two great articles on what to expect at ACC.11 and the i2 Summit 2011 next April in New Orleans. New this year, the first class of Cardiac Care Associates who have advanced to Associates of the American College of Cardiology (A.A.C.C.) will take part in convocation.

Mary Norine Walsh, M.D., F.A.C.C., sums it up well in the cover story when she writes that, "we have an opportunity with patient-centered care to make even greater strides in reducing cardiovascular disease risk and mortality, but we will need to work together to overcome the challenges along the way." This issue of *Cardiology* provides a look at many of these opportunities, as well as some of the challenges (Medicare cuts included). Great leaders like James Dove have paved the way, and it is up to all of us to carry on their legacy.

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

November – December 2010

Cover illustration by Julia Green

ACC MOVING FORWARD WITH PATIENT-CENTERED STRATEGIES

By Mary Norine Walsh, M.D., F.A.C.C.

In its 2001 report, "Crossing the Quality Chasm: A New Health System For The 21st Century," the Institute of Medicine (IOM) listed patient-centered care as one of the six principles necessary for the improvement of health care. Patient-centered care was defined as "care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions."

At its core, patient-centered care is based on empowering patients to become active participants in their own health. To succeed, it requires patients to both understand their disease(s) and to be able to self-monitor their condition. It is through this lens that the American College of Cardiology (ACC) over the last several years has been focused on developing partnerships, programs and tools to help bridge the gaps that currently exist between clinicians and their patients and/or patients' families and to make patient-centered care a reality.

Approximately one-third of adults lack the level of health literacy that would allow them to plan and follow through on recommended diagnostic testing, medical treatments and maintenance of preventive health. CardioSmart, the ACC's nationwide initiative to improve cardiovascular health, is one of the key ways the College is working to reverse this trend and encourage patient involvement and understanding of disease. CardioSmart is designed to provide people with (or at risk of) heart disease with information on risk factors, specific conditions, diagnostic tests, treatments and more. In addition, the *CardioSmart.org* web-based platform provides practical tools and information for clinicians to use with their patients, including online blood pressure and condition tracking, a video library, patient stories and news/editorials of relevance to cardiovascular disease.

The ACC is also working with strategic external partners to allow broader dissemination of practical tools and patient-centered information and to sponsor community-based events and programs promoting cardiovascular health. In addition, the College has partnered with organizations like the National Alliance for Hispanic Health to develop resource materials that meet the needs of a specific community.

Once patients understand their disease(s), they are in a better position to communicate their values, preferences and expressed needs to clinicians, who can then take the next steps toward fulfilling the true definition of patient-centered care. Shared decision-making is one model the ACC is exploring that allows physicians and other clinicians to communicate personalized information, including the existence of alternatives and their merits and shortcomings, to patients (see page 7). Through this process, a patient is able to weigh the costs/benefits and make the best decision for himself/herself.

The ACC is also developing ways to infuse patient perspectives into its quality initiatives and educational programming and exploring the best way to form a patient advisory board to help with these efforts. An organization that dedicates such a significant portion of its mission to improving patient care needs to hear and obtain feedback from those whose lives are being impacted.

The Coalition to Reduce Racial and Ethnic Disparities in CV Outcomes (credo) is another way the College is working to ensure that clinicians, regardless of practice setting, have the tools and information to meet the needs of all of their patients regardless of race, ethnicity, gender or other factors. Through credo, cardiovascular professionals have access to emerging data, analyses and policies related to the impact and implications of health care disparities. They also have access to performance improvement educational activities based on their own data, as well as tools for improving the collection of race, ethnicity and primary language data.

Patient-centered care requires an enormous amount of coordination and integration across the health care system. The patient-centered medical home (PCMH) is being touted as a way to improve this coordination and restore patient-centered care, while enhancing quality and reducing costs. There are several challenges to the PCMH model, including how specialists like cardiologists can serve as a "home," as well as questions about payment and health information technology adoption and implementation (see page 6). The College is actively exploring this model and is in the process of developing principles for what could constitute a cardiac PCMH.

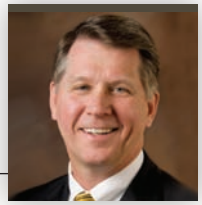
Other ACC initiatives such as "Hospital to Home" (H2H) are also getting to the issue of improved coordination and integration. In the case of H2H, the ultimate goal is to reduce the number of cardiac-related hospital readmissions by improving the transitions for patients from the hospital setting to "home." H2H focuses on three core concepts including post-discharge medication management, early follow-up and symptom management. In all three concepts, coordination between the hospital, the cardiac and/or primary care team, and the patient is key to success.

Guaranteeing physical comfort, emotional support and patient and/or family engagement are also elements necessary for patient-centered care, and the ACC is undertaking several pilot projects to address these aspects. One pilot will help support families of children with congenital heart disease and another will encourage patient interaction with local cardiovascular professionals in an outdoor setting with a focus on physical activity. ACC initiatives like H2H and credo also include elements aimed at patients and their families. For example, H2H strongly recommends that patients and/or their families be properly educated on how to use their prescribed medications before leaving the hospital. The CardioSmart Hypertension Program, which is currently being piloted in California, also requires patient engagement. Patients are asked to track their blood pressure for an extended period of time in order to benchmark against guideline-recommended targets.

Moving forward, it will take more than a few, knowledgeable and committed cardiovascular professionals to sustain patient-centered care. The health care delivery system must be reformed to breakdown the current silos in care and provide incentives for clinicians to accumulate and share information to the greatest extent possible so that everyone – including patients – can make the best and most appropriate health care decisions. We have an opportunity with patient-centered care to make even greater strides in reducing cardiovascular disease risk and mortality, but we will need to work together to overcome the challenges along the way.

Walsh is a member of the ACC's Board of Trustees and chair of the College's Chair Patient Centered Care Committee.

Patient-Centered Medical Home Model an Answer to Patient-Centered Care?



By David May, M.D., Ph.D., F.A.C.C.

Introduced in 1967 by the American Academy of Pediatrics (AAP) as a way to describe a central location for archiving a child's medical record, the Patient-Centered Medical Home (PCMH) concept has resurfaced over the last several years as a way to invigorate primary care. These days, PCMH is being touted as a way to reduce costs, improve access to care, enhance quality and ultimately restore patient-centered care.

Under PCMH principles developed in 2007 by the AAP, the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP) and the American Osteopathic Association (AOA), every person should have a personal physician trained to provide first contact and oversee continuous and comprehensive care. This personal physician should lead a team of individuals who collectively take responsibility for the ongoing health care needs, as well as take responsibility for "appropriately arranging care with other qualified professionals." Quality and safety, enhanced access and coordinated and/or integrated care are also hallmarks of the PCMH model. Payment should also recognize the added value provided to patients who have a PCMH.

This PCMH model is almost universally viewed as a primary care-driven system. It assumes that the vast majority of the public has a primary care physician who can provide a wide range of general care and serve as the proverbial "home." In addition, it is assumed that specialists like cardiologists, pulmonogists, nephrologists, oncologists, rheumatologists, and endocrinologists, although capable of being the principal physician in the PCMH, would rarely choose to do so.

However, given the increasing complexity of the medical management of chronic medical condition, many internal medicine specialists – particularly cardiovascular specialists – are often serving as the first contact for chronically ill patients and in some cases are often providing the majority of their general care as well. When it comes to cardiovascular disease, the growing number of people needing care, coupled with the increasing complexity of the care and the financial constraints on its coverage, dictate a need to consider changes in the way cardiovascular physicians organize their practices.

While controversial, I believe that cardiovascular care teams must be prepared to serve as the PCMH for a select portion of patients.

While controversial, I believe that cardiovascular care teams must be prepared to serve as the PCMH for a select portion of patients. Cardiologists excel at delivering, documenting and communicating the right care in the right place at the right time for the right price. Cardiovascular professionals managing the care of a patient with advanced heart failure, for example, should be the "medical home" for that patient. To this end, the American College of Cardiology is developing customized principles for a "Cardiovascular PCMH." Like the general PCMH, the cardiac PCMH would involve a personal physician in a physician-directed medical practice. However, the expertise of the CV specialist to optimally coordinate cardiac and non-cardiac comprehensive care would be more focused than one would have in a more generalist PCMH. The advantage for the patient would be enhanced access to quality of care for their major disease.

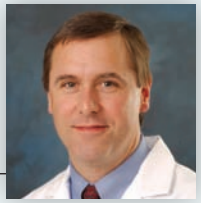
The challenges for the cardiac PCMH, as well as the PCMH, are in many ways similar. Practice infrastructure in both cases requires extensive information technology availability in order to mobilize and link patients with the most appropriate systems and community resources. In a cardiac PCMH scenario the cardiac care team would also need to manage the referral process, and participate in decisions regarding appropriateness decisions and evaluation of outcomes – all of which requires interoperability among health IT systems.

Administrative and leadership support for the PCMH model of care is also critical. In both cases, it is important that care management plans are the product of interaction and agreement among the physicians involved in their patients' care. The challenge for a cardiac PCMH would be to get the buy-in of primary care physicians, policymakers and even other cardiovascular specialists who feel that specialty care providers should not be at the center of the PCMH.

Finally, payment is also a huge challenge for both models. Most of the currently proposed payment models have some form of enhanced payment to the PCMH practice. In many proposals this is a per member/per month (PMPM) payment in addition to a fee for service or episode of care payment for services with potential for shared savings

Article continues on page 8

Shared Decision-Making Poses Opportunity to Improve Outcomes; Involve Patients



By William Lewis, M.D., F.A.C.C.

One of the most important areas in which the physician community can influence change in the health care system is by partnering with patients to improve access and ensure value. The challenge lies in how to develop strategies and tools that enable patients to get involved with their care decisions and outcomes.

In the current health care system, patients have traditionally played relatively passive roles in their own health care. They have little knowledge of their disease(s) and treatment options, leaving them not only ill-prepared to communicate their needs and wishes to their health care team, but to implement health plans when necessary.

This trend is changing with the advent of increased and improved access to online information over the last 10-15 years. More and more patients and/or their family members are going online for answers about symptoms and treatment options and even sharing their personal stories via blogs and social networking sites. At the same time, the changing health care landscape is forcing discussions among health policymakers, Congress and health care providers about new models of care delivery and payment that reward efforts to reduce costs and improve quality in a patient-centered manner.

Shared decision-making is one concept that is garnering closer attention for its ability to potentially improve outcomes, while at the same time facilitate patient involvement in their own health care decisions. The purpose behind shared decision-making is not to persuade but to improve patient knowledge and to provide information about the disease and clarify the risks and benefits of treatment or screening options and their associated outcomes. A 1996 article in the *Annals of Internal Medicine* found that "patients who ask questions, elicit treatment options, express opinions, and state preferences about treatments during office visits with physicians have measurably better health outcomes than patients who do not."

Key to shared decision-making is the ability of patients to become acquainted with the options available, the risks of each option and the outcomes anticipated from treatment with each option. Cardiovascular disease is particularly well-suited for the development of shared decision-making tools that enable clinicians to provide patients with an understanding of their options. Guidelines and evidence-based therapies form a solid foundation from which evidence can be distilled and shared with patients. In addition, there are many validated risk models of outcomes that can be used to inform patients of the outcomes of previously treated patients.

Shared decision-making is one concept that is garnering closer attention for its ability to potentially improve outcomes, while at the same time facilitate patient involvement in their own health care decisions.

Cardiovascular care also involves many treatments for which no differences in outcomes exist, allowing opportunities for patients' values and perspectives to play larger roles in the decision making process. For example, while bare metal stents result in more frequent repeat procedures than drug eluting stents, they require less dual anti-platelet therapy. As a result, patients concerned about bleeding/bruising, or who can't afford medications, may select a bare metal stent, even if a drug eluting stent might minimize the likelihood of restenosis.

While shared decision-making has its clear benefits, there are also many challenges. For one, patients not fully educated about their disease may lack the ability to participate in treatment decisions. There is no denying the difficulty in communicating and supporting patients' abilities to acquire the requisite knowledge to make informed choices. There is also the issue of patients wanting to be informed, but not involved in their care.

Speaking at the American College of Cardiology's (ACC) Medical Directors' Institute this past October, John B. Wong, M.D., chief of the Division of Clinical Decision Making at Tufts Medical Center, also noted that physicians don't feel like they have enough time to talk to their patients. Additionally, physicians are not rewarded for spending the requisite time to fully inform a patient and guide them through the decision making process. Ultimately, physicians end up making a decision for the patient rather than with the patient, he said. Care providers also may not have the appropriate competencies with risk communication, which can prove problematic when patient preferences differ from those of their doctor or even evidence-based guidelines. Wong noted that innovative

Article continues on page 8

May

Continued from page 6

if cost and quality targets are achieved. I believe these payment models should be stratified for complexity/acuity. In terms of a cardiac PCMH model, while the transition may involve new technical, personnel, and workflow resources, with commensurate new costs, implementation would permit greater efficiencies of care and potentially allows net financial savings. New reimbursement systems need to be implemented to allow these models to function. It is my belief that interest in the cardiac PCMH model will expand if reimbursement systems are modified to reward this "medical home" model of care.

The jury is still out over what the ultimate PCMH will look like. The ACC continues to be at the table with primary care physician groups, policymakers and other specialty societies to discuss potential models and to ensure that the interests of cardiac care providers and their patients are represented.

May is a member of the Patient-Centered Care Committee and Chief of Staff at the Presbyterian Hospital of Flower Mound in Texas.

Lewis

Continued from page 7

research and appropriate professional training is needed to find solutions to these problems and to support doctors committed to involving their patients in decision making.

Other challenges to shared decision-making include current silos in the health care system that impede easily sharing information between sources and sites of care. Quality care standards also may run counter to a patient's individual preferences or beliefs. One other issue of note, is the lack in many cases of strong evidence-based science around procedures involving use of newer technologies like medical imaging. The science related to the use of these technologies is constantly evolving and changing, which can make it difficult to communicate options to patients. It also means care providers need to stay on top of the latest guidelines and appropriate use criteria to ensure their patients have the timeliest information on which to base their decisions.

