

MEMBER PUBLICATION OF THE A MEMBER PUBLICATION OF THE AMERICAN COLLEGE OF CARDIOLOGY

# 1949 - 2009

# **AMERICAN COLLEGE** OF CARDIOLOGY

60 Years of Quality and Education

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# SOMETIMES, AN OUNCE OF PREVENTION REALLY IS WORTH A POUND OF CURE

The case for 23 almonds a day.

Protein · 6

Dietary fiber: 3.3g Potassium: 206mg

#### THE EVIDENCE WEIGHS IN

The heart-healthy benefits of almonds are giving people plenty to chew on these days. Nine clinical studies over the last thirteen years have shown that almonds can lower cholesterol as part of a diet low in saturated fat. These groundbreaking studies show how a handful of almonds a day consistently lowered LDL cholesterol levels.\*

Calcium: 70n

#### DOES A HANDFUL A DAY KEEP THE CARDIOLOGIST AWAY?

As you well know, cardiovascular disease is the leading cause of death in America, but the good news is that regular exercise and a healthy diet can help lower the risk. No wonder more active people are snacking on a handful of almonds everyday. In fact, per capita consumption of almonds has doubled in

just five years. Are your patients part of this trend?

#### MOTHER NATURE'S NUTRIENT POWERHOUSE

Analyses show that almonds are the most nutritionally rich nut, compared ounce per ounce. Talk about good things coming in a small package.

#### AN ANTIOXIDANT OVERACHIEVER

Next time someone asks you what's a leading food source of alpha-tocopherol vitamin E, just smile and say "almonds." Alpha-tocopherol is the kind of vitamin E the human body absorbs best. And with data showing that most Americans

Phosphorus: 134m

Magnesium: 78mg

Vitamin E: 7.3mg

get only half of their recommended vitamin E per day, almonds are the ideal way to close that gap.

#### EVEN GREAT WHEN YOU'RE WATCHING YOUR WEIGHT

Almonds are considered a good fit with many popular weight loss plans. They offer key benefits to anyone trying to shed a few pounds, namely satiety, fewer calories for more nutrients, crunch and taste. A plan that delivers taste and nutrition usually is easier to comply with.

### MAKE THE CASE TO YOUR PATIENTS

Get your patients doing their 23 crunches a day. To make it easier, have them visit our website to get this handy portion-control tin. Sturdy, decorative and portable, this tin holds exactly one ounce of almonds and will go anywhere.

\*Find more information at www.AlmondsAreIn.com/9studies. Scientific evidence suggests, but does not prove, that eating 1.5 ounces per day of most nuts, such as almonds, as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. ©2009 Almond Board of California. All rights reserved.



{ Nutrients: per ounce }



# Looking Ahead to 2009

his year, the College celebrates 60 years of quality and education. Since 1949, we have grown substantially in membership, purpose and impact. Thanks to prudent leadership and the hard work of volunteers and staff over the years, we enter the year in good financial shape with very healthy reserves, despite the economic turmoil that surrounds us. Yet we should not suppose that we will not be affected, and for that reason, the Board of Trustees has chosen to take a conservative financial approach to the year. We will be initiating some of our projects in phases this year so that full commitment is not made until after the Scientific Sessions in March. As you are aware, this is a significant source of revenue for the College, and it seemed prudent not to fully resource all initiatives until we know the outcome of our meeting

However, as a profession and as individuals, we do face turmoil. The move to enact health care reform takes on new possibilities – some good, some perhaps worrisome – with the changing political landscape, a new president and economic crises. Certainly, adequate incentives to strengthen primary care will be a key proposal. Whether this comes at the cost of specialties is an unknown. What will the first 100 days of the new administration hold for us? **Jim Fasules, M.D., F.A.C.C.,** ACC's new Senior Vice President of Advocacy offers some projections in this issue.

I can add that under the circumstances of our times, we can truly appreciate the visionary goals of quality and education established by the 14 cardiovascular pioneers who formed the ACC. Those original goals, carried forth and developed through the years, have positioned us well as we enter this period of change. Defining and ensuring quality of patient-centered health care needs to be an important component in reform. Equally important is including the physician's voice in the discussions. The ACC has worked hard to be included at the table with those who will be a force in health system reform, and with every step we take to ensure quality and value, we solidify our position at the table. We start 2009 with the publication of Appropriate Use Criteria for Coronary Revascularization, the first time the College has provided recommendations for the use of coronary artery revascularization procedures. These new criteria will help to inform cardiovascular professionals who need to consider safety, efficacy and cost when making therapeutic decisions for their individual patients who have conditions not fully covered in clinical practice guidelines.

Efforts such as the appropriate use criteria, guidelines, performance measures and the NCDR® registries provide examples of how our profession is leading and contributing to advancing quality, reducing disparities and accelerating the application of science at the point of care. Nearly all the CV quality statistics bandied about these days are derived from insurance or Medicare claims data – except the data that comes from ACC (and STS). Congress is beginning to understand why clinical data is so important and needed.

The ACC's *Quality First* campaign is resonating with congressional, business, consumer and policy leaders. As we proceed into the potential maelstrom of 2009, it is important that all of us pick up the *Quality First* mantra and make it the essence of our clinical practice, research and patient interaction. Our ship is righted on a stable ocean and together we need to continue to steer it in the right direction.

Finally, as many of you may know by now, we have lost a person who, in his lifetime, made significant contributions to ACC, to our profession and – most important, to patients. ACC Past President **Henry McIntosh, M.D., M.A.C.C.**, passed away on Dec. 26 at the age of 89. I encourage you to read more about him on page 26 and in the Feb. 10 *Journal of the American College of Cardiology*.

In Daylor heren, MO

W. Douglas Weaver, M.D., F.A.C.C. ACC President

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# The ACC 1949 – 2009: 60 Ye

By Alfred Bove, M.D., Ph.D., F.A.C.C.

Sixty years ago, on a snowy Monday afternoon in Manh office to form a revolutionary new society. Dedicated to to improving the quality of cardiovascular care by

Six decades later, their remarkable vision has resulted in the world's leading advocate for quality cardiovascular care: the American College of Cardiology. As the College kicks off its 60<sup>th</sup> Anniversary year, we have much to celebrate — and even more to anticipate.