The ACC is in the early stages of identifying some of the challenges and opportunities associated with shared decision-making. The College is piloting several projects, one of which is focused on the use of ACC's Appropriate Use Criteria for Coronary Revascularization. The goal is to use the results of these pilots to ensure that future shared decision-making models best meet the needs of patients and their families.

Lewis is chair of the 2010 ACC MDI and chief of clinical cardiology at MetroHealth Medical Center in Cleveland, Ohio.

The concepts of the patient-centered medical home and shared decision-making are generating much discussion and debate among health policymakers and care providers themselves. The December Cardiology discussion forum is dedicated to both of these issues. After reading the thoughtful commentaries by David May, M.D., F.A.C.C., and William Lewis, M.D., F.A.C.C., what are some of the challenges and opportunities that you believe are associated with both issues? Do you believe that cardiovascular professionals should have the option to be a medical home in certain cases? What are some opportunities for shared decision-making in the cardiovascular arena? Share your thoughts at *cardiosource.org/cardiologydiscussion*. Excerpts of the discussions will be included in the next issue of the magazine.

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In Memoriam: James T. Dove, M.D., M.A.C.C.

Past American College of Cardiology (ACC) President **James T. Dove, M.D., M.A.C.C.,** a renowned leader in the field of cardiology, passed away on Sunday, Nov. 7 in Springfield, Ill. surrounded by his loving family. He was 71 years old.

Dove had a longstanding interest in improving patient access to quality cardiovascular care and facilitating care delivery between subspecialty physicians and primary care physicians. He was a recognized leader when it comes to the use of medical informatics and was instrumental in the development of electronic medical record software that improves adherence to practice guidelines and performance measures at the point of care.

Dove graduated from Wittenberg University in 1961 and later obtained his medical degree from Case Western Reserve Medical School. He completed a residency in internal medicine and a fourth year as chief resident at the Mount Sinai Hospital in New York City. His cardiology training was completed at the University of Rochester.

In 1973, he began practice in Springfield, Ill., and was since affiliated with the Southern Illinois University School of Medicine. In addition to his clinical professorship, Dove served as chief of the division of cardiology from 1991 until 1999. Dove was President Emeritus of Prairie Cardiovascular Consultants in Springfield Ill., and a founding partner of the 47-member cardiology practice, nationally known for its physicians and their expertise in quality, comprehensive and compassionate care. He was recently honored by the hospital for his contributions to cardiac care with the establishment of the "James T. Dove, M.D. Endowment for Cardiac Care."

Dove's leadership and service spanned across many organizations, including the Clinical Information Interchange Collaborative (CIIC) for Health Level 7, the Clinical Decision Support Technical Expert Panel for the Agency for Healthcare Research and Quality, Expert Panel for the Integrated Clinical Guideline for Cardiovascular Risk Reduction for the National Institutes of Health, National Quality Forum's Clinical Decision Support Technical Expert Panel, Cardiovascular Medicine Work Group for the Certification Commission for Health Information Technology (CCHIT®), the Prairie Education and Research Cooperative, the United Way Board of Central Illinois and the Network Knowledge Board. Most recently, the Abraham Lincoln Council Boy Scouts of America in Illinois awarded Dove its "2010 Trailblazer Award," which honors an individual who has been a leader in his field and the community and has lived his life according to the Scout Oath and Law.

Dove was a past governor for the American College of Physicians Downstate Illinois Chapter and received the "Outstanding Clinician Laureate Award" from the Illinois Chapter of the American College of Physicians in 1992. He became a Master of the American College of Physicians in 2002.

> "We have lost a close friend, a super colleague, and one of most valuable FACC volunteers the College has ever had in its 61 years of existence. The nation and the College are in a much better place with Jim's seven-decade presence and unending service for all of us. His absence leaves a great chasm in all of our hearts."
>
> ACC President Ralph G. Brindis, M.D., M.P.H., F.A.C.C.

At the ACC, Dove served as an Illinois Chapter Councilor and was elected president and governor of the chapter in 1997. Nationally, he served on numerous ACC committees, working groups and task forces, including the ACC's Quality Strategic Directions Committee, Guidelines Applied in Practice, International Committee Work Group, Twenty-First Century Task Force, Board Effectiveness Task Force, and the Medical Informatics Committee. He was chair of the ACC's Board of Governors from 1999 to 2000, secretary, chair of the Budget, Finance and Investment Committee, treasurer, vice president and ultimately ACC president from 2007 to 2008. In 2008, he was awarded mastership in the ACC.

In March 2010, the ACC honored Dove for his countless contributions to improving the quality of cardiovascular care by endowing a lectureship in his name at the Annual Scientific Session, as well as naming its annual Chapter Recognition Award for Quality the "James T. Dove Chapter Recognition Award for Quality."

Dove is survived by his beloved wife Carol Ann Proctor, their two children, Laura and Steven, and six grandchildren – Noah, Adam, Ainsley, Connor, Sierra and Madison.

For more on the life of Dove and his contributions to cardiology or to share stories, visit *CardioSource.org/ACC*.

PARTNER Trial a Breakthrough for Patients with Inoperable AS

News from TCT 2010

As many as one-third of patients with severe aortic stenosis (AS) are high-risk surgical candidates and are conservatively managed, while other patients with AS and coexisting conditions are not candidates for surgical replacement of the aortic valve at all. Recently, a promising new development shows treating inoperable AS patients with a less invasive catheter-based valve could be the answer.

A breakthrough study called the PARTNER Trial presented at the 2010 Transcatheter Cardiovascular Therapeutics (TCT) conference and published in the *New England Journal of Medicine,* compared outcomes between standard therapy for patients with inoperable severe AS and transcatheter aortic valve implantation (TAVI).

Between May 11, 2007, and March 16, 2009, a total of 358 patients were enrolled at 21 sites (17 in the United States) and half were randomly assigned to TAVI and the other half to standard therapy. All the patients were followed for at least one year.

TAVI resulted in a 45 percent reduction in all-cause mortality and 61 percent reduction in cardiovascular mortality at one year in high-risk AS patients compared with standard therapy. The rate of death from any cause was 30.7 percent in the TAVI group, as compared with 50.7 percent in the standard-therapy group. The rate of death from cardiovascular causes at one year was also lower in the TAVI group than in the standard-therapy group (20.5 percent vs. 44.6 percent).

"The important issue is what is the mortality of the procedure [and] it turns out at 30 days the TAVI patients had a mortality of only 6.4 percent – less than 10 percent. That's an extraordinary number for these very sick patients," said **Peter Block, M.D., F.A.C.C.,** during an interview on CardioSource Video News. He is one of the lead investigators of the PARTNER Trial.

A breakthrough study called the PARTNER Trial presented at the 2010 Transcatheter Cardiovascular Therapeutics (TCT) conference and published in the *New England Journal of Medicine*, compared outcomes between standard therapy for patients with inoperable severe AS and transcatheter aortic valve implantation (TAVI).

TAVI is a new procedure not yet approved as a treatment option in the U.S., though extensively used in Europe and other areas of the world, where a bioprosthetic aortic valve is inserted either femorally or transapically by catheter and then implanted within the native aortic value. Previous to the release of PARTNER, the assessment of efficacy and safety of TAVI was confined to registries and various modest-sized Phase I trials.

Although the TAVI procedure can reduce mortality, there was a significantly higher risk of major vascular complications (16.2 percent vs. 1.1 percent at 30 days) and major bleeding (16.8 percent vs. 3.9 percent at 30 days), and a trend towards a higher risk of major stroke (5 percent vs. 1.1 percent at 30 days) in the TAVI arm.

While the overall results are very encouraging, researchers say the high complication rate should temper any tendencies toward the overaggressive use of TAVI (if approved by the Food and Drug Administration for the treatment of AS) in lower-risk patients, and surgical aortic valve replacement should still be considered the gold standard for treatment of AS in these patients. Long-term follow-up is still needed.

"But these are extraordinary results, much better than anticipated and probably will change the way we think about taking care of patients with inoperable AS in the future," said Block.

Will the PARTNER trial alone be enough to earn FDA approval? And if approved, what can the FDA and professional societies like the ACC and SCAI do to ensure patient safety with the diffusion of this new technology into the community? Join the discussion at *CardioSource.org/cardiologydiscussion* and share your thoughts.

NCDR®
National Cardiovascular Data Registry

Published NCDR Research Highlights Benefits of Data Collection in the Real World

Several National Cardiovascular Data Registry (NCDR®) manuscripts were recently published in the *Journal of the American College of Cardiology*, highlighting the ways registry data is applied to answer a wide range of research questions in the real world. An overview of the manuscripts and their respective topics is below:

The NCDR ACTION Registry® -GWTG™: Transforming Contemporary Acute Myocardial Infarction Clinical Care

Heart

ACTION Registry-GWTG™ Based on analysis from 147,165 records submitted by 383 sites between January 2007 and September 2009, the study assesses care provided by the top and bottom 10 percent of performing hospitals, highlighting the dual functionality of ACTION Registry-GWTG as a national surveillance system for acute myocardial infarction (AMI) and as a mechanism to promote local quality improvement at participating sites.

Review of the ICD Registry's Fourth Year, Incorporating Lead Data and Pediatric ICD Procedures, and Use as a National Measuring Performance,

Heart Rhythm Journal

ICD Registry™ Reviewing the ICD Registry shortly after its expansion to collect data on leads associated with implantable cardioverter defibrillators (ICD) implantation and pediatric ICD implants, authors determined that the ICD Registry now holds data collected from 486,025 ICD implantations performed by 5,246 implanting physicians at 1,434 hospitals between 2006 and 2009. Quarterly benchmark reports allow individual hospitals to assess their outcomes from ICD implantation compared with hospitals of similar procedure volume and a national aggregate, and on a broader scale, several important research studies have been published based on analysis from registry data.

The Relation Between Hospital Procedure Volume and Complications of Cardioverter-Defibrillator Implantation From the ICD Registry

JACC

ICD Registry™ Researchers examined initial implantable cardioverter defibrillator (ICD) implantations between January 2006 and December 2008 at hospitals participating in the ICD Registry. Showing that the rate of adverse events declined progressively with increasing procedure volume, the results indicate that patients who have an ICD implanted at a high-volume hospital are less likely to have an adverse event associated with the procedure than patients who have an ICD implanted at a low-volume hospital.

Prevalence and Predictors of "Off-label" Use of Cardiac Resynchronization Therapy in Patients Enrolled in the NCDR ICD Registry™

JACC

ICD Registry™ Results show that the use of cardiac resynchronization defibrillators in clinical practice is frequently noncompliant with evidence-based consensus guidelines. Nearly one in four devices placed from 2006 to 2008 did not conform to contemporaneous guidelines, and many of these might presently be considered inappropriate even when allowing for potential future guideline changes. This pattern of practice is not easily explained by geographic, hospital, or physician factors. Implantation of a CRT-D (vs. standard ICD) in patients with a low probability of incremental benefit should be discouraged.

National NCDR® analysis points to benefits of secondary prevention therapies for patients with non-obstructive CAD

NCDR® Findings from a recent paper based on NCDR data show that patients with non-obstructive coronary artery disease (CAD) receive fewer secondary prevention therapies than those with obstructive CAD. Using analysis from the registry, researchers examined records from 1,489,745 CAD patients undergoing cardiac catheterization in 786 U.S. centers between 2004 and 2007. Analysis of the data showed that patients with non-obstructive CAD were significantly less likely to receive secondary prevention medication prescriptions at hospital discharge, as compared to patients with obstructive CAD. Similar gaps occurred among patients with non-obstructive CAD who had Class I indications for secondary prevention medications.

For more information about NCDR research, visit *www.NCDR.com/research*

ACC Releases Updated Appropriate Use Criteria for CCT and Echo

The American College of Cardiology (ACC) recently released updated and expanded appropriate use criteria (AUC) for cardiac computed tomography (CCT) and echocardiography (echo). In both cases, the new criteria reflect changes in test utilization and incorporate new clinical data and clarify where omissions and/or lack of clarity existed in previously published versions.

In the case of CCT, the original criteria were published in 2006 when the technology was still relatively new. Since then, studies have shown that inappropriate use of CCT may be potentially harmful to patients and generate unwarranted costs to the health care system, whereas appropriate procedures are likely to improve patient care. This is a critical shift because the intent of AUC is for the potential benefits and risks of the treatment to be explicitly considered, rather than the potential usefulness of a diagnostic test as a prelude to further treatment.

"As the field of cardiac CT continues to advance along with other biomedical imaging tests, this document reflects this progress in knowledge and our desire to make the criteria more comprehensive to more closely match a patient situation to the test and help in clinical decision making," said **Allen J. Taylor, M.D., F.A.C.C.** chair of the AUC for CCT writing committee and professor of medicine at Georgetown University.

The new CCT criteria address 93 clinical scenarios – an increase from 39 in 2006. Examples of the scenarios, which were drawn mostly from common applications or anticipated uses, include acute and chronic chest pain; testing in symptomatic and asymptomatic patients; heart failure; preoperative risk assessment before both cardiac and noncardiac surgery; and evaluation of cardiac structure and function. Of the clinical scenarios evaluated, cardiac CT was deemed appropriate in 37 percent, and the others were considered either inappropriate uses or uncertain.

In general, use of CCT angiography for diagnosis and risk assessment in patients with low or intermediate risk or pretest probability for coronary artery disease (CAD) was viewed favorably, whereas testing in high-risk patients, routine repeat testing and general screening in certain clinical scenarios was not considered appropriate.

Use of noncontrast computed tomography for calcium scoring was rated as appropriate within intermediate- and selected low-risk patients (particularly women or younger men) who have a family history of heart problems. Appropriate applications of CCT are also within the category of cardiac structural and functional evaluation. It is expected these results will have an impact on physician decision making, performance and reimbursement policy and will help guide future research.

The new criteria for echo, revise and combine the AUC for transthoracic (TTE) and transesophageal (TEE) echo, which were published in June 2007, with the AUC for stress echo, published in March 2008. The new criteria assess 202 clinical situations (98 TTE, 15 TEE and 89 stress echo), of which 97 were found to be appropriate, 34 uncertain and 71 inappropriate.