#### **The Early Years**

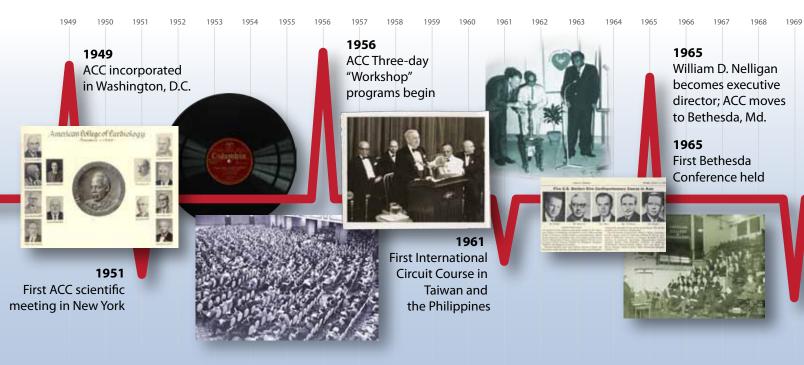
The founders hoped to improve cardiovascular education for clinicians. The first meeting of the membership, the precursor to today's Annual Scientific Session, took place in 1951 with 275 attendees. Just a few short years later, in the late 1950s, ACC educational programs drew as many as 2,500 attendees, a tribute to the founders' plan.

By the 1960s, the College had expanded its educational mission worldwide, offering international circuit courses in more than 40 countries. As technology grew, the ACC took

advantage of new delivery methods to ensure that those who could not attend programs in person could benefit through offerings like the ACCEL audio journal.

In 2001, the College launched its pioneering cardiovascular education Web site, Cardiosource. Since its inception, Cardiosource has been a thriving Web-based center for cardiovascular information and education. Today, it receives more than 300,000 visitors a month.

As the ACC grew, it became clear that to truly improve quality, the College would have to influence health policy. The ACC moved from New York to Bethesda, Md., in 1965 to be closer to the National Institutes of Health and the nation's capital. Soon after, the College's Government Relations Committee formed, and the ACC assumed an active role with legislators, advocating for physicians and their patients.



# ars of Quality and Education

attan, 14 cardiovascular pioneers met in Franz Groedel's the practicing physician, this group would devote itself offering cardiologists education and other services.

#### **Putting Quality First**

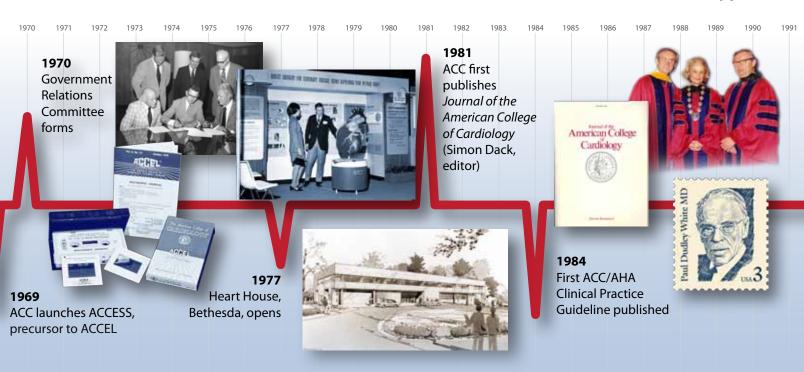
Beginning in the 1980s, the ACC emerged as a leader in determining quality care when it partnered with the American Heart Association to develop the first clinical practice guidelines. In addition to building standards for care, the College was breaking new ground in measuring quality. In the 1990s, the ACC used the guidelines to lay the groundwork for studies documenting discrepancies in optimal care. The result was the earliest national clinical performance measures.

The launch of the National Cardiovascular Data Registry (NCDR<sup>®</sup>) in 1997 allowed hospitals to benchmark the quality of care delivered in their cath labs. The natural next step was quality improvement programs. Beginning in 2001, the ACC began investing in Guidelines Applied in Practice (GAP) programs to help clinicians apply ACC/AHA guidelines at the point of care. The results of the Michigan GAP program, published in 2005, demonstrated a 21 percent to 26 percent improvement in mortality at 30 days and one year post-MI. In 2006, more than 1,000 hospitals worldwide signed on for a similar program, the Door-to-Balloon (D2B) campaign, designed to save lives by reducing D2B times to 90 minutes or less.

In 2005, the College developed and released the first set of Appropriate Use Criteria (AUC). That set defined appropriate use for SPECT MPI, and AUC for CCT and CMR soon followed. The ACC is now participating in a pilot program with UnitedHealthcare to implement AUC with a health plan for the first time.

Last year, the College launched the Quality First campaign, a visionary campaign well-suited to the legacy of our

continued on next page



#### Cover Story

founders. Quality First sets a new standard for health system reform and brings our physicians and cardiac care team members to the forefront of reform efforts. The campaign advocates for patient value, universal access and more to elevate the quality of health care in America.

The members of ACC — now more than 36,000 worldwide — continue to believe, as did our founders, that quality cardiovascu-

In 2009, we will place special emphasis on the cardiovascular patient. Along with CardioSmart, our Web site for CV patients and their families, we plan a variety of initiatives to help patients partner with their care team — our members — to improve outcomes. Stay tuned for more on the "Year of the Patient." As we celebrate 60 remarkable years dedicated to quality, we are mindful of the future's promise.

The members of ACC — now more than 36,000 worldwide — continue to believe, as did our founders, that quality cardiovascular care is not only our greatest goal but our sacred duty.

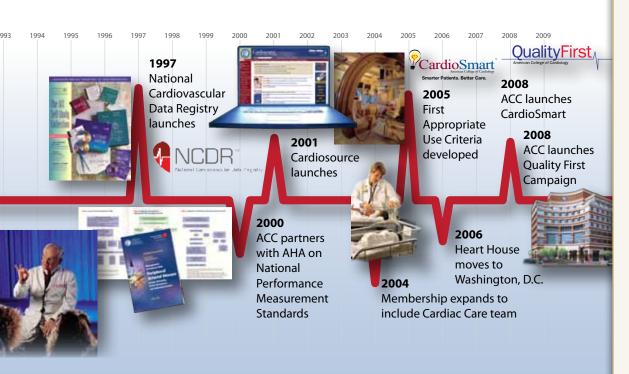
lar care is not only our greatest goal but our sacred duty.