According to **Pamela S. Douglas, M.D., M.A.C.C.,** the Ursula Geller Professor for Research in Cardiovascular Diseases at Duke University, director of the Duke Clinical Research Imaging Program and senior fellow in Clinical Health Policy at the Duke Center for Clinical Health Policy Research, the use of echocardiography for initial diagnosis, when there is a change in clinical status, or when the results of the echocardiogram are anticipated to change patient management was generally rated appropriate.

Routine testing when there was no change in clinical status or when results of testing were unlikely to modify management were more likely to be inappropriate than appropriate/uncertain, she noted.

"We hope that by providing broadened and more defined clinical scenarios, these criteria will impact clinical decision making, performance and reimbursement policy," said Taylor. "But these criteria are only as good as the level to which they are implemented. If used broadly, they can help us deliver higher quality and more efficient cardiac care."

For more information on AUC and to view the updated criteria go to *CardioSource.org/focus*.

Doubling Clopidogrel Dose Doesn't Benefit Post-PCI Outcomes

In patients with high residual platelet reactivity, doubling the maintenance dose of clopidogrel did not reduce the risk of further ischemic events after percutaneous coronary intervention (PCI). According to the results of the GRAVITAS (Gauging Responsiveness With A VerifyNow Assay-Impact On Thrombosis And Safety) Trial, patients with high residual platelet reactivity also demonstrated almost twice the risk of ischemic events compared to patients without high residual platelet reactivity.

News from AHA 2010

The trial was conducted at more than 80 centers in the U.S. and Canada and used a point-of-care platelet function test called the VerifyNow P2Y12 assay to identify patients who had undergone elective or urgent PCI and who had residual platelet reactivity with the standard clopidogrel dose 12 to 24 hours after the procedure.

The goal of the trial was to evaluate treatment with an additional loading dose (600 mg) and higher maintenance dose of clopidogrel (150 mg) compared with no additional loading dose and standard maintenance dose of clopidogrel (75 mg) among patients with high residual platelet activity after percutaneous coronary intervention (PCI). All patients also received aspirin (81 to 162 mg daily). Overall, 2,214 patients were randomized in the GRAVITAS trial. In the high-clopidogrel dose group, the mean age was 64 years, 35 percent were women and 44 percent had diabetes.

The six-month rate of cardiovascular death, heart attack or stent thrombosis was 2.3 percent with both a double dose and a standard dose of clopidogrel, said **Matthew Price, M.D., F.A.C.C.** of Scripps Clinic and Scripps Translational Science Institute in Calif., and principal investigator of the trial. At 30 days, persistently high platelet reactivity was present in 40 percent of the high-clopidogrel dose group versus 62 percent of the standard-dose group. He said in patients with high reactivity measured after PCI, six months of high-dose clopidogrel did not reduce the rate of the primary endpoint and did not increase GUSTO severe or moderate bleeding.

"The GRAVITAS findings do not support adopting a treatment strategy of 150 mg of clopidogrel in patients with high reactivity identified by a single platelet function test after PCI," said Price. "Alternative therapies or testing a patient multiple times to treat to a specific target of reactivity deserve consideration."

New Drug Significantly Raises HDL, Cuts LDL Nearly in Half

An experimental drug more than doubles the level of HDL cholesterol and cuts LDL nearly in half without the blood pressure increase linked to another agent in its class, according to the recently released Determining the EFficacy and Tolerability of CETP INhibition with AnacEtrapib (DEFINE) study.

In the randomized, double-blind trial, 1,623 patients took either 100 milligrams of the cholesterylester transfer protein (CETP) inhibitor anacetrapib or a placebo for 18 months. Anacetrapib reduced LDL by 40 percent and more than doubled the level of HDL.

"Anacetrapib has a knock-your-socks-off effect on HDL and a jaw-dropping effect on LDL," said **Christopher P. Cannon, M.D., F.A.C.C.,** senior investigator of the TIMI Study Group in the cardiovascular division of Brigham and Women's Hospital in Boston. "No treatments raise HDL levels as substantially as seen here."

> **"Anacetrapib has a knock-your-socks-off effect on HDL and a jaw-dropping effect on LDL, no treatments raise HDL levels as substantially as seen here."** Christopher P. Cannon, M.D., F.A.C.C.

Patients in DEFINE averaged 62.5 years old; 23 percent were women; 17 percent were Asian, black or multiracial and 15 percent were Hispanic.

"With the explosion of obesity and diabetes in the world, a treatment that increases the good cholesterol and reduces the bad cholesterol could prevent countless numbers of cardiac problems and disabilities," said former American College of Cardiology President **Douglas Weaver, M.D., M.A.C.C.** "Anacetrapib could totally change our ability to manage the increasing obesity population."

Proton Pump Inhibitors and Antiplatelet Drugs Can Be Used Together

Using proton pump inhibitors (PPIs) and antiplatelet drugs (thienopyridines) together is an appropriate way of treating patients with cardiovascular (CV) disease who are at high risk of upper gastrointestinal (GI) bleeds, despite recent concerns about an adverse interaction between these two types of drugs, according to an Expert Consensus Document released jointly by the American College of Cardiology (ACC), the American College of Gastroenterology (ACG), and the American Heart Association (AHA).

News from AHA 2010

The potential benefits of antiplatelet therapy for patients with atherosclerotic CV disease have been adequately demonstrated, especially among patients at higher risk of CV events. However, use of antiplatelet drugs increases the risk of upper GI bleeding from pre-existing ulcers, lesions and other tissue breaks in the GI tract. Those at highest risk for GI bleeding are patients with a history of previous GI bleeding, as well as patients with multiple risk factors for upper GI bleeding, including: a history of peptic ulcer disease; advanced age; use of anticoagulants, steroids, or NSAIDs; and H. pylori infection.

"PPIs are prescribed together with antiplatelet drugs for one reason — to reduce the increased risk of GI complications caused by antiplatelet drugs," according to the new expert consensus document. PPIs suppress gastric acid production, which helps heal the pre-existing lesions and aspirin-related ulcers.

After the publication of the organizations' 2008 document recommending simultaneous prescription of a PPI in high-risk patients, new research suggested an adverse interaction between the two drugs that may lessen the antiplatelet effects of thienopyridines and put patients at an increased risk of CV events. Physicians have had a hard time taking the flood of information and developing optimal treatment strategies for managing patients who might benefit from antiplatelet therapy, but might suffer from GI bleeding.

Also, the recent publication of a randomized trial (COGENT) of 3,761 patients with cardiovascular disease demonstrated a substantial decrease (56 percent) in GI bleeding, with no significant difference in cardiac events, among the patients randomized to concomitant use of clopidogrel and a PPI compared with patients randomized to clopidogrel alone.

"Our goal was to carefully evaluate recent studies that suggested a potential dangerous interaction between PPIs and thienopyridines, in order to provide clinicians with a pragmatic evidence-based approach for safer prescribing of antiplatelet drugs, especially among patients in whom the risk-benefit ratio requires a careful assessment," said Neena S. Abraham, M.D., MSCE, FACG, a gastroenterologist at the Michael E. DeBakey VAMC and Baylor College of Medicine, the chair of the document's writing committee.

"The document summarizes the best evidence and incorporates the expert clinical viewpoints of both cardiologists and gastroenterologists, who face this dilemma on a daily basis."

The new recommendations include:

- The use of PPIs is recommended for patients with a history of upper GI bleeding or for those with multiple risk factors for upper GI bleeding, including a history of peptic ulcer disease; advanced age; use of anticoagulants, steroids, or NSAIDs; and H. pylori infection.
- PPIs are not recommended to reduce upper GI bleeding in patients who have a lower risk of upper GI bleeding, and who have much less potential to benefit from prophylactic therapy.
- Future studies are required to assess the impact of concomitant PPI and antiplatelet use among the small subset of high-risk cardiac patients with an impaired ability to metabolize antiplatelet drugs.

Full text of this report will be published in the *Journal of the American College of Cardiology* and is available at *CardioSource.org*.

Drugs Comparable in Pivotal Atrial Fibrillation Trial

News from AHA 2010

A new anti-clotting drug is as effective as the standard medication in preventing stroke and blood clots and does not increase bleeding risk in patients with atrial fibrillation (AF). The findings are from the clinical trial Stroke Prevention Using the Oral Direct Factor Xa Inhibitor Rivaroxaban Compared With Warfarin in Patients with Nonvalvular Atrial Fibrillation (ROCKET AF) - the largest double blind study completed to date for the prevention of stroke in patients with AF. The goal of the trial was to compare the new drug rivaroxaban with the traditional medicine warfarin among AF patients. Both drugs prevent dangerous blood clots by blocking the action of clotting factors. Rivaroxaban, however, targets a specific clotting factor called Xa.

In the study, rivaroxaban was 21 percent better able to reduce strokes caused by AF. It also resulted in a 41 percent reduced risk of hemorrhagic stroke. Rivaroxaban-treated patients had fewer heart attacks (0.9 percent vs. 1.1 percent), and a reduction in rates of all-cause mortality compared to warfarin (1.9 percent vs. 2.2 percent). Intercranial bleeding occurred in 55 patients on rivaroxaban and 84 on warfarin. Though the improvements weren't considered statistically significant enough to declare the drug superior, rivaroxaban is noninferior to warfarin.

"Given the prevalence and morbidity associated with atrial fibrillation, and the well-known difficulties with warfarin use, it is exciting to have an alternative which was documented in this study to be effective with no increase in significant bleeding," said **Robert M. Califf, M.D., M.A.C.C.,** co-principal investigator and Vice Chancellor for Clinical Research at Duke University.

Investigators evaluated the drugs in 14,264 patients with AF at more than 1,100 hospitals in 45 countries. The average age was 73, 40 percent of participants were women and 83 percent were white. More than half (55 percent) had suffered a prior stroke, transient ischemic attack (TIA) or systemic embolism and 40 percent had diabetes. Patients were randomized to receive either 20 milligrams of rivaroxaban daily or an appropriately adjusted dose of warfarin. The study was conducted from December 2006 to May 2010, and average treatment lasted 19 months.

Bayer and Johnson & Johnson, who funded the study, are looking for approval of rivaroxaban from the U.S. Food and Drug Administration (FDA). In 2009, an FDA advisory panel recommended rivaroxaban be approved for short-term use in patients undergoing knee or hip replacements. Rivaroxaban is already approved in Europe for use in certain surgery patients.

"The main implication is that we have an alternative to warfarin," said Califf. "…We have a drug you can take once a day, without monitoring, that is at least as good as warfarin and carries no additional risk."

> **"Given the prevalence and morbidity associated with atrial fibrillation, and the well-known difficulties with warfarin use, it is exciting to have an alternative which was documented in this study to be effective with no increase in significant bleeding."** Robert M. Califf, M.D., M.A.C.C.

Will this data change your treatment recommendations for AF patients? Join the discussion at *CardioSource.org/Cardiologydiscussion*. For more on AF, visit the A-Fib Community at *afibprofessional.org*.

Guidelines Tell Physicians More Tests Don't Always Equal Better Outcomes

According to a new practice guideline, physicians don't need to give patients multiple tests to determine their risk for heart disease. A basic risk assessment that includes taking into account cholesterol levels, blood pressure, age, sex, family history and whether you smoke or have diabetes is still the best way a physician can predict the likelihood of heart disease.

News from **AHA 2010**

The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults, which will be published in the Dec. 14/21 issue of the *Journal of the American College of Cardiology* and the Dec. 21 issue of *Circulation: Journal of the American Heart Association*, tells physicians which diagnostic tests are most useful in assessing cardiovascular risk in people who have no obvious signs of heart disease and which tests do little to clarify the health picture

In an opposing view, the Society for Heart Attack and Prevention and Eradication, an independent group of cardiologists and researchers, released its own set of guidelines which emphasizes the benefit of using more diagnostic tests in patients.

But after reviewing more than 400 scientific studies, the ACCF/AHA expert panel determined most tests claiming to predict heart disease risk are helpful only in select cases. They said only a global cardiovascular risk score and family history were necessary for everyone, starting at age 20, and beyond that, few diagnostic test results would change a physician's treatment plan, a patient's health habits, or be enough to improve health outcomes, specifically in low-risk patients. As a result, many tests were found useful only in intermediate-risk patients—those with a 10 to 20 percent risk of developing heart disease within 10 years. In high-risk patients, the global risk score and family history make it obvious what the physician should do next. The guideline also highlights the importance of assessing cardiovascular risk in all women, despite a lack of symptoms, using a global risk score and family history.

"The ACC continues to strive for a health care system that rewards better patient outcomes and quality rather than quantity," said **Alfred A. Bove, M.D., Ph.D., M.A.C.C.,** immediate past President of the ACC, about the guidelines.

Even tests that have captured intense public interest, such as C-reactive protein and coronary calcium scoring, received nuanced and limited recommendations that reflect the data currently available from clinical studies.

The ACCF/AHA guideline tells physicians which diagnostic tests are most useful in assessing cardiovascular risk in people who have no obvious signs of heart disease and which tests do little to clarify the health picture:

Tests that should be performed in all adults for cardiovascular risk assessment

- Global risk scoring, taking into account such factors as cholesterol level, blood pressure, age, sex, diabetes and smoking
- Family history

Tests that have no benefit in people without symptoms of heart disease

- Genetic testing
- So-called "advanced" lipid testing (e.g., apolipoproteins, particle size and density)
- Natriuretic peptide levels
- Coronary computed tomography angiography
- Magnetic resonance imaging for detection of vascular plaque
- Stress echocardiography
- Flow-mediated dilation
- Measures of arterial stiffness

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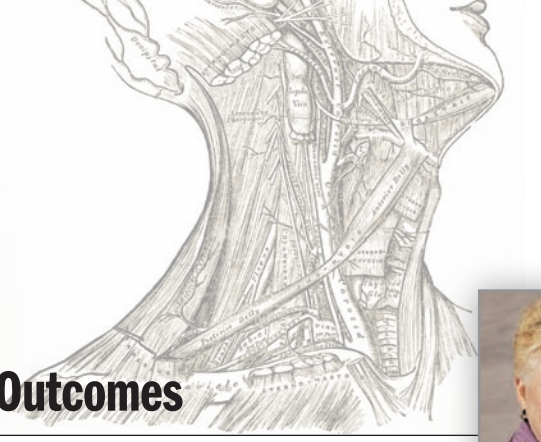

New ACE Accreditation Looks to Provide Better Patient Outcomes

By Bonnie H. Weiner, M.D., F.A.C.C.

Recently, the Accreditation for Cardiovascular Excellence (ACE) began providing accreditation to hospitals performing carotid artery stenting (CAS) procedures. The overall purpose is to accredit facilities performing invasive cardiovascular and endovascular procedures that have achieved predetermined benchmarks for quality care. By doing so, it sets an objective, independent, professional and peer-based standard for what should be occurring at those institutions.

The Centers for Medicare and Medicaid Services (CMS) require all facilities where carotid artery stenting (CAS) is performed to collect, submit and report data biannually to qualify for reimbursement. Considering it is not something that CMS does regularly, nor have they provided feedback on data submitted, other options should be available. Compared to the CMS process, the ACE accreditation is designed to be a more robust and more outcomes and quality driven process. Programs that achieve full accreditation are recognized by ACE for two years, and then their facility must be reviewed again for continued recognition. ACE also provides tools and guidance for quality improvement.

Right now, carotid stenting is the only area where there is any kind of regulatory mandate for accreditation, but we are looking at the much broader landscape of invasive procedures and believe we should be doing this for all of these things and that we should be, as a professional organization, setting the standards and essentially providing the resources for facilities to do the best possible job for the patients they take care of.

Recent studies in *Health Affairs* and other journals have shown accreditation improves patient outcomes and promotes progress toward enhanced patient safety standards. Specifically, ACE accreditation signifies to patients, insurers and the health care community at large that the facility offers the highest level of cardiac endovascular care by meeting the standards set by peers in the field.

ACE offers independent evaluation of facilities' processes and objective peer review of outcomes based on established standards derived from scientific evidence in peer-reviewed medical literature and national practice guidelines. Applicants complete a comprehensive application followed by a site visit from ACE's team of expert reviewers who assess the facility itself, its personnel, quality assurance and safety protocols, and patient indications for procedures and outcomes. This standardized, unbiased assessment ensures quality patient care.

ACE's founding sponsor, the Society for Cardiovascular Angiography and Interventions (SCAI) and the American College of Cardiology Foundation (ACCF) are working together with a common commitment to promoting high-quality, evidence-based care for cardiovascular patients. A recent comment from ACC President **Ralph Brindis, M.D., M.P.H., F.A.C.C.** described our joint effort well when he said that by developing accreditation standards in this area we are working to advance quality and provide for even better patient outcomes in invasive cardiovascular care facilities across the country. That is what this is about – better care for our patients. The accreditation process is patient centric. We want to make sure patients undergoing these procedures can be confident that where they are having them done, the people who are involved, and the systems built around them provide the best quality of care available.

We are also looking to the future. Right now, carotid stenting is the only area where there is any kind of regulatory mandate for accreditation. However, we are looking at the much broader landscape of invasive procedures and believe we should be doing this for all of these things and that we should be, as a professional organization, setting the standards and essentially providing the resources for facilities to do the best possible job for the patients they take care of. For example, it is anticipated that the program to accredit cardiac catheterization and PCI facilities will be available by the end of the year. Multiple CAS program applications are already in process. We hope that accreditation will ultimately improve patient outcomes across the board.

For more information and to submit an application, visit *www.cvexcel.org*.

Weiner is board chair and chief medical officer of ACE and director of interventional cardiology research at Saint Vincent Hospital at Worcester Medical Center, Mass.

ICD-10: A Checklist for Compliance

On Oct. 1, 2013, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. To accommodate the ICD-10 code structure, the transaction standards used for electronic health care claims, Version 4010/4010A, must be upgraded to Version 5010 by Jan. 1, 2012.

ICD-10 affects coding for diagnosis and inpatient procedures (the changes do not affect outpatient procedures) for everyone covered by the Health Insurance Portability and Accountability Act (HIPAA), not just those who submit Medicare or Medicaid claims. Those covered by HIPAA who transmit electronic claims also have to switch to Version 5010 transaction standards.

ICD-10 codes must be used for all health care services provided and hospital inpatient procedures performed in the U.S. on or after Oct. 1, 2013. After that, claims can't be paid.

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To prepare for the transition, CMS has some tips to help make the conversion run smoothly:

- Identify the current systems and work processes that use ICD-9 codes.
- Talk with the practice management system vendor about accommodations for both Version 5010 and ICD-10 codes.
- Providers should develop an implementation strategy that includes an assessment of the impact on the organization, a detailed timeline and budget. This includes checking with billing service, clearinghouse, or practice management software vendors about their compliance plans. Providers who handle billing and software development internally also should plan for medical records/coding, clinical, IT, and finance staff to coordinate on ICD-10 and Version 5010 transition efforts.
- Payers should review payment policies since the transition will involve new coding rules and have an implementation plan and transition budget in place.
- Software vendors, clearinghouses, and third-party billing services should have products and services in development allowing payers and providers to fully implement Version 5010 on Jan. 1, 2012, and ICD-10 on Oct. 1, 2013.

For more information, visit *CardioSource.org/Practice-Management/Coding-and-Billing.aspx* **or visit** *www.cms.gov/ICD10* **for ICD-10 and Version 5010 resources from CMS.**

CMS Compliance Timeline

2010	
January 1	Payers and providers should begin internal testing of Version 5010 standards for electronic claims
December 31	Internal testing of Version 5010 must be complete to achieve Level I Version 5010 compliance
2011	
January 1	Payers and providers should begin external testing of Version 5010 for electronic claims
	CMS begins accepting Version 5010 claims
	Version 4010 claims continue to be accepted
December 31	External testing of Version 5010 for electronic claims must be complete to achieve Level II Version 5010 compliance
2012	
January 1	All electronic claims must use Version 5010

Accountable Care: Perspective of a Cardiac Nurse

Under the Patient Protection and Affordable Care Act (PPACA), the Department of Health and Human Services (HHS) by 2012 must establish a "Medicare Shared Savings Program" that allows groups of providers who meet certain statutory criteria to be recognized as accountable care organizations (ACOs). Eligible ACOs would be groups of providers and suppliers that have an established mechanism for joint decision making, including: practitioners in group practices; networks of practices; partnerships or joint ventures between hospitals and practitioners; and hospitals employing practitioners.

Cardiology sat down with **Suzanne Hughes, M.S.N., R.N.,** director of System Population Health at the Summa Health System in Akron, Ohio, who recently joined a team tasked with creating and implementing an ACO at Summa.

Why did you take on this new position and begin working on the ACO project? I embraced the opportunity to become part of a team in a health system that truly believes that accountability in health care is a "moral imperative." Our integrated system, encompassing a network of hospitals, community-based health centers, a health plan, a multi-specialty group practice, multiple foundations and a physician-hospital organization, is well-positioned to take on the creation of an ACO.

I have always been interested in population-based approaches to cardiovascular risk reduction. As a nurse working in a cardiovascular practice setting and in a preventive cardiology department, it was important to learn about factors that impact adherence to treatment recommendations. I spent some time working in the worksite health world, an important venue where disease management strategies are combined with worksite health promotion to drive down costs for both the individual and the employer. I also have a strong interest in the area of health literacy/health care communications and have always been drawn to learning how the public obtains health care information. It seemed to me that all of these important concepts, with which I had some background and experience, were components of this new model of care. Most importantly, I was excited to be involved in such a cutting edge project.

> **"I embraced the opportunity to become part of a team in a health system that truly believes that accountability in health care is a "moral imperative."**
>
> Suzanne Hughes, M.S.N., R.N.

What has been done to create and implement Summa's ACO? Our system is part of the Premier collaborative. There is a great deal of work to be done in this project to not only develop new models of care and the corresponding operational plans, but even more important, to gather all of the players to collaborate on the initiative and to communicate this true paradigm shift to all stakeholders. The role of the primary care community is absolutely critical, and the communication between and among PCPs and cardiologists and other specialists is key to success. The communications team and our colleagues in IT and in finance have major roles to play, as do all of our nurses, dietitians and pharmacists who participate in patient education. We have been very busy bringing all of these groups together with representation from all of our hospital entities, our health plan, and our community physicians to set strategy and plans.

How do ACOs fit with the patient-centered care initiative at the ACC? Over the past several months, as I was reading and learning more about the ACO concept, I have also been working with the ACC's Patient-Centered Care initiative, and participating in the draft of the college's health policy statement regarding patient-centered care. The goals of the

> **"I am excited to have the opportunity to be part of a strategy that when fully operational, will be rewarded for doing the right thing for patients."**

Patient-Centered Care Committee are to:

- Make care patient-centered
- Strengthen the provider/patient relationship
- Engage and educate patients to be partners in care
- Provide a virtual office for the provider/patient encounter
- Provide necessary elements to transform the care experience
- Recommend ACC's strategy for the cardiovascular specialist's participation in the Patient-Centered Medical Home health care delivery model.

You can see again that the recurrent themes appear. As has often been stated, our current "health care" system is really a sick-care system, where care occurs episodically, rather than in a coordinated fashion that values prevention and evidence-based management of chronic disease. In the ACO model of care, the system will be designed to keep patients healthy and out of the hospital setting, while simultaneously shifting reimbursements to increasingly pay based on the achieving performance goals that drive improved patient outcomes and cost effectiveness.

What are some of the challenges of ACOs? There are many questions, concerns, and skepticism about the ACO model and about the implementation of health care reform. What we do know is that how we as patients pay for health care and how providers and hospital systems are reimbursed will be changing over the next several years. In this shift, we are looking toward moving from a volume-based health delivery system to becoming a value-based health care system. Right now we are all wrestling with the challenge of straddling two worlds. With some of the best minds in health care delivery, IT, and health economics, we are designing a new system while simultaneously continuing to provide care according to long-established norms and traditions. I am excited to have the opportunity to be part of a strategy that when fully operational, will be rewarded for doing the right thing for patients.

FDA Looks to Prevent Radiation Overdoses During CT Scans

As part of its efforts to improve patient radiation safety, the Food and Drug Administration (FDA) has released the results of its investigation into accidental radiation exposure in patients undergoing computed tomography (CT) brain perfusion scans and proposed possible CT equipment enhancements that could improve patient safety.

The FDA investigation, which started in 2009, found improper use of CT scanners resulted in at least 385 patients receiving excessive radiation from CT brain perfusion scans – not CT malfunctions. While the investigation was not specific to cardiac CT scans, the agency's list of potential changes could be applicable to all CT providers. These changes include:

- A console notification to alert the operator of a high radiation dose
- Clarification of parameters affecting dose, along with clear instructions on how to appropriately set those parameters
- Organization of all dose-related information into one section of each user manual, in a dedicated dose manual, or indexed comprehensively in a concordance covering all manuals

The ACC supports a pragmatic approach to radiation safety that balances the intended benefits of the procedure against the radiation risk. For more information on the FDA's radiation safety initiatives, and ACC's efforts, go to: *CardioSource.org/Advocacy* and click on "Imaging" in the Issues section.

ACC Urging Wide Latitude to Take Risks, Test Different ACO Models

While the obvious arrangements for an ACO resembles today's integrated health systems, the ACC is urging the Centers for Medicare and Medicaid Services (CMS) and others to craft regulations that permit and encourage other collaborative payment models.

In a recent letter to CMS Administrator Donald Berwick, M.D., the College urged CMS and others to give individuals and organizations interested in the ACO concept wide latitude to take risks and attempt new ways of providing high quality care to patients while experimenting with new payment models.

Also this fall, **Janet Wright, M.D., F.A.C.C.,** ACC's senior vice president for Science and Quality, was part of two Federal Trade Commission-moderated panels that looked at methods of clinical integration without affecting market power. In response to whether there needs to be a consistent commitment to integration ahead of time, Wright noted that a community of committed providers is necessary in order to collect data, reflect on practice patterns and use the data to implement quality improvement activities, develop guidance and/or conduct research.

A proposed rule from CMS on the design of the ACO shared savings program is expected to be released before the end of the year. For more information about the ACC's comments on ACOs, visit the "Health Reform" issues section at *CardioSource.org/Advocacy*.

CMS Releases Final 2011 Medicare Physician Fee Schedule

The Centers for Medicare and Medicaid Services (CMS) in November released its final 2011 Medicare Physician Fee Schedule, which sets the Medicare payment rates for the more than 7,000 covered CPT codes, as well as establishes other policies for physicians and how they work with Medicare moving into next year. While the rule does not contain changes to the extent of those included in the 2010 rule, cardiovascular professionals will continue to see payment changes – the exact amount of which will depend on the mix of services provided – as a result of health reform implementation, the second year phase-in of the 2010 cuts and new or changing services.

Diagnostic Cardiac Catheterization, Lower Extremity Revascularization

One of the most significant changes in this year's physician fee schedule was the implementation of wholesale coding changes to two significant cardiovascular services: diagnostic cardiac catheterization and lower extremity revascularization. In both cases, services have traditionally been reported using a series of codes. As part of an ongoing effort to bundle services that are commonly reported together, these cases will now typically be reported with a single code.

Because the method of reporting these services was changed so substantially, the services were revalued through the typical processes that determine payment for Medicare services. In the case of lower extremity revascularization services, CMS calculates that the services received an average 27 percent reduction in payment from the 2010 to 2011 and that diagnostic cardiac catheterization services received an average payment decrease of 10 percent. The actual payment reduction is somewhat difficult to calculate due to the complexity of the combinations and the many other factors that determine Medicare payment.

The old codes for these services have been deleted and will be rejected if reported on Medicare or private coverage patients. ACC will be releasing more information on understanding and using these new codes in the near future.

Additional Changes for Cardiovascular Services

In addition to payments for individual services, CMS continues adjustments to the inputs and formulae that change payments for all physician fee schedule services. For example, CMS finalized its decision to continue with a four-year implementation of the AMA Physician Practice Information Survey (PPIS), which helps to set the payment rates for all physician services. The implementation of this survey continues to cause significant reductions in payment for cardiology services, particularly those that have high practice expense values such as in-office imaging. Despite significant outcry from ACC and others about the implementation, CMS has not deviated from its plan.