We have much left to do to improve the quality of cardiovascular care. We will continue to define quality care through clinical documents and guidelines. We will continue to forge new ground in measuring quality with NCDR registries. We will continue to bring quality to the point of care with new appropriate use criteria, quality improvement programs and support for health information technology. The American College of Cardiology will continue to fulfill the great vision of our founders. We will meet the future, in the words of Franz Groedel, "not

merely by dreams, but by concerted action and unextinguishable enthusiasm."

Bove is the President-elect of the American College of Cardiology.





# Cardiology

January 2009 Vol. 38, No. 1

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#### Cardiology

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

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# NPs in the Cath Lab — Will It Cost Us?

his letter is in response to "NPs in the Cath Lab" in October 2008 *Cardiology*, which was about family nurse practitioners performing interventional cardiac caths

I'm a board-certifed cardiologist but I am not certified in interventional cardiology, so I am neither qualified nor credentialed to do interventions. Nevertheless, at Mount Sinai Heart, uncertified non-physicians are allowed to do those same interventions without physician participation. How can they justify such a blatant double standard?

I know there is a cardiologist shortage, but this is not the answer. Quality comes from judgment, derived from knowledge earned through training and experience. Every case deserves the best, even the so-called simple ones.

To the doctors at Mount Sinai Heart you and I worked long and hard to become cardiologists. Our profession has worked just as hard to develop training and experience criteria to enhance the safety of our patients, but you mock our efforts, profession and accomplishments by giving away our station so cheaply.

And as you know, nurse practitioners are fully independent in at least 12 states, where they offer primary and subspecialty care. Now, they're working for preferred provider status, meaning our patients will only see us under limited circumstances, assuming the primary care nurse practitioner doesn't refer them to a cardiology nurse practitioner who now does caths.

Guys, if you keep acting like nurses can do your job, don't be surprised when they have your job.

Charles A. Trant Jr., M.D., F.A.C.C. McLeod Pediatric Cardiology Florence, S.C.

# Maybe We Need to Think Out of the Box..

urse practitioners (NPs) in the Mount Sinai Hospital cath lab have the same setup and status as if they were in a physician's office — that is, to facilitate the medical care and help the physicians do their jobs faster and more efficiently. They do not work as substitutes for licensed or credentialed interventionalists but instead work as substitutes for cardiology and interventional fellows.

Rather than using cardiovascular technicians or nurses to assist in procedures, we at Mount Sinai Hospital have established a program of cardiology NPs to fulfill the role of assistant. No cases are being done by NPs substituting for attending physicians.

Clearly, this process of physician/NP collaborative practice takes some time, but it has certainly been worth the effort as the NPs overall provide excellent care to our cath patients. In fact, at our center, cath/ PCIs assisted by NPs have significantly fewer complications than those assisted by the cardiology fellows. The main reason is probably their overall attentiveness to the whole patient's care and their limited responsibilities. Of course, training NPs to assist in complex PCIs takes extra skills, close supervision, training and education; however, it can be done well as we have shown at Mount Sinai.\*

We perform about 5,200 interventions per year and have the largest Interventional fellowship in the country with eight interventional fellows. Yet, we still need extra hands to do all the interventional cases, which we have from 7 a.m. to 11 p.m. every day. At present, we have one interventional NP and are in process of adding one more in 2009 and may add another in 2010 if our volume continues to grow. All the cath lab attending physicians and I are extremely satisfied and comfortable with the NP assistance in cath cases.

We believe that it's important for all of us to think out of the box and to think in terms of multiple people being cross-trained to do many tasks, including cath/PCI assistance by NPs.

Samin K. Sharma, M.D., F.A.C.C. Mount Sinai School of Medicine New York

\* MaryBeth Duffy, author of the original article, is a licensed NP and certified by the American Nurses Credentialing Center. She had performed more than 800 diagnostic caths with an attending physician or fellow and participated in more than 250 interventional procedures when Dr Sharma asked the Mount Sinai Medical Board to approve her to perform diagnostic caths and Type A PCI as a senior operator.

### Internet-Based Medicare Enrollment Now Available

hysicians and non-physician practitioners in 15 states and the District of Columbia may now enroll for Medicare or change their enrollment information using the Internet, the Centers for Medicare and Medicaid Services (CMS) announced in December 2008. The Internetbased Provider Enrollment, Chain and Ownership System (PECOS) also allows users to view their Medicare enrollment information on file with Medicare and check on the status of an enrollment application.

The states in which PECOS is available include —

Delaware	Minnesota	New Jersey
Idaho	Missouri	North Carolina
Illinois	Nebraska	Pennsylvania
Iowa	Maryland	Tennessee
Kansas	Michigan	Wisconsin

#### **PECOS Has Its Advantages**

According to CMS, enrollment applications through Internetbased PECOS can be processed as much as 50 percent faster than by paper, considerably reducing the time it takes to enroll. Also, physicians and non-physician practitioners are required by regulation to report certain changes in their enrollment information within specified time frames. Internetbased PECOS will allow them to update, make corrections and check on the status of their Medicare enrollment applications — again, as much as 50 percent faster than by paper. Changes include a change in practice location, ownership or final adverse action, such as medical license suspension or revocation.

Internet-based PECOS meets all required government security standards in terms of data entry, data transmission and electronic storage of Medicare enrollment information. Only authorized individuals can enter enrollment information into PECOS or view PECOS data from the Internet. Authorized individuals secure their information and its access with user IDs and passwords. CMS does not disclose Medicare enrollment information to anyone except when they are authorized or required to do so by law.

#### **User-friendly Application**

Internet-based PECOS is a scenario-driven application process with front-end editing capabilities and built-in help screens. The scenario-driven application process ensures that users complete and submit only the information necessary to enroll or make a change in their Medicare enrollment record. In contrast to the information collected on the CMS-855I, users will no longer see questions that are not applicable to their enrollment scenarios when they use Internet-based PECOS.

#### **Coming Soon to Other States**

CMS plans to expand the availability of Internet-based PECOS to all states early in 2009. In addition, CMS will make Internet-based PECOS available next year to all providers and suppliers, except for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers.