However, CMS also finalized its decision to revise and rebase the Medicare Economic Index, a formula adjustment that impacts all services paid under the physician fee schedule. This decision has a modest impact on cardiology overall, but does slightly moderate projected cuts to imaging services, such as echocardiography, that are scheduled to be implemented in 2011. It also helps to moderate projected increases in services like office visits.

Self Referral

On Jan. 1, practices relying on the in-office ancillary services exception to the physician self-referral (Stark) law to provide PET, CT and/or MRI services will need to disclose their ownership interests in those services to their patients. This provision does not impact echocardiography services or SPECT nuclear cardiology services. The written disclosure must be accompanied by a list of at least five alternate providers of those services, and the alternate sites must be located within a 25-mile radius of the practice. The list may include hospital providers of those services, but those do not count towards the list of five. If there are not five alternative sources of PET, CT and/or MRI services within a 25-mile radius of the practice, the practice should include as many as it can. Even if there are no others, the practice must still provide the written disclosure to the patient, and document that the information has been provided. There are no exceptions to this requirement.

Physician Quality Reporting

CMS makes some changes to physician quality reporting, which it previously called the PQRI program. As in 2010, there are multiple methods of reporting, including claims-based, registry, and electronic health record based reporting. Most of the performance measures that were developed by ACC/AHA have been removed from the claims-based reporting, but there are still substantial opportunities to participate through registries or direct EHR reporting.

The bonus for participation decreases from 2 percent in 2010 to 1 percent in 2011. Starting in 2012, the bonus will be reduced even further to half a percent. Starting in 2015, those who do not participate will have their payments reduced by 1.5 percent and then increasing to 2 percent in 2016.

As part of the implementation of bonus payments for the meaningful use of electronic health records that start in 2014, CMS will examine ways to harmonize the quality reporting of its various requirements, so the quality reporting program of 2014 may look very different from the quality reporting program of 2010.

Health Reform Implementation

The 2011 final rule is the first since passage of the landmark health reform bill in April. As a result, it begins to lay the groundwork for implementing several provisions, including value-based purchasing, included as part of the law. Traditionally, physician payment has been entirely based on the resources required for the physician and/or his/her practice to provide the service. Starting in 2015, CMS will begin to adjust payments to physicians based on the quality of care they provide and the number of Medicare resources consumed by their patients. The implementation of this requirement will require a tremendous effort on the part of CMS to appropriately measure both quality and resource use. The ACC will be working closely with CMS to ensure that physicians are appropriately protected in this endeavor.

Electronic Prescribing Incentive Program

Much like in 2010, physicians who report that they are using electronic prescribing (e-prescribing) will receive a bonus payment, although the bonus payment is reduced from 2 percent in 2010 to 1 percent in 2011. More importantly, CMS indicates that data from 2011 will be used to establish the implementation of a legislatively mandated penalty to physicians who do not participate.

The rule indicates that if a physician does not report that he or she has e-prescribed between January and June of 2011, that physician will have all payments reduced by 1 percent starting in 2012. While there are some limited exceptions for physicians who are hospital-based or in rural areas with no high speed internet access, the vast majority of cardiologists will be potentially subject to this penalty if they do not report on e-prescribing.

Physicians can avoid this penalty by reporting the same G code that they have used to report their participation in order to receive the bonus. Physicians must report 10 e-prescribing incidents to avoid the penalty and 25 to receive the bonus.

ACC.11

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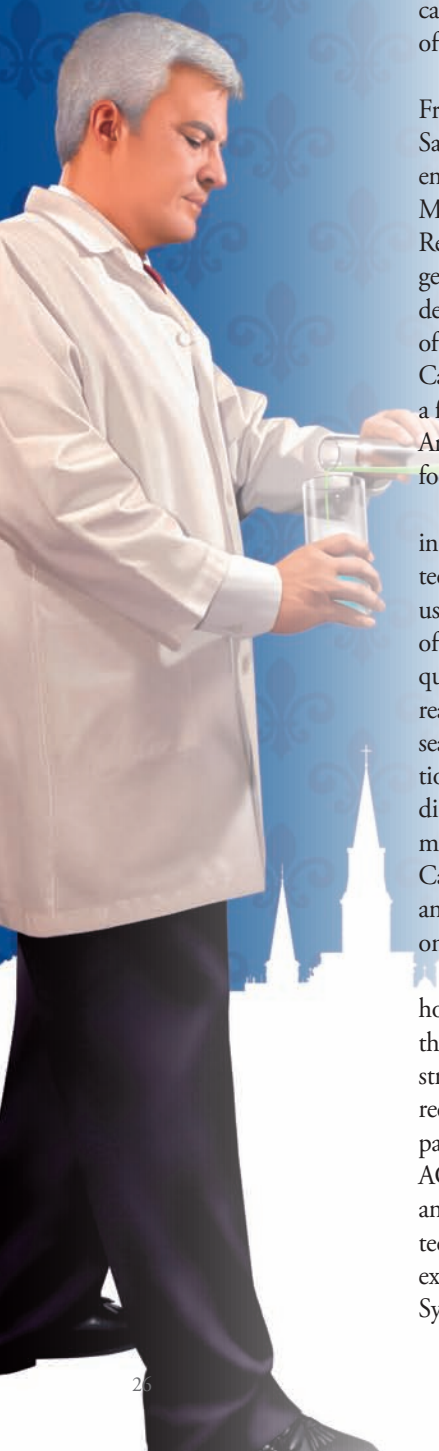
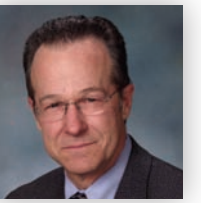


ACC.11 to Offer New Technologies and Opportunities to Attendees



By Michael H. Crawford, M.D., F.A.C.C.

The 2010 Annual Scientific Session (ACC.10) in Atlanta was the College's highest-rated meeting among attendees to date. As the chair of ACC.11, I am looking forward to building on this momentum in New Orleans and celebrating 60 years of cutting-edge and innovative education aimed at helping cardiovascular professionals improve the quality of care for patients.

New this year, plan to arrive on Friday, April 1, so as not to miss enriched Saturday programming on April 2. The enriched programming will feature a Practice Management Spotlight and a new Translational Research Spotlight focused on cell therapies, genomics and tissue engineering and new devices. There will be also be three Maintenance of Certification (MOC) review sessions, the Cardiology Fellowship Directors Boot Camp, a full-day pharmacology program and the 3rd Annual International Cardiovascular Conference focused on the Middle East.

Sunday, Monday and Tuesday will include an extensive list of new and exciting technologies and learning opportunities. New use of SMS technology will allow attendees of case-based Meet the Experts sessions to ask questions by iPhone or iPad. In addition, a new real-time iPhone app will allow attendees to search the meeting program and add selections to their iCalendars. It will also provide directions around the "Big Easy." For the true multi-taskers, the Heart Hub and Cardiology Café areas will allow attendees to access slides and audio of simultaneously presented sessions on their smart phones and iPads.

Health information technology (IT) is a hot topic among cardiovascular professionals these days, especially since providers demonstrating "meaningful use" of electronic health records (EHRs) will be eligible for positive payment incentives between 2011 and 2015. At ACC.11 attendees can learn how to automate and streamline their workflows with the latest technologies and services showcased in the expanded EHR Pavilion. A special Health IT Symposium also will be held on Sunday to help care providers understand the new EHR incentive program. Attendees will also hear from cardiovascular professionals about their experiences at different phases in the EHR selection and adoption process.

As in past years, ACC.11 will host dedicated sessions to help attendees earn MOC points in medical knowledge at no additional charge. However, there will be two new MOC sessions designed for pediatric cardiologists, with questions from the American Board of Pediatrics modules. ACC.11 attendees will also have the opportunity to gain first-hand training in the Hands-On Learning Labs, which combine a presentation by a clinical or technical expert on a specific topic with a tutorial on the procedures associated with a particular device, piece of equipment or workstation.

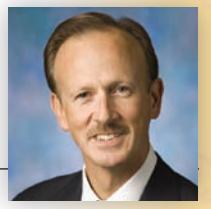
As always there will also be cutting-edge keynote lectures from leading researchers, ACC leaders and health policy officials. More information will be available in the coming months. And of course ACC.11 will have the best late-breaking science. Other highlights include:

- An enhanced poster area
- The Industry-Expert Theater that includes promotional presentations about the latest in cardiovascular products, services and technologies
- Lunchtime case reviews and 17 international lunchtime symposia
- "The Trialist Is In" round-table discussions with late breaking clinical trial investigators
- Enhanced opportunities for the general cardiologists to interact with the i2 Summit

I couldn't be more excited about all of the new and innovative opportunities at ACC.11. We've had 60 productive years of quality and are looking forward to decades more. Register now at *www.accscientificsession.org*.

Crawford is chair of ACC.11 and Chief of Clinical Cardiology at the University of San Francisco Medical Center.

i2 Summit 2011 Looks to Bridge Clinical Science with Real-World Practice



By David J. Moliterno, M.D., F.A.C.C.

The ACC's Innovation in Intervention: i2 Summit 2011 in partnership with the Cardiovascular Research Foundation includes an enriched schedule with many new sessions this year to keep cardiovascular professionals informed, educated, and engaged while in New Orleans.

This year there is a heightened focus on case-based education. After making a trial run at i2 Summit 2010, the "Challenging Case Submissions," which allow cardiovascular professionals to review intriguing cases submitted by colleagues from around the world, are now a permanent feature of the i2 Summit. Similar to scientific abstracts, these challenging cases are submitted into categories for reviewers to grade on merit, teaching points, and overall interest. Attendees can choose from five different challenging case sessions each day with topics covering all aspects of peripheral, structural and coronary artery disease. The sessions, which are being hybridized with lunchtime meet-the-expert sessions, will be chaired by working group leaders and expert panelists who can help reflect on the application of guidelines and clinical trial information to real-world cases.

Other lunchtime options include joint sessions between ACC-i2 and international cardiovascular societies. For 2011, i2 will be teaming up with international societies from France, Greece, Turkey and Pakistan covering key cardiovascular topics from around the globe. This year's themes will include percutaneous treatments for mitral valve disease, advanced vascular imaging, radial artery access interventions and complex bifurcation coronary interventions. The 75 -minute sessions will include talks and discussions from leaders in the fields from both the ACC-i2 and the guest foreign society.

Live cases will again be a case-based feature of the i2 Summit. Three institutions will be broadcasting live cases with sessions slotted for Sunday and Monday afternoons. Each live-case session will have a focused theme including complex coronary intervention, structural heart disease, and peripheral vascular disease.

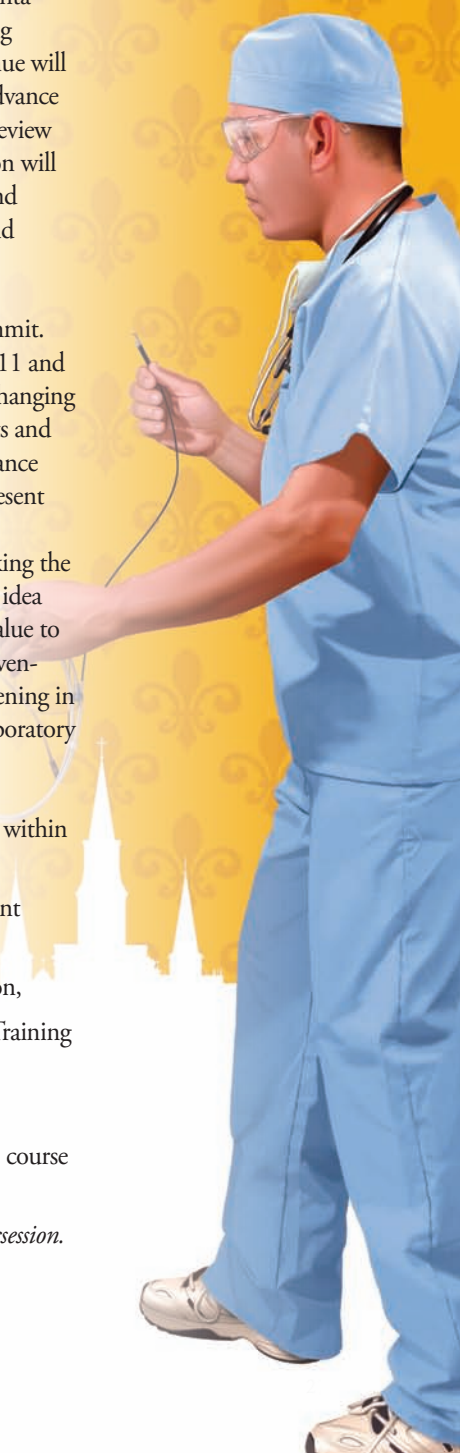
Also new for 2011, attendees can start the morning with the new i2 taped-case session format—a power-packed highlight reel of pre-recorded cases. The case-in-a-box presentations will be highlighted by a corresponding state-of-the-art lecture. The taped-case venue will allow cases to be selected and distilled in advance to provide the audience with an enriched review of technical and clinical pearls. Each session will be hosted by the interventional operator and a panel of experts to provide perspective and commentary.

Late-Breaking Clinical Trials (LBCTs) again will be the crown jewel of the i2 Summit. However, LBCTs will be open to all ACC.11 and i2 Summit registrants, with the goal of exchanging information between non-interventionalists and interventionalists alike. These open-attendance sessions also provide the opportunity to present a condensed tape case of an interventional procedure studied in a LBCT, thereby making the data more visceral. It is a remarkably novel idea and hopefully will be a great educational value to all attendees. The idea is to keep non-interventional cardiologists abreast of what is happening in interventional cardiology with a near in-laboratory experience.

Other meeting highlights include:

- Oral abstracts, organized thematically within program tracks
- Joint ACC/i2 sessions, including a Joint ACC/i2 Vascular Learning Pathway
- The i2 Summit Interventional Pavilion,
- Special programming for Fellows-in-Training and Cardiac Care Associates
- In-depth Hemodynamics course
- Maintenance of Certification (MOC) course for board re-certification

Be sure to register soon at *www.accscientificsession.org*.