Physicians and non-physician practitioners in the District of Columbia and the states shown here who wish to access Internet-based PECOS may go to *pecos.cms.hhs. gov.* For general information about Internet-based PECOS, including important information that users should know before submitting a Medicare enrollment application via Internet-based PECOS, go to *www.cms.hhs.gov/ MedicareProviderSupEnroll.* 

# ACC Comments on 'Never Events,' MRI Flow

he ACC in late December issued comment letters to the Centers for Medicare and Medicaid Services (CMS) on two national coverage determinations (NCD). In the first letter, the ACC commented on NCDs for three "never events" for wrong surgical or other procedures performed on a patient, surgical or other procedures performed on a wrong body part, and surgical or other procedures performed on the wrong patient. According to the letter, "[w]hile it is clear that the medical community must continually strive to establish systems to ensure these surgical 'never events' are eliminated, the College would encourage CMS to establish an appeals process to allow physicians and other providers to gain recourse against any agency non-coverage decisions that may be made inappropriately."

In the second letter, the ACC, American College of Radiology, North American Society for Cardiovascular Imaging and the Society for Cardiovascular Magnetic Resonance formally requested a reconsideration of the NCD for magnetic resonance imaging (MRI) to permit local contractor discretion for the coverage of cardiac MRI for morphology and function with flow/velocity quantification. The groups write that they "believe that accepted clinical practice of flow and the ability of treating physicians to make downstream decisions serve as surrogate evidence of beneficial outcomes for patients." The primary rationale for requesting a reconsideration of the coverage policy is that when new CPT codes for cardiac MR were introduced in 2008, CMS denied payment for the codes that included flow/ velocity quantification because one element of the service (blood flow) is designated as non-covered in an existing NCD. Modifying the coverage policy for cardiac MRI would allow local contractors to determine medical necessity for the full procedure.

### 2009 Ushers in Changes for Cardiology Coding and Payment

ignificant changes in cardiac device monitoring codes, as well as echocardiography codes, will mark 2009 as a sentinel year for cardiology coding and payment. The ACC has prepared a guide to help physician practices navigate the new changes. The guide is available online at *www.acc.org*. It will also be included in the February issue of *Cardiology*.

In addition to the coding changes for cardiac device monitoring and echocardiography, cardiology practices should be aware of a National Correct Coding Initiative (NCCI) edit that affects reporting of the physician service and technical service codes for remote interrogation of pacemakers and ICDs. The edit will prevent reporting of the physician service (CPT 93294 or 93295) and the technical service (CPT 93296) by the same physician on the same day. The ACC believes that this edit is incorrect and is working with CMS to resolve the problem. For questions about the coding changes, contact Brian Whitman at *bwhitman@acc.org.* 

## Drug Industry's New Marketing Guidelines Take Effect

The pharmaceutical industry's voluntary moratorium on branded gifts officially began Jan. 1, with about 40 drug companies agreeing to follow the code, *The New York Times* reported in late December. Created by the Pharmaceutical Research and Manufacturers of America, the new code bans pharmaceutical companies from gifting pens, staplers, flash drives and other non-educational items to physician offices. The guidelines also prohibit pharmaceutical sales representatives from providing restaurant meals to health care professionals but do allow occasional in-office meals that feature informational presentations. Companies are also required to ensure that sales representatives are trained about applicable laws, regulations and industry codes of practice, among other provisions. The guideline requests that companies set an annual limit on speaking and consulting arrangements between drug manufacturers and physicians, but does not state what that limit should be.



## New Criteria Assess Appropriate Use of Coronary Revascularization

By Gregory Dehmer, M.D., F.A.C.C.; Manesh Patel, M.D., F.A.C.C.; and Peter K. Smith, M.D., F.A.C.C.

linicians, payers, patients and others are increasingly interested in the specific benefits of coronary revascularization, especially given the prevalence of coronary artery disease (CAD). Current advances in surgical and percutaneous techniques for revascularization and concomitant medical therapy for CAD have the ability to improve patients' clinical outcomes when used appropriately. ation and the American Society of Nuclear Cardiology, conducted an appropriateness review of the majority of clinical indications for revascularization. The resulting criteria assess whether coronary revascularization is appropriate, inappropriate or uncertain based on whether the expected benefits, in terms of survival or health outcomes, exceed the expected negative consequences of the procedure.

### However, inappropriate use may fail to provide benefits and even pose potential harm to patients and result in unwarranted costs to the health care system.

However, inappropriate use may fail to provide benefits and even pose potential harm to patients and result in unwarranted costs to the health care system.

In an effort to address the heightened interest in coronary revascularization, the American College of Cardiology Foundation (ACCF), along with the Society for Cardiovascular Angiography and Interventions, the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, the American Heart AssociUnlike previous appropriateness criteria that addressed the appropriateness of certain cardiovascular diagnostic tests, this newest round of criteria is the first to look at the appropriateness of therapeutic procedures — specifically two distinct approaches to coronary artery revascularization. This critical shift was made with the intent to explicitly consider the potential benefits and risks of the treatment, rather than the potential usefulness of a diagnostic test as a prelude to further treatment.

Like previous appropriateness criteria, the scope of indications was purposely broad and intended to represent the most common patient scenarios for which, in this case, coronary revascularization is considered. In developing the indications, the writing group estimated that more than 4,000 separate clinical scenarios would be required to incorporate all permutations of the many variables involved in coronary revascularization decision-making. As a result, the 180 clinical scenarios presented and scored were developed to represent common situations encountered in everyday practice and included information on symptom status, extent of medical therapy, risk level as assessed by non-invasive testing and coronary anatomy. They are not inclusive of every possible clinical situation.

Among the key findings, the use of coronary revascularization for patients with acute coronary syndromes and combinations of significant symptoms and/or ischemia was generally viewed favorably. In contrast, revascularization of asymptomatic patients or patients with low risk findings on non-invasive testing and minimal medical therapy was viewed less favorably.

For patients with acute coronary syndrome, the technical panel rated

the majority of clinical scenarios as appropriate for revascularization, with two notable "inappropriate" exceptions. First, in patients with STEMI presenting greater than 12 hours from symptom onset without ongoing symptoms of ischemia or clinical instability, immediate revascularization was deemed inappropriate. Second, after successful treatment of the culprit artery by percutaneous coronary intervention (PCI) or fibrinolysis, revascularization of non-culprit arteries before hospital discharge in patients without clinical instability, no evidence of recurrent or provocable ischemia and with a normal LVEF was rated as inappropriate.

For patients with stable ischemic heart disease without prior coronary artery bypass surgery (CABG), the presence of high risk findings on non-invasive testing, higher severity of symptoms or an increasing burden of CAD tended to elevate the rating to appropriate. Inappropriate ratings tended to cluster among asymptomatic patients and groups receiving no or minimal anti-ischemic treatment or with low-risk findings on non-invasive testing.