ACC Promotes Heart Health in Hispanic Communities

Heart disease, while the leading cause of death among all Americans, affects minority ethnic populations at a higher rate, including Hispanics. According to the Centers for Disease Control and Prevention (CDC), nearly 23 percent of Hispanic deaths in the U.S. were caused by heart disease.

To help improve these alarming statistics and promote better heart and overall health outcomes in the Hispanic population, the American College of Cardiology (ACC) and the National Alliance for Hispanic Health (the Alliance) have formed the National Hispanic Cardiology Leadership Network (NHCLN). The network, which is comprised of Hispanic cardiologists from across the country, is focused on a number of key issues, including workforce development, provider and patient education, international efforts and science and public policy.

National Hispanic Cardiology Leadership Network

Pedro Lozano, M.D., F.A.C.C., a member of the NHCLN's Provider and Patient Education and Support Workgroup, said one of the toughest parts of patient education is making people aware of their unhealthy diets. As chief of the cardiovascular section at the VA Medical Center in Oklahoma City and an assistant professor at Oklahoma University Health Sciences Center, he sees patients who must be taught how to look at food labels and understand that fresh fruits and vegetables are better than processed foods. To help better educate patients, his workgroup produced patient videos in Spanish on 13 topics ranging from hypertension to cardiac rehabilitation. The patient videos complement English language videos on the ACC's *CardioSmart.org* video library.

Mayra Guerrero, M.D., F.A.C.C, senior staff interventional cardiologist and director of the structural heart disease program at Henry Ford Heart and Vascular Institute in Detroit, said breaking the language barrier is key to reaching patients. She said the future of the network includes partnering with more Mexican consulates nationwide to expand services to more patients. The NHCLN also wants to connect with more if its members to have them expand the programs into their hospitals and practices.

Jane Delgado, Ph.D., M.S., president and CEO of the Alliance said the goal of NHCLN is to keep people moving and to foster healthy relationships with a regular health care provider. "It starts with awareness and education," said Guerrero. "We want to help multiply the number of people who have access to this information."

For more information visit *CardioSmart.org* or *hispanichealth.org*.

ACC President Receives International Awards

American College of Cardiology (ACC) President **Ralph Brindis, M.D., M.P.H., F.A.C.C.,** received the "Gold Medal of the Spanish Society of Cardiology" from the Executive Committee of the Spanish Society of Cardiology. He received the award during the opening ceremony of the Congress of Cardiovascular Diseases, SEC 2010, in Valencia.

The award was presented for Brindis' "personal contribution to the field of cardiology in our country during [his] time as President of the American College of Cardiology," according to the nomination letter from **Carlos Macaya, M.D., F.A.C.C.,** President of the Spanish Society of Cardiology.

"I am incredibly humbled by the great honor of receiving the Gold Medal of the Spanish Society," Brindis said. "The SEC Congreso itself is a terrific opportunity for both Spain's and the world's cardiovascular (CV) professionals to attend a broad, diverse, in-depth and up-to-date scientific forum on cardiovascular disease."

The SEC and the ACC have developed a relationship over the past six years, which was formalized in 2008 when Brindis and SEC Immediate Past President **Maria Salvador, M.D., F.A.C.C.,** signed an agreement at the SEC's 2008 Bilbao annual meeting outlining the scope of the two organizations' collaborations. The agreement focused on areas of mutual interest in cardiovascular science, education and quality in cardiovascular medicine. It also outlined strategies for continued dialogue to explore other potential areas of beneficial collaboration to the members of the SEC and the ACC, and for both countries' cardiovascular patients.

"Dr. Brindis is smart and generous, with a very open mind," Salvador said. "He has led an enormous push in recent years to carry out joint activities, both in the field of health organization such as harmonization of the treatment of acute myocardial infarction and in continuous education with the reinforcement given to the annual ACC-SEC symposium, showing that the framework agreement signed two years ago between both entities was more than a signature on paper."

Six meetings have been held between both societies in the past 10 years, where participants and faculty from both the ACC and the SEC network and socialize. Both groups are working to partner on future opportunities, including collaborations with South American cardiovascular leaders on scientific and educational exchanges and delivering high quality cardiovascular care throughout the Americas. Both groups are also finding ways to reduce disparities in health care in poorer populations in Spain and in the U.S.

"The SEC and the ACC need to advise and lead their respective countries to offer the solutions for better integrated and cost effective CV care," Brindis said. "Our professional societies are the most knowledgeable in developing these important answers for CV health care delivery for our respective governments. I look forward to future ACC-SEC partnerships along with hopefully having many opportunities to further mature our personal friendship with our Spanish colleagues over the coming decades."

Brindis also recently traveled to Beijing, China, where he received the International Cooperation Outstanding Contribution Prize of Cardiology at the 21st Great Wall International Congress of Cardiology.

ACC Partners With Organization to Help Physicians in War-Torn Countries

The ACC has joined efforts with **Operational Medical Libraries** (OML), a grassroots organization whose mission is to collect and distribute current medical textbooks and journals to war-torn countries through a partnership with American medical schools, hospitals, physicians and the United States military.

The ACC and OML hope to shrink the educational gap in all areas of the health sciences in developing countries where doctors and nurses go without the latest professional information they need to provide proper health care to their patients. For more information about OML and how to donate, visit the ACC's new International page on *CardioSource.org*.

North Carolina Event Shows Legislators a Day in the Life of a Cardiologist

The North Carolina Chapter of the American College of Cardiology (ACC) held a five-day "Cardiologist for a Day" event for legislators to experience a day in the life of a cardiologist – each day in a different city – and experience first-hand how their decisions could affect medicine and patient care.

The program's goal was to give participants a behind-the scenes look at how a medical practice operates — from what it takes to get reimbursed for treating a patient, to the infrastructure needed to address regulatory requirements, to observing procedures such as the implantation of a defibrillator or the placement of a stent to open up a blocked artery.

Legislators visit Winston Salem Cardiology. From L-R, Dr. Nick Cavros, State Rep. Larry Womble (D), Rep. Virginia Foxx (R), Dr. David Bohle, Dr. Mark Mitchell, and State Rep. William McGee (R). State Senator Peter Brunstetter (R) and State Rep. Dale Folwell (R) also attended.

From L-R, Rep. Edith Warren (D), Sen. Clark Jenkins (D), Rep. Marian McLawhorn (D), Sen. Don Davis (D), Rep. Arthur Williams (D), and Dr. Eric Carlson.

According to the ACC's 2010 Practice Census survey of more than 2,400 cardiovascular practices in the U.S., 43 percent of practices in North Carolina have reduced staff and physician salaries as a direct result of reimbursement cuts for cardiovascular services included in the 2010 Medicare Physician Fee Schedule. Another 41 percent are not able to purchase any new equipment and nearly half (49 percent) have either merged with another practice, integrated with a hospital or are considering doing so.

"Cardiologist for a Day" will hopefully educate legislators about what happens at the ground level, and they'll think more about the effects their decisions have on us," said **David Bohle, M.D., F.A.C.C.,** whose Winston-Salem practice was the program's first stop. "My patients are scared they won't be able to continue seeing the cardiologists they have come to know and trust. Maybe this will change things a little."

Five legislators - U.S. Rep. Virginia Foxx (R), State Sen. Peter Brunstetter (R) and State Reps. Larry Womble (D), Dale Folwell (R) and Bill McGee (R) - received an overview of how the cuts to cardiology have affected Bohle's practice. For example, there have been no salary increases, and he has cut spending in places such as waiting room reading material to groundskeeping.

Day two took legislators to Greenville where **Eric Carlson, M.D., F.A.C.C.,** showed the attendees around his practice, Eastern Cardiology, then took them on a tour of the new East Carolina Heart Institute (ECHI) at Pitt County Memorial Hospital. Five legislators attended -- Sen. Clark Jenkins (D), Sen. Don Davis (D), Rep. Marian McLawhorn (D), Rep. Arthur Williams (D) and Rep. Edith Warren (D). They also viewed the practice's new electronic health record (EHR) system and saw how it has streamlined processes for patients.

Two legislators visited Mid-Carolina Cardiology on the third day of the program in Gastonia/Charlotte – Reps. Bill Current (R) and John Torbett (R). **Dustin Letts, M.D., F.A.C.C.,** led the duo on a tour of his facility and the connecting hospital, where they interacted with much of the staff, witnessed an echo and a catheterization, and learned about the benefits of EHRs.

Day four in Raleigh was the largest group of the week, featuring six legislators - Rep. Bob Etheridge (D), Rep. Brad Miller (D), State Sen. Neal Hunt (R), State Rep. Rosa Gill (D), Rep. Darren Jackson (D) and North Carolina Secretary of Health Lanier Cansler. **Lee Jobe, M.D., F.A.C.C.,** of Wake Heart Associates led the group, which donned scrubs and lead vests to witness him perform a catheterization of a 65 year-old Vietnam veteran. The group also visited WakeMed's new

Dr. Lee Jobe chats with Reps. Bob Etheridge (center) and Brad Miller as part of their visit to Wake Heart.

hospital and viewed its new testing rooms, ICU and EHR system. They also heard about North Carolina's successful STEMI system, RACE, and how it has reduced door-to-balloon times across the state.

The final day of the program was held in Asheville, where ACC's North Carolina Governor **Oscar Jenkins, Jr., M.D., F.A.C.C.,** gave a tour of Asheville Cardiology to State Reps. Susan Fisher (D), Jane Whilden (D) and Patsy Keever (D) and Rep. Heath Shuler's regional representative, Randy Flack. The group saw several different procedures and talked with patients about their experiences at the hospital and with health care in general.

While the goal of the program was to educate legislators, the events also started the process of building valuable relationships with state and national lawmakers. In addition, the events allowed for bipartisan discussion about health care issues and opportunities to continue educating members about the impacts of ongoing

"'Cardiologist for a Day' will hopefully educate legislators about what happens at the ground level, and they'll think more about the effects their decisions have on us. My patients are scared they won't be able to continue seeing the cardiologists they have come to know and trust. Maybe this will change things a little."

David Bohle, M.D., F.A.C.C.

Medicare cuts, including those that occurred in 2010. Many legislators were unaware of the severity of the cuts to cardiology and their effect on patients and practices. Lawmakers were also interested in working with cardiovascular professionals to develop programs specifically for things like childhood obesity, as they saw some children undergoing procedures as a result of being overweight.

"We stressed the continuum of care from the cardiologist's office, to the hospital and then to an integrated health system (RACE) to optimize cardiology care," said Carlson. "The ultimate goal was to establish a positive connection to our legislators so that future communications from us to them would be received in a positive way."

Cardiologist for a Day Programs in KY, SC and UT Put Faces to Cardiology

In addition to the five practice visits in North Carolina, several other American College of Cardiology (ACC) state chapters recently hosted "Cardiologist for a Day" programs in their states.

Kentucky Chapter

In Louisville, Ky., **Jesse Adams, M.D., F.A.C.C.,** hosted a tour for Rep. John Yarmuth (D) at Medical Center Cardiologists and told him that by the end of the first quarter of 2011, a majority of cardiologists in Louisville will be employed either by hospitals or by an academic institution - a significant change from the predominantly private practice model that has been in existence up until now. According to the ACC Practice Census, 31 percent of cardiovascular practices in Kentucky have integrated with other hospitals, while 14 percent have merged with another practice.

Also in Kentucky, Rep. Ed Whitfield (R) took a tour of Western Baptist Hospital in Paducah with cardiologists including ACC members **Patrick Withrow, M.D., F.A.C.C.,** Western Baptist's chief medical officer and vice president, **James Gwinn, M.D., F.A.C.C.,** and Kenneth Ford, M.D., from The Heart Group, as well as hospital president and CEO Larry Barton. During his tour, Rep. Whitfield was able to observe nuclear imaging and echocardiography procedures, as well as a cardiac catheterization to determine a revascularization strategy. The cardiologists also discussed current challenges in their practice, specifically cuts for reimbursement for cardiovascular services included in the 2010 Physician Fee Schedule. According to the Practice Census, 14 percent of cardiovascular practices in Kentucky have had to limit the number of new Medicare patients.

"The Kentucky chapter is dedicated to tackling challenging issues including childhood obesity, tobacco, practice overhead expenses, precertification requirements and health reform," said Kentucky Chapter President **Juan Villafane, M.D., F.A.C.C.** "We hope our legislative leaders listen to what we have to say and can take our concerns to Washington and help us take better care of our patients."

Utah Chapter

In Salt Lake City, Utah, Governor **Brent Muhlestein, M.D., F.A.C.C.,** and **Jeffery Anderson, M.D., F.A.C.C.,** led a tour of Sorenson Heart and Lung Institute. Three legislators attended: State Rep. Johnny Anderson (R), State Sen. Pat Jones (D), and U.S. Rep. Jim Matheson (D).

South Carolina Chapter

In Greenville, South Carolina, **Arthur Eberly, M.D., F.A.C.C.,** provided a tour of Carolina Cardiology to Rep. Trey Gowdy (R), who asked Dr. Eberly to join a committee of four or five physicians to meet with him twice a year to discuss health care matters.

For more information on Cardiologist for a Day programs contact Frank Ryan, head of ACC's state advocacy activities, at *fryan@acc.org*.

New A.A.C.C. Designation Recognizes the Cardiovascular Care Team

The first class of Cardiac Care Associates who have advanced to Associates of the American College of Cardiology (A.A.C.C.) will join the ranks of the new Fellows of the American College of Cardiology (F.A.C.C.) during Convocation at ACC.11 in New Orleans.

The A.A.C.C. designation was created in 2009 to recognize nurse practitioners, clinical nurse specialists, registered nurses, clinical pharmacists and physician assistants, who – through advanced education, training and professional development – have dedicated themselves to providing the highest level of cardiovascular care.

"The A.A.C.C. exemplifies professionalism among nurses, physician assistants and pharmacists to highlight those who are experts in their field and hold national board certifications in their specialty," said **Margo Minissian, A.C.N.P.-B.C., M.S.N., C.N.S., A.A.C.C., F.A.H.A.,** key member champion of the designation and co-chair of the ACC's Cardiovascular Team Council.

Since adding CCA as a member type in 2003, College membership among this group has grown from 400 in its first year to more than 4,000 in 2009. Now with the new designation, CCAs have another opportunity to showcase their dedication to the highest cardiovascular care standards. Successful A.A.C.C. candidates must hold an ACC-recognized national board certification, have completed continuing education in cardiovascular medicine and demonstrate a commitment to professional development with the ACC.