For the majority of the clinical scenarios, the technical panel only considered the appropriateness of revascularization irrespective of whether this was accomplished by PCI or CABG. This was done because there are frequently many nuances in clinical care where the judgment of the clinician is necessary to determine which form of revascularization is best for an individual patient. For example, although CABG and PCI might both be considered appropriate in a clinical scenario, PCI might be preferred in a patient with significant comorbidities, making CABG less attractive.

#### Practice Guidelines vs. Appropriate Use Criteria

The ACC/AHA practice guidelines provide a foundation for summarizing evidence-based cardiovascular care and, when evidence is lacking, providing expert consensus opinions. However, in many areas, marked variability remains in the use of cardiovascular procedures, raising questions about over- or under-use.

Appropriate use criteria provide practical tools to measure this variability and to examine utilization patterns. They are designed to examine the use of diagnostic and therapeutic procedures to support efficient use of medical resources, while also providing patients with high quality, appropriate care.

It is important to note that while appropriate use criteria ratings are shaped by practice guidelines, they often contain more detailed scenarios then the more generalized situations covered in clinical practice guidelines and thus subtle differences are possible. Finally, appropriate use criteria are based on current understandings of the technical capabilities and potential patient benefits of the procedures examined. Future evidence development may require these ratings to be updated.

However, in a select subgroup of clinical scenarios, where revascularization was generally considered appropriate and the patient was a reasonable candidate for either procedure, the technical panel rated each method of revascularization (CABG and PCI) independently. This select group of clinical scenarios consisted of patients with advanced CAD (CCS angina greater than or equal to Class III and/or evidence of intermediate – to high – risk findings on non-invasive testing).

CABG was rated as appropriate in all of the clinical scenarios developed. PCI was rated appropriate in patients with two vessel CAD with involvement of the proximal LAD and uncertain in patients with three vessel disease. For patients with left main stenosis and/ or left main stenosis and multivessel coronary artery disease, CABG was deemed to be appropriate and likely to improve the patients' health outcomes or survival. PCI for this patient group

> was deemed inappropriate based on current published data and guidelines.

In patients with prior CABG, there was a similar pattern of appropriateness for revascularization with either PCI or CABG in the presence of high-risk findings on non-invasive testing, higher severity of symptoms, or an increasing burden of disease in either the bypass grafts or native coronaries. The only inappropriate ratings in patients with prior CABG were noted in patients receiving no or minimal anti-ischemic therapy or having low-risk findings on non-invasive testing. More uncertain ratings occurred in this group of patients, reflecting their higher complexity, higher risk and the limited availability of published evidence regarding management outcome.

It is hoped that physicians will use the Appropriateness Criteria for Coronary Revascularization to help guide shared decisionmaking with their patients. It also anticipated that the criteria may help guide future research and lead to patient education regarding expected benefits and risks from revascularization. For the complete document, go to *www.acc.org*.

Dehmer, Patel and Smith are members of the Appropriateness Criteria for Coronary Revascularization Writing Committee.



ehmer



Smith

#### New Name, Same Criteria

Given the growing interest in appropriateness criteria from lawmakers, the media, payers, and others, future criteria will be called "Appropriate Use Criteria" to better reflect the important role the criteria play in identifying the appropriate *use* of medical technology and procedures.



# Surgeon – Cardiologist Collaboration: A Patient-Centered Approach to Emerging Technologies and Appropriateness Criteria

February 27-28, 2009 Heart House Washington, D.C.



Program Directors John G. Byrne, M.D., F.A.C.C. E. Murat Tuzcu, M.D., F.A.C.C. Co-Sponsored by:



**CARDIOVASCULAR RESEARCH** F O U N D A T I O N



# i2.09 Formulates Comprehensive Approach, Closes Gaps

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

he ACC.09 and i2 Summit 2009 meeting represents a unique opportunity for teaching, learning, sharing of ideas and skills, and making and expanding both professional and personal contacts. As the explosion of cardiovascular evidence continues to accrue, it has become increasingly difficult to remain current. ACC's Annual Scientific Session, which provides so comprehensively for all cardiovascular specialties, offers the opportunity to fill in any gaps in our knowledge.

All the stakeholders in the big tent of cardiovascular care gather at ACC's Annual Scientific Session. Attendees include clinical cardiologists, interventional cardiologists, electrophysiologists, surgeons, radiologists, basic and clinical scientists, administrators, clinical pharmacists, nursing professionals and industry colleagues.

For ACC.09 and i2.09, the Annual Scientific Session Program Executive Committee has focused on, formulated and implemented several specific goals. One major new advance is a program built of specific broad topics to showcase the roles of interventional cardiology and cardiovascular surgery, in concert with medical therapy, in treating a broad spectrum of diverse patient groups. This program, which is aimed at clinical cardiologists, will include controversy, debate, state-of-theart lectures and late-breaking clinical trials.

The track in i2.09, which is aimed at interventional cardiologists and radiologists, will include live cases from U.S. facilities and international sites. This year the cases will be grouped by themes such as left main coronary artery disease, multivessel disease, complex interventions, carotid arterial disease and so on. This type of grouping allows more complete discussions and evaluations of technical approaches to take place. There will also be sessions on complication management and specific disease and patient subsets.

As you may know, original science abstracts are taking the center ring in the big tent of ACC.09 and i2.09. Abstracts are meant to be the highlights of meetings such as these. Part of our plan to reinvigorate the role of abstracts, we have interspersed them in sessions dealing with specific topics, such as

treatment of acute myocardial infarction.

The i2 Summit begins Saturday, March 28, and of course, we once again have specialized sessions targeted to meet specific needs. Our nursing colleagues will find the Cardiac Care Spotlights on Saturday. The i2.09 3rd Annual Fellow's Boot Camp 2009 takes place on Tuesday, March 31, and features these choices: Coronary Track I or Endovascular Track in the morning with Coronary Track II or Valvular and Structural Heart Disease in the afternoon.

Unique to this year are the maintenance of certification (MOC) sessions in both the ACC.09 and i2.09 programs. These special sessions are filling up fast, so if you were thinking about attending them, you need to register soon.

Important Dates	
Feb. 18	Advance Registration Ends
Feb. 19	Registration Available at the Onsite Rate
March 28 - 31	i2 Summit 2009
March 29 - 31	ACC.09 Scientific Session and Exposition

The i2.09 program committee has assembled a broadbased group of outstanding domestic and international interventional cardiologists and other heart disease specialists to provide a forum for interventional cardiology experts to discuss new developments and to train, educate and guide their colleagues in intervention and cardiac care.

The collaborative programming approach taken with ACC.09 and i2.09 will make this the most important and comprehensive scientific meeting for all cardiovascular professionals. This venue promises to take the science and art of interventional cardiology to the highest level. I hope to see you in Orlando, March 28 – 31, and remember, a Full Access registration gives you access to both i2.09 and ACC.09.

Holmes is chair of i2 Summit 2009. For more information on i2.09, go to *i2summit09.acc.org* 



# Will the First 100 Days Mean Health Care Reform?

BLK PENN

By Jim Fasules, M.D., F.A.C.C.

he idea of a new president's "first 100 days" extends back to 1932. A country in crisis, Congress granted every request of President Franklin Delano Roosevelt, resulting in the passage of the New Deal. These days, while a new president is not likely to have every request granted, the first 100 days is still considered a honeymoon period where the president has a better chance of passing major initiatives. Some consider it the *only* chance a new president has to pass major initiatives.

What does this mean for President-elect Obama? The jury's still out. Some pundits have called the first 100 days Obama's best chance of passing major health care reform legislation, while others have said this is unlikely to occur if it occurs at all — until late 2009 or 2010. House Ways and Means Health Subcommittee Chair **Pete Stark** (D-Calif.) said in December that Congress has too many other issues to address in the first 100 days to consider a health care overhaul.

To learn more about the College's commitment to health care reform, visit: qualityfirst.acc.org. However, to be successful, Stark said the issue must be addressed before mid-term elections in 2010.

Whether in 2009 or 2010, Obama has made it clear that health care reform is a priority. He has called health care reform a necessary component to any economic stimulus package, echoing

a sentiment presented by economist **Uwe Reinhardt**, **Ph.D.**, at ACC's 2008 Health System Reform Summit. The ACC, hopeful that Obama will take up major health care reform after taking office, answered Obama's call to offer health care reform ideas by holding a Health Care Community Discussion in late December.

#### Working through Congress

Although quick passage of major health care reform is unclear, it is highly likely that Obama will work with Congress on an economic stimulus package, which he has said should include health information technology (IT) provisions. Senate Finance Chair **Max Baucus** (D-Mont.) is in favor of the idea and said he supports authorizing up to \$50 billion in funds for health IT — the amount that Obama proposed in his health care reform plan during the election. This would be a much-needed investment in the health care infrastructure and would make a dent in a formidable barrier to practices adopting health IT.

Congress has much to tackle when it resumes Jan. 6. It still must pass fiscal year 2009 appropriation bills to fund federal activities. This could be a "win" for cardiology if Congress includes appropriate funding for health agencies, such as the National Institutes of Health, the National Heart, Lung and Blood Institute, and the Centers for Disease Control and Prevention.

It is also expected that Congress will reauthorize the State Children's Health Insurance Program (SCHIP), which provides health insurance to children in lower-income households that do not qualify for Medicaid. The ACC supports the reauthorization of SCHIP as part of its commitment to expanding access to health care.

2009 and 2010 will be watershed years for health legislation. We must use this momentum to pass health care initiatives that better enable us to provide high quality, cost-effective care. Let's work together as a profession and make this happen.

Fasules is ACC's new Senior Vice President of Advocacy and a pediatric cardiologist.



### CMS Releases 2009 PQRI Technical Specifications

CMS has released the 2009 technical specifications for the Physician Quality Reporting Initiative (PQRI). As part of these specifications, CMS has included a new measure for cardiology, measure #152: CAD: Lipid Profile in Patients with CAD. In addition, CMS has determined that some of the PQRI measures used during 2008 are not conducive to claims-based reporting and, in 2009, will only be accepted via registry-based reporting. Measure #7, "CAD: Beta-Blocker Therapy for CAD patients with Prior Myocardial Infarction," affects cardiology. Practices should discontinue submitting this measure via their claims process effective Jan. 1, 2009. For a list of 2009 measures and reporting options per measure, go to www.cms.hhs.gov/PQRI/ Downloads/2009PQRIMeasuresList.pdf.



## CBO Releases Two Reports on Health Care

he Congressional Budget Office (CBO) released in December two new reports examining issues within the U.S. health care system. The first report, "Key Issues in Analyzing Major Health Insurance Proposals," examines background information, as well as large-scale reform proposals. The report finds that the rising costs of health care and health insurance will be a significant problem to the country's financial stability. Meanwhile, the number of non-elderly residents without health insurance is likely to increase substantially, from at least 45 million in 2009 to about 54 million in 2019. According to the report, the problems cannot be solved without making major changes in the financing or provision of health insurance and health care.

The second report, "Budget Options, Volume 1: Health Care," discusses the projected effects of 115 discrete options for the financing and delivery of health care. The options range in topic and include the private health insurance market, tax treatment of insurance, quality and efficiency of health care, health behavior and health promotion. The report provides cost or savings estimates on a year-by-year basis for five years and a 10-year total. ACC staff is currently reviewing the reports. The College applauds CBO's efforts to address these critical issues related to health care reform. For more information, visit *qualityfirst.acc.org*.

### **E-Prescribing Program Begins**

The Centers for Medicare and Medicaid Services' e-Prescribing incentive program began on Jan. 1. Under this program, physicians who successfully e-prescribe under the program requirements will receive incentive payments of 2 percent in 2009. The size of the payment will decrease to 1 percent in 2011 – 2012 and 0.5 percent in 2013. Tools and resources to assist practices in adopting e-prescribing are available at www.acc.org/HealthIT.

ACC Informatics Committee Co-Chair **Michael Mirro, M.D., F.A.C.C.**, discusses health information technology (IT) as the January contributor to ACC's online forum, *The Lewin Report*. Mirro writes, "Of the recent activities to accelerate health IT adoption, the CMS e-prescribing initiative will likely have the greatest impact. The current adoption of health IT has been slow" and the "development of e-prescribing incentives by CMS will clearly move the needle for health IT." Mirro's post in full is available at *lewinreport.acc.org*.





58<sup>th</sup> Annual Scientific Session MARCH 29 - 31 • ORLANDO



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eorgia

## Georgia Chapter Holds Highly Successful Meeting

his past November, ACC's Georgia Chapter held its most successful annual meeting in recent history. Both attendance and exhibitor sales exceeded numbers of previous years, with more than 350 attendees — including 140 physicians — and 38 companies purchasing booth space.