"Obtaining the A.A.C.C. designation has provided me with a sense of accomplishment and personal pride," said **Margaret Barnett, N.P., A.A.C.C.** and co-chair of the CCA Publication Working Group. "I would highly encourage CCA's who meet the qualifications to apply for the A.A.C.C. designation."

"The A.A.C.C. designation will assure my colleagues and patients that I am committed to learning and keeping abreast of the most up-to-date knowledge in cardiovascular care," said **Victoria Miltnersen, R.N., A.A.C.C.,** of the Alaska Heart Institute and one of four registered nurses to advance to A.A.C.C. According to **Kimberly Birtcher, Pharm.D., A.A.C.C.,** of the University of Houston College of Pharmacy, the new. designation is a tribute of the College's efforts to "embrace the philosophy of team-based care."

To learn more about the A.A.C.C. designation or other CCA member opportunities, visit *CardioSource.org/AboutAACC* .

Don't Miss the CCA Track at ACC.11 in New Orleans

Members of the Cardiac Care Team are on the front lines, making sure patients receive the best possible care every day. The CCA track at ACC.11 and i2 Summit is designed to help CCAs both strengthen clinical skills and enhance patient value. Meeting highlights include:

- **Focused learning** pathways with 11 topic tracks and education for every interest
- **Two** Cardiac Care Team Spotlights
- **Full-day** pharmacology program
- **Cardiology Core Curriculum**, an intensive program that features an all-star line-up of speakers and a comprehensive review of all major areas of cardiology
- The CCA **Community Lounge**
- Cardiac Care Associate **reception**
- Cardiovascular **Team Section meeting**

For more information and to register, go to: *accscientificsession.org*.

FDA Awards Contract to ACC for IMPACT Registry™

For the second year in a row, the Food and Drug Administration (FDA) has awarded a contract to the ACC for the development of the NCDR®'s IMPACT Registry™.

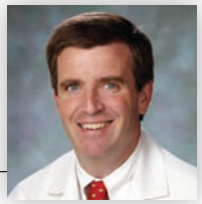
Slated to launch in December, the IMPACT Registry will track prevalence, demographics, management and outcomes of pediatric and adult patients with congenital heart disease who are undergoing diagnostic catheterizations and catheter-based interventions.

Ultimately, the registry will help increase the scientific knowledge base for CHD and support the development of evidence-based guidelines.

For more information and to enroll in the IMPACT Registry, visit *www.ncdr.com/impact*.

IMPACT Registry™

ACC Section Focused on Improving Outcomes for Adult Congenital and Pediatric Cardiology Patients



By Gerard Martin, M.D., F.A.A.P., F.A.C.C.

The American College of Cardiology's Adult Congenital and Pediatric Cardiology (ACPC) section has made great strides over the last year in developing a cohesive strategy that addresses the numerous legislative, medical, workforce and training issues pediatric and congenital cardiologists and surgeons face daily.

On the advocacy front, the ACPC section lobbied successfully for the Congenital Heart Futures Act, which was included as part of the larger health reform law passed this spring. Funding for the Act, which designates establishment of a national surveillance program and increased federal funding for congenital heart disease research, was the focus of the 4th Annual Congenital Heart Lobby Day in Washington, D.C., in April. Other provisions included in the health reform law will also improve coverage and access for congenital heart disease patients. For example, starting in 2010 for children and 2014 for adults, no patient can be denied health insurance coverage. In addition, young adults are now able to stay on their parents' insurance policy through the age of 26. Finally, health insurance plans cannot retroactively cancel a policy, unless it is deemed a case of fraud or deliberate misrepresentation of materials facts.

The ACPC section has also played a major role in strengthening educational programming for congenital cardiology care providers. At ACC.10 in Atlanta, the ACPC section inaugurated the first Dan G. McNamara Lecture, established to recognize the accomplishments and contributions of the pediatric cardiologist pioneer. In addition, one day of ACC.10 was devoted to live pediatric and congenital interventional cases. Plans for ACC.11 in April are already well underway, with former ACC president **Arthur Garson, M.D., M.A.C.C.,** delivering the second Dan G. McNamara lecture. A special maintenance of certification (MOC) session specifically designed for pediatric cardiologists will also be available to attendees for no additional charge.

In addition to educational programming, the College continues to spear-head the multi-society effort to establish a sub-specialty certification in Adult Congenital Heart Disease. Both the American Board of Internal Medicine (ABIM) and the American Board of Pediatrics (ABP) have been involved in ongoing discussions.

The ACPC Section has also had several significant accomplishments in science and quality. The IMPACT Registry™, which will track diagnostic and interventional cardiac catheterization in pediatric and congenital heart disease patients, will launch in December. This registry has been in development since 2007 and represents tremendous commitment from ACC leadership, collaboration with smaller congenital registries and exciting partnerships with the Society for Cardiovascular Angiography and Interventions, the American Academy of Pediatrics and strong alliances with the U.S. Food and Drug Administration and the Society of Thoracic Surgeons.

Also new this year, the ICD Registry™ now includes data elements specific to the pediatric population. Pediatric ICD implantations are estimated to constitute less than 1 percent of the volume of total ICD implantations and experimental data in this patient population is sparse. While not a clinical study, outcomes from the ICD Registry™ are still expected to yield important information. The College was privileged to have the opportunity to collaborate with the Pediatric and Congenital Electrophysiology Society (PACES) on this critical effort.

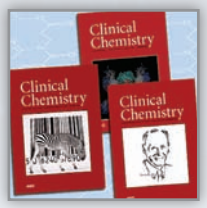
Finally, within the ACPC Section, more than 80 members of the Quality Metrics Work Group tackled quality improvement by dividing into teams to define quality measures in eight areas: heart failure/transplantation, imaging, adult CHD, ambulatory congenital care, electrophysiology, cardiac intervention, critical care and nursing. The focus was to determine not only what constituted a valid indicator of quality, but also how to accurately measure it. The ultimate goal is to create a scorecard which pediatric and congenital heart centers can use to establish internal protocols to judge and improve quality of care..

Moving into 2011, the ACPC Section will continue to execute its strategy to make sure the needs of the pediatric and congenital cardiology community are met. As always, continuing to build new leaders and engage the pediatric and congenital cardiology community will be a top priority.

For more information and news from the ACPC Section, go to: *www.cardiosource.org/acpc*. To become involved in ACPC Section work groups, contact Stephanie Mitchell at *smitchel@acc.org*.

Martin is chair of the ACC's Adult Congenital and Pediatric Cardiology Section.

New on *CardioSource.org*



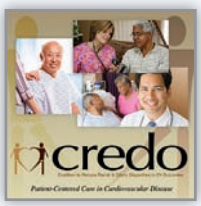
Journal Scans from the journal *Clinical Chemistry* are now available! Through a partnership with the American Association for Clinical Chemistry, users can now read Journal Scan summaries of *Clinical Chemistry* articles. The full-text of the articles can also be accessed through the citation link in each Journal Scan. Visit *CardioSource.org/Science-And-Quality/Journal-Scan.aspx* to read this new content.

Do you specialize in sports cardiology? Join the **Sports Cardiology Group**, which is dedicated to discussing the biggest issues in this area. Members recently have discussed ECG screening in high school and college athletes, among other topics. Moderated by **Christine Lawless, M.D., F.A.C.C.** Visit *CardioSource.org/communities* to join.

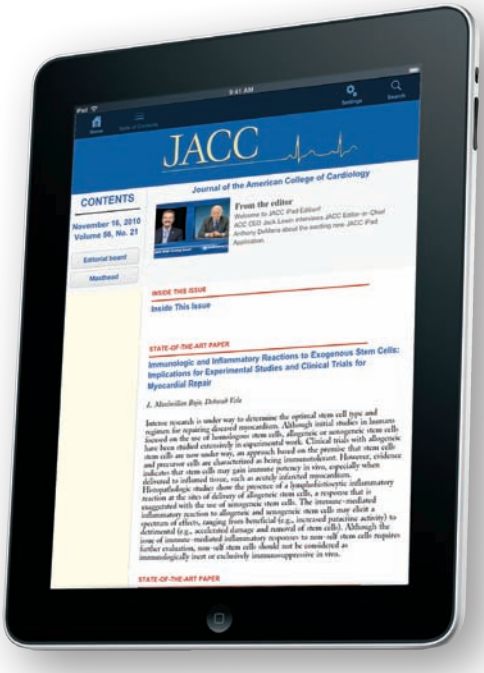
ACC Update is a new monthly video series featuring news from all areas of the College: Science & Quality, Education, Advocacy and Member Services. The videos also feature members of the ACC leadership discussing topics of importance to members. December's Update highlights the NCDR's launch of its newest registry, the IMPACT Registry, for adult and pediatric congenital heart patients. It also looks at what the College is doing to promote patient-centered care, including efforts from the ACC's CardioSmart initiative to improve heart health. To watch the videos, visit *CardioSource.org/News-Media/CardioSource-Video-News* and click on "ACC Update."

The **Patient Cardiovascular Education Forum** hosts a dialogue on how to approach health literacy and what steps can be taken to improve cardiovascular patient education. The forum also addresses the need created by the RE-LY trial to address medication compliance for anticoagulants and how to measure compliance. Created by **Joy Burnette, R.N.,** Join the discussion at *CardioSource.org/communities*.

Perfect your test-taking skills with the **ACCF Cardiovascular Board Review Meeting on Demand** and the **ACCF/SCAI Interventional Cardiology Board Review Meeting on Demand**. The programs provide comprehensive reviews, along with key strategies for Board preparation Learn more at *CardioSource.org/CVBoardMOD* and *CardioSource.org/IVBoardMOD.*



Interested in reducing racial and ethnic disparities in CV outcomes? Visit the new **credo coalition webpage**. It provides information and tools from the ACC and other sources that help promote equity in care for the CVD clinician. Learn more at *CardioSource.org/credo.*

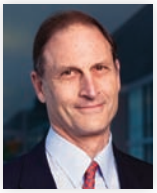


JACC Now Available on the iPad

The *Journal of the American College of Cardiology* (JACC) is now available in a special iPad application. The JACC iPad edition allows readers to quickly navigate from journal articles to related videos, guidelines, slide sets, clinical trial summaries, ACCEL interviews and more. Users can also save the articles, slides and almost any content to a custom personal folder for later reference.

"With electronic readers like the iPad, we have a really good way to present the journals in the digital format," said JACC Editor-in-Cheif Tony DeMaria. "I think the digital age is here, and we're going full speed ahead."

The application is available for free to ACC members and JACC subscribers. For more information, visit: *CardioSource.org/JACCipad.aspx.*



CORRECTION
In the September/October issue of *Cardiology*, a photo of Roger Blumenthal, M.D., F.A.C.C., was mistakenly used instead of a photo of ONC Head David Blumenthal. We regret the error.

About
Writing for Cardiology

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

Upcoming in

JACC

December 7

- Vascular Pathophysiology In Response To Increased Heart Rate
- Antiplatelet Therapy and CABG Surgery: A Fallow Land
- Massive Anterior Mediastinal Mass Causing Cardiac Compression

December 14-21

- Novel Anticoagulants for Stroke Prevention in Atrial Fibrillation: Current Clinical Evidence and Future Developments
- Outcomes in Diabetic and Non-Diabetic Patients Treated with Everolimus or Paclitaxel-Eluting Stents: Results from the SPIRIT IV Clinical Trial
- Biomarker-Guided Treatment of Heart Failure: Still Awaiting A Definitive Answer

December 28 - January 4

- The Aging Heart and Post-Infarction Left Ventricular Remodeling
- Genetic Testing in Subjects With No Clinical Abnormality: The Tip of a Huge Iceberg
- Cardiac Effects of Antiretroviral Therapy in HIV-Negative Infants Born to HIV-Positive Mothers: The NHLBI CHAART-1 Cohort Study

JACC cardiovascular Imaging

November

- Towards Real-time Intravascular Endoscopic MRI
- Getting Closer for High Resolution Vascular MRI
- Image Quality and Radiation Exposure With Low Voltage Protocol for Coronary CT Angiography: Results of the PROTECTION II Trial
- Dose Optimization in Coronary CT Angiography

JACC cardiovascular Interventions

November

- The Global Experience with Percutaneous Aortic Valve Replacement
- An Embolic Deflection Device for Aortic Valve Interventions
- Outcomes After TAVI with Edwards SAPIEN and CoreValve Devices
- Multislice CT for Optimal Deployment During TAVI

Educational Programs Calendar

December 3 - 4, 2010 — *Washington, D.C.* — CME
How to Become a Cardiovascular Investigator
Valentin Fuster, M.D., Ph.D., M.A.C.C.

December 10 - 12, 2010 — *New York City* — CME CE
43rd Annual New York Cardiovascular Symposium: Major Topics in Cardiology Today
Valentin Fuster, M.D., Ph.D., M.A.C.C.

January 10 - 14, 2011 — *Snowmass, Colo.* — CME CE
42nd Annual Cardiovascular Conference at Snowmass
Spencer B. King, III, M.D., M.A.C.C.

January 21 - 22, 2011 — *Washington, D.C.* — CME CE
5th Annual Heart of Women's Health
Joanne M. Foudy, M.D., F.A.C.C.
Suzanne Hughes, M.S.N., R.N.

January 28 - 30, 2011 — *Lake Buena Vista, Fla.*
The 30th Annual Perspectives on New Diagnostic and Therapeutic Techniques in Clinical Cardiology
C. Richard Conti, M.D., M.A.C.C.

February 11 - 13, 2011 — *Phoenix* — CME CE
3rd Annual Clinical Practice of Peripheral Vascular Disease
Michael R. Jaff, D.O., F.A.C.C.
Christopher J. White, M.D., F.A.C.C.

February 21 - 25, 2011 — *Big Sky, Mont.* — CME
33rd Annual Cardiology at Big Sky
Kim A. Eagle, M.D., M.A.C.C.
Sidney Goldstein, M.D., F.A.C.C.