Attendees heard updates on the latest developments in general and interventional cardiology, and they took advantage of the gathering to discuss everyday practice issues. The meeting provided a forum for attendees to discuss 2009 Chapter goals and possible responses to the potential changes in the U.S. health care delivery system.

#### **Williams Honored**

At the meeting, the Chapter presented its Lifetime Achievement Award to **Willis Williams, M.D.,** a pediatric cardiologist. The Georgia Lifetime Achievement Award is given to a cardiologist who has demonstrated a lifetime of outstanding achievements in the field of cardiovascular disease and has also served as a role model through service, basic or clinical research and teaching. Williams was the first dedicated pediatric cardiac surgeon in Georgia. Before he retired five years ago, he was a professor of surgery (cardiothoracic) at the Emory School of Medicine and the Emory Clinic, where he had been since 1976. Williams has been an active member of the pediatric cardiovascular community and was nominated for the award by his pediatric cardiology peers.

#### **Rep. Lewis Speaks**

Also at the meeting, **Rep. John Lewis** (D-Ga.) reflected on the recent election and its connection to the Civil Rights movement, in which he was intimately involved. Rep. Lewis is one of 10 leaders who spoke along with Martin Luther King, Jr., on the day of his "I have a dream" speech. During his presentation, Rep. Lewis tied the Civil Rights movement to the election of the first African-American U.S. president, Barack Obama.

Excited with its successes in 2008, the Georgia Chapter is enthusiastic about planning its 2009 meeting. According to planners, next year's meeting will once again provide cuttingedge, highly relevant research and interesting speakers, and planners are already looking at ways to build on this year's record attendance.

#### State-Level Advocacy, Grassroots Outreach to Increase in 2009

After launching its state advocacy and grassroots outreach division last year, the ACC will increase its efforts and presence on the state level in 2009. The College will pursue a multi-faceted policy and legislative agenda that reflects the diverse needs and interests of members and proactively work to expand state-based programs that relate to cardiology. These efforts will include enhanced lobby days and "Cardiologist for a Day" programs, improved online advocacy tools, and increased collaboration with the American Heart Association and other groups. In particular, the College will work closely with chapters with emerging advocacy programs.

In addition, the State Advocacy Workgroup, which was formed by the Board of Governors in 2008, will continue its mission of increasing and improving state advocacy and outreach. The Workgroup has identified six chapters that have the staff and resources to be models for other states. Using ACC National Funding Proposals, these chapters will build relationships with other medical groups and the state legislature to influence policy. The Chapters are Alabama, Arizona, Iowa, Kentucky, Rhode Island and Washington.



# The State of STEMI Care, Taking the Next Step

By Pat Lucken, R.N., M.S., B.C.-N.P., and Venkat Devineni, M.D., F.A.C.C.

handful of states have been early adopters for the regionalization of ST Elevation Myocardial Infarction (STEMI) Receiving Centers, and California is one of them. STEMI Receiving Centers (SRCs) work within geographic regions, partnering with local emergency medical services (EMS), pre-hospital transport agencies and transferring facilities to expedite care of STEMI patients and facilitate PCI times of less than 90 minutes. If the estimated time of arrival is less than 30 minutes, a positive pre-hospital ECG and possibly a manual read or transmitted ECG by the EMS crew will direct a patient to the nearest SRC.

Some 400,000 persons in the U.S. experience a STEMI each year. Of those, 30 percent fail to receive any reperfusion strategy. For every 15 minutes beyond the 90-minute window, there is an increase in mortality. Only half of U.S. hospitals have cardiac catheterization laboratories, and of those with cath labs, only half are equipped to perform PCI.

SRCs operate in much the same way as the "Golden Hour of trauma" concept, which has been established for a number of years, particularly with motor vehicle accidents. Yet, deaths from MI are three times more common than deaths from motor vehicle accidents. The SRC concept is to have a patient sent to a destination (SRC) hospital, which is equipped to handle STEMIs on a 24/7/365 basis. The main hypothesis in favor of establishing SRCs is that the more procedures a facility performs, the better the outcomes.

The main hypothesis in favor of establishing STEMI Receiving Centers is that the more procedures a facility performs, the better the outcomes.

The American College of Cardiology (ACC) and the American Heart Association (AHA) have been leaders in promoting PCI times of less than 90 minutes. The ACC's Door-to-Balloon Alliance (D2B) began in November 2006 and has more than 1,000 national and international hospitals participating. The D2B Alliance for Quality is a Guidelines Applied to Practice project (GAP). Many tools are available at their Web site *www.d2balliance.org* to achieve this goal. The AHA began Mission Lifeline in May 2007, and now the ACC and AHA are working to coordinate the two programs. Mission Lifeline information is available at *www.americanheart.org*. Other strategic partners in these efforts include the National Heart, Lung and Blood Institute and the Institute for Healthcare Improvement.

#### **Stepping Beyond D2B**

**Ivan Rokos, M.D., F.A.C.E.P.**, who has lectured extensively on the D2B topic, proposes raising the D2B bar higher by focusing on E2B. E2B time is ECG time-to-balloon, and it is the first positive pre-hospital ECG, which is time-stamped, that sets the clock in motion. The goal of E2B is to attain a positive pre-hospital ECG to balloon time less than 90 minutes.

Barriers for E2B do exist and include the potential for false positive reads. However, these barriers can be addressed with ongoing educational efforts for pre-hospital personnel in interpretation, access or proper lead placement and not "overtriaging" the use of pre-hospital ECG.

We can go even further than E2B by considering F2B, or first dispatch-to-balloon time. The F2B clock begins in motion when the call originates until the balloon inflation. Finally, there is S2B or the first symptom-onset-to-balloon time, which, of course, measures how well the community understands symptoms and is educated about accessing emergency cardiac care. This time includes first symptom onset to balloon time.

#### **Becoming a Destination Facility**

St. Mary Medical Center in Apple Valley, Calif., recently finished their site visit for becoming a STEMI-destination facility. The site visit included an assessment of the medical records of the last 20 STEMI patients. Of those patients, 75 percent arrived by EMS. We had kept good documentation on why two patients did not have a pre-hospital ECG. The remaining patients all had positive pre-hospital ECGs that confirmed AMI on the computer printout as well as paramedic notation

of ST elevation. All of these also correlated later to the coronary anatomy and culprit lesion. Only one outlier was greater than 90 minutes.

Having perfected St. Mary's D2B program at 92 percent of the time for 2008, we plan to focus on E2B with our EMS partners in 2009. Following that, we will move to F2B, then S2B. SMMC would love to hear about your D2B experiences through *Cardiology*.

Lucken and Devineni are both at SMMC.





Devineni

# CNE Now Available for D2B Participation

he ACC is pleased to announce that continuing nursing education credits (CNE) are now being provided for nurses who participate in the D2B national quality improvement program at their hospitals.

The Door-to-Balloon: An Alliance for Quality (D2B) is a national quality improvement program for

hospitals that perform primary percutaneous coronary intervention (PCI) on non-transfer ST-segment myocardial infarction (STEMI) patients. The D2B campaign provides all primary PCI hospitals with the evidence-based strat-



An Alliance for Quality

egies, supporting tools and educational resources necessary to achieve D2B times of 90 minutes or less. Accomplishing this level of performance is an organizational challenge for many institutions and represents an opportunity to improve the quality of patient care in a meaningful way.

The Performance Improvement (PI) continuing education process involves three separate but integrated stages of learning —

**Stage A:** learning from active involvement in identifying and analyzing important organizational and individual performance gaps

**Stage B:** learning from designing interventions to close performance gaps identified in Stage A and implementing the interventions to patient care using suitable tracking tools

**Stage C:** learning from evaluating the PI effort, reflecting on performance in practice outcomes and comparing to the assessment done in Stage A.

All three stages are used to develop a complete, structured performance improvement activity.

If your organization has been involved in this quality improvement initiative and you have been actively involved in the effort for at least three months, you may qualify for the appropriate education credits. You will need to complete all three stages of ACC's D2B Performance Improvement, then complete and submit the Attestation Form available on Cardiosource in order to qualify for nursing continuing education. You are eligible to claim up to 20 hours of continuing education (CE) credits for your participation in the D2B Performance initiative. Join the ACC's Adult Congenital and Pediatric Cardiology Section for National Congenital Heart Lobby Day

February 10, 2009 7:00 a.m. - 4:00 p.m.

ACC and members of the National Congenital Heart Coalition will join forces to lobby for funding to enhance surveillance programs, education and research in congenital heart disease.

A welcome reception will be hosted by ACC on February 9, 2009 at Heart House, Washington, DC.

Visit www.achaheart.org/lobbyday to register today.

For information about the Adult Congenital and Pediatric Cardiology Section, please visit www.acc.org/acpcsection.

A limited number of travel awards will be available to ACPC Section members. Please contact Stephanie Mitchell at smitchel@acc.org.



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Mended

Little Hearts



# 'Good News, Bad News' Scenario from WIC Survey

he recently-reported results from a 10-year follow-up survey of women in cardiology showed cause for some celebration in that the number of female cardiologists has nearly doubled. Yet, evident challenges remain, particularly as they relate to under-representation and discrimination. Women still account for less than 20 percent of all cardiologists, despite nearly equal numbers of men and women graduating from medical schools. Moreover, two-thirds of women continue to report discrimination, mostly due to competing demands of parenting and family responsibilities — and this has not changed.

"The perception is that cardiology is more demanding and the hours less easy to control than other areas of mediWOMEN IN CARDIOLOGY American College of Cardiology • Member Section

According to the report, women are also less likely to pursue interventional cardiology due, in part, to concerns about radiation exposure. One in four women reported selecting tracks to reduce their radiation risk. Female cardiologists are also more likely to have brief interruptions in their training or practice, but fewer long interruptions. Similar to other demanding professions such as law and business, women cardiologists are much less likely to be married or have children than their male colleagues. These differences have not changed in the past 10 years.

"We need to find ways to reduce discrimination, establish greater flexibility in work hours and expand opportunities for mentorship to better meet the needs of women and men

**66** We need to find ways to reduce discrimination, establish greater flexibility in work hours and expand opportunities for mentorship to better meet the needs of women and men as they plan their careers in cardiology **77** 

cine." says **Athena Poppas, M.D., F.A.C.C.,** associate professor of medicine, Brown University Alpert Medical School, R.I. "But the work is incredibly rewarding and it shows. Cardiologists of both genders love what they do — nine out of 10 say they are moderately to highly satisfied."

As more and more Americans live with chronic heart conditions, the need to ensure a stable and competent cardiology workforce, including the recruitment of women, has become increasingly urgent. With the potential of one-third of Americans having cardiovascular disease, we must attract the best and the brightest — and that includes women — to keep up with demand and provide the highest level of patient care and research to help advance the field, added Poppas.

Poppas serves as chair of ACC'sWomen in Cardiology (WIC) Council, which commissioned the study, a follow-up to an original study conducted in 1996.

"Women in cardiology continue to face the same institutional and personal roadblocks as those in other areas of medicine and science," Poppas says. as they plan their careers in cardiology," said Poppas.

The need for greater flexibility is no longer gender-specific; both male and female doctors are striving for a better worklife balance. In fact, a similar proportion of male and female cardiologists are working less than full-time (80% vs 82%). In addition, both men and women report caring for aging parents in addition to parenting.

This survey is part of the College's larger efforts to address workforce issues and to play a leadership role in helping to attract and retain medical students and residents to the field through training, leadership and professional development. These efforts include a number of initiatives led by the ACC WIC Council, such as the ACCF Women's Career and Leadership Development conference, a mentoring Web site, visiting women professor program and the Bright Futures Program for women medical students and residents. The full survey report survey is published in the December 16/23, 2008, issue of the Journal of the American College of Cardiology, which is available on *www.acc.org* through Cardiosource.

# The ABCs of the Metabolic Syndrome

By Michael J. Blaha, M.D., M.P.H., and Roger Blumenthal, M.D., F.A.C.C.

ncreased caloric intake, increased refined carbohydrate consumption and lack of regular physical activity have led to an explosion in the incidence of abdominal obesity and an emerging epidemic of insulin resistance.

The term "metabolic syndrome" evolved from observations that cardiovascular risk factors cluster in obese, insulin-resistant individuals. Now, the term extends to include the "metabolically obese," normal weight patient. Currently, the metabolic syndrome is best thought of as a multiplex risk factor that comprises five interrelated metabolic risk conditions — atherogenic