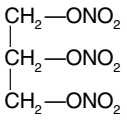
May 5 - 7, 2011 — *Washington, D.C.* — CME
33rd Annual Recent Advances in Clinical Nuclear Cardiology and Cardiac CT: Featuring Case Review with the Experts
Daniel S. Berman, M.D., F.A.C.C.
Guido Germano, Ph.D., F.A.C.C.
Jamshid Maddahi, M.D., F.A.C.C.

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

Nitrolingual® Pumpspray

(nitroglycerin lingual spray)
400 mcg per spray, 60 or 200 Metered Sprays

DESCRIPTION: Nitroglycerin, an organic nitrate, is a vasodilator which has effects on both arteries and veins. The chemical name for nitroglycerin is 1,2,3-propanetriol trinitrate ($C_3H_5N_3O_9$). The compound has a molecular weight of 227.09. The chemical structure is:



Nitrolingual® Pumpspray (nitroglycerin lingual spray 400 mcg) is a metered dose spray containing nitroglycerin. This product delivers nitroglycerin (400 mcg per spray, 60 or 200 metered sprays) in the form of spray droplets onto or under the tongue. Inactive ingredients: medium-chain triglycerides, dehydrated alcohol, medium-chain partial glycerides, peppermint oil.

CLINICAL PHARMACOLOGY: The principal pharmacological action of nitroglycerin is relaxation of vascular smooth muscle, producing a vasodilator effect on both peripheral arteries and veins with more prominent effects on the latter. Dilation of the post-capillary vessels, including large veins, promotes peripheral pooling of blood and decreases venous return to the heart, thereby reducing left ventricular end-diastolic pressure (pre-load). Arteriolar relaxation reduces systemic vascular resistance and arterial pressure (after-load).

The mechanism by which nitroglycerin relieves angina pectoris is not fully understood. Myocardial oxygen consumption or demand (as measured by the pressure-rate product, tension-time index, and stroke-work index) is decreased by both the arterial and venous effects of nitroglycerin and presumably, a more favorable supply-demand ratio is achieved.

While the large epicardial coronary arteries are also dilated by nitroglycerin, the extent to which this action contributes to relief of exertional angina is unclear.

Nitroglycerin is rapidly metabolized *in vivo,* with a liver reductase enzyme having primary importance in the formation of glycerol nitrate metabolites and inorganic nitrate. Two active major metabolites, 1,2- and 1,3-dinitroglycerols, the products of hydrolysis, although less potent as vasodilators, have longer plasma half-lives than the parent compound. The dinitrates are further metabolized to mononitrates (considered biologically inactive with respect to cardiovascular effects) and ultimately glycerol and carbon dioxide.

Therapeutic doses of nitroglycerin may reduce systolic, diastolic and mean arterial blood pressure. Effective coronary perfusion pressure is usually maintained, but can be compromised if blood pressure falls excessively or increased heart rate decreases diastolic filling time.

Elevated central venous and pulmonary capillary wedge pressures, pulmonary vascular resistance and systemic vascular resistance are also reduced by nitroglycerin therapy. Heart rate is usually slightly increased, presumably a reflex response to the fall in blood pressure. Cardiac index may be increased, decreased, or unchanged. Patients with elevated left ventricular filling pressure and systemic vascular resistance values in conjunction with a depressed cardiac index are likely to experience an improvement in cardiac index. On the other hand, when filling pressures and cardiac index are normal, cardiac index may be slightly reduced. In a pharmacokinetic study when a single 0.8 mg dose of Nitrolingual® Pumpspray was administered to healthy volunteers (n = 24), the mean C_{max} and T_{max} were 1,041pg/mL · min and 7.5 minutes, respectively. Additionally, in these subjects the mean area-under-the-curve (AUC) was 12,769 pg/mL · min. In a randomized, double-blind single-dose, 5-period cross-over study in 51 patients with exertional angina pectoris significant dose-related increases in exercise tolerance, time to onset of angina and ST-segment depression were seen following doses of 0.2, 0.4, 0.8 and 1.6 mg of nitroglycerin delivered by metered pumpspray as compared to placebo. Additionally the drug was well tolerated as evidenced by a profile of generally mild to moderate adverse events.

INDICATIONS AND USAGE: Nitrolingual® Pumpspray is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

CONTRAINDICATIONS: Allergic reactions to organic nitrates are rare. Nitroglycerin is contraindicated in patients who are allergic to it. Nitrolingual® Pumpspray is contraindicated in patients taking certain drugs for erectile dysfunction (phosphodiesterase inhibitors), as their concomitant use can cause severe hypotension. The time course and dose-dependency of this interaction are not known.

WARNINGS: Amplification of the vasodilatory effects of Nitrolingual® Pumpspray by certain drugs (phosphodiesterase inhibitors) used to treat erectile dysfunction can result in severe hypotension. The time course and dose dependence of this interaction have not been studied. Appropriate supportive care has not been studied, but it seems reasonable to treat this as a nitrate overdose, with elevation of the extremities and with central volume expansion. The use of any form of nitroglycerin during the early days of acute myocardial infarction requires particular attention to hemodynamic monitoring and clinical status.

PRECAUTIONS: (General) Severe hypotension, particularly with upright posture, may occur even with small doses of nitroglycerin. The drug, therefore, should be used with caution in subjects who may have volume depletion from diuretic therapy or in patients who have low systolic blood pressure (*e.g.*, below 90 mm Hg). Paradoxical bradycardia and increased angina pectoris may accompany nitroglycerin-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and anti-anginal effects of nitrates has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. In industrial workers continuously exposed to nitroglycerin, tolerance clearly occurs. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In various clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of nitroglycerin is not known.

PRECAUTIONS: (INFORMATION FOR PATIENTS)

Physicians should discuss with patients that Nitrolingual® Pumpspray should not be used with certain drugs taken for erectile dysfunction (phosphodiesterase inhibitors) because of the risk of lowering their blood pressure dangerously.

DRUG INTERACTIONS: Alcohol may enhance sensitivity to the hypotensive effects of nitrates. Nitroglycerin acts directly on vascular muscle. Therefore, any other agents that depend on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending upon the agent.

Marked symptomatic orthostatic hypotension has been reported when calcium channel blockers and oral controlled-release nitroglycerin were used in combination. Dose adjustments of either class of agents may be necessary. Concomitant use of nitric oxide donors (like Nitrolingual® Pumpspray) and certain drugs for the treatment of erectile dysfunction (phosphodiesterase inhibitors) can amplify their vasodilatory effects, resulting in severe hypotension. The concomitant use of these drugs is contraindicated (see **CONTRAINDICATIONS**) and alternative therapies should be used to treat acute angina episodes.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Animal carcinogenesis studies with sublingual nitroglycerin have not been performed. Rats receiving up to 434 mg/kg/day of dietary nitroglycerin for 2 years developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes. At high dose, the incidences of hepatocellular carcinomas in both sexes were 52% vs. 0% in controls, and incidences of testicular tumors were 52% vs. 8% in controls. Lifetime dietary administration of up to 1058 mg/kg/day of nitroglycerin was not tumorigenic in mice. Nitroglycerin was weakly mutagenic in Ames tests performed in two different laboratories. Nevertheless, there was no evidence of mutagenicity in an *in vivo* dominant lethal assay with male rats treated with doses up to about 363 mg/kg/day, p.o., or in *in vitro* cytogenic tests in rat and dog tissues.

In a three-generation reproduction study, rats received dietary nitroglycerin at doses up to about 434 mg/kg/day for six months prior to mating of the F_0 generation with treatment continuing through successive F_1 and F_2 generations. The high dose was associated with decreased feed intake and body weight gain in both sexes at all matings. No specific effect on the fertility of the F_0 generation was seen. Infertility noted in subsequent generations, however, was attributed to increased interstitial cell tissue and aspermatogenesis in the high-dose males. In this three-generation study there was no clear evidence of teratogenicity.

PREGNANCY: Pregnancy Category C – Animal teratology studies have not been conducted with nitroglycerin-pumpspray. Teratology studies in rats and rabbits, however, were conducted with topically applied nitroglycerin ointment at doses up to 80 mg/kg/day and 240 mg/kg/day, respectively. No toxic effects on dams or fetuses were seen at any dose tested. There are no adequate and well-controlled studies in pregnant women. Nitroglycerin should be given to pregnant women only if clearly needed.

NURSING MOTHERS: It is not known whether nitroglycerin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nitrolingual® Pumpspray is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness of nitroglycerin in pediatric patients have not been established.

ADVERSE REACTIONS: Adverse reactions to oral nitroglycerin dosage forms, particularly headache and hypotension, are generally dose-related. In clinical trials at various doses of nitroglycerin, the following adverse effects have been observed: Headache, which may be severe and persistent, is the most commonly reported side effect of nitroglycerin with an incidence on the order of about 50% in some studies. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop. Occasionally, an individual may exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration and collapse) may occur even with therapeutic doses. Drug rash and/or exfoliative dermatitis have been reported in patients receiving nitrate therapy. Nausea and vomiting appear to be uncommon. Nitrolingual® Pumpspray given to 51 chronic stable angina patients in single doses of 0.4, 0.8 and 1.6 mg as part of a double-blind, 5-period single-dose cross-over study exhibited an adverse event profile that was generally mild to moderate. Adverse events occurring at a frequency greater than 2% included: headache, dizziness, and paresthesia. Less frequently reported events in this trial included (≤2%): dyspnea, pharyngitis, rhinitis, vasodilation, peripheral edema, asthenia, and abdominal pain.

OVERDOSAGE: Signs and Symptoms:

Nitrate overdosage may result in: severe hypotension, persistent throbbing headache, vertigo, palpitation, visual disturbance, flushing and perspiring skin (later becoming cold and cyanotic), nausea and vomiting (possibly with colic and even bloody diarrhea), syncope (especially in the upright posture), methemoglobinemia with cyanosis and anorexia, initial hyperpnea, dyspnea and slow breathing, slow pulse (dicrotic and intermittent), heart block, increased intracranial pressure with cerebral symptoms of confusion and moderate fever, paralysis and coma followed by clonic convulsions, and possibly death due to circulatory collapse.

Methemoglobinemia:

Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrates could produce harmful concentrations of methemoglobin.

Treatment of Overdosage:

Keep the patient recumbent in a shock position and comfortably warm. Passive movement of the extremities may aid venous return. Administer oxygen and artificial ventilation, if necessary. If methemoglobinemia is present, administration of methylene blue (1% solution), 1-2 mg per kilogram of body weight intravenously, may be required. If an excessive quantity of Nitrolingual® Pumpspray has been recently swallowed gastric lavage may be of use.

WARNING: Epinephrine is ineffective in reversing the severe hypotensive events associated with overdosage. It and related compounds are contraindicated in this situation.

DOSAGE AND ADMINISTRATION: At the onset of an attack, one or two metered sprays should be administered onto or under the tongue. If chest pain is unrelieved 5 minutes after taking the first dose, prompt medical attention (9-1-1) is recommended. No more than three metered sprays are recommended within a 15-minute period. Nitrolingual® Pumpspray may be used prophylactically five to ten minutes prior to engaging in activities which might precipitate an acute attack.

Each metered spray of Nitrolingual® Pumpspray delivers 48 mg of solution containing 400 mcg of nitroglycerin after an initial priming of 5 sprays. It will remain adequately primed for 6 weeks. If the product is not used within 6 weeks it can be adequately reprimed with 1 spray. Longer storage periods without use may require up to 5 repriming sprays. There are 60 or 200 metered sprays per bottle. The total number of available doses is dependent, however, on the number of sprays per use (1 or 2 sprays), and the frequency of repriming.

The transparent container can be used for continuous monitoring of the consumption. **The end of the pump should be covered by the fluid level.** Once fluid falls below the level of the center tube, sprays will not be adequate and the container should be replaced. As with all other sprays, there is a residual volume of fluid at the bottom of the bottle which cannot be used.

During application the patient should rest, ideally in the sitting position. The container should be held vertically with the valve head uppermost and the spray orifice as close to the mouth as possible. The dose should preferably be sprayed onto the tongue by pressing the button firmly and the mouth should be closed immediately after each dose. THE SPRAY SHOULD NOT BE INHALED. The medication should not be expectorated or the mouth rinsed for 5 to 10 minutes following administration. Patients should be instructed to familiarize themselves with the position of the spray orifice, which can be identified by the finger rest on top of the valve, in order to facilitate orientation for administration at night.

HOW SUPPLIED: Each box of Nitrolingual® Pumpspray contains one glass bottle coated with red transparent plastic which assists in containing the glass and medication should the bottle be shattered. Each bottle contains 4.9 g or 12 g (Net Content) of nitroglycerin lingual spray which will deliver 60 or 200 metered sprays containing 400 mcg of nitroglycerin per spray after priming. Nitrolingual® Pumpspray is available as:

- 60-dose (4.9 g) single bottle NDC 59630-300-65
- 200-dose (12 g) single bottle NDC 59630-300-20

Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F) [see USP Controlled Room Temperature].

Note: Nitrolingual® Pumpspray contains 20% alcohol. Do not forcefully open or burn container after use. Do not spray toward flames. Rx Only.

SHIONOGI PHARMA, INC.

Manufactured for
SHIONOGI PHARMA, Inc., Atlanta, GA 30328
by G. Pohl-Boskamp GmbH & Co. KG,
25551 Hohenlockstedt, Germany.

NLPS-PI-7 Rev 1/10

Reliable angina relief –
Nitrolingual® Pumpspray
(nitroglycerin lingual spray)

Fire extinguisher image does not depict actual product.

Stability & Potency

Rapid Pain Relief

Ease of Use

Indications and Usage Nitrolingual® Pumpspray is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

Important Safety Information Nitrolingual Pumpspray should not be used while taking phosphodiesterase inhibitors which are used for the treatment of erectile dysfunction. Nitrolingual Pumpspray should be used with caution if patients have low systolic blood pressure, are undergoing diuretic therapy, or show hypersensitivity to this and other nitrates or nitrites. Headache is the most commonly reported side effect with nitroglycerin. Patients may also experience episodes of dizziness, weakness, and other related side effects.

Nitrolingual® Pumpspray
(nitroglycerin lingual spray)
0.4 mg nitroglycerin per spray

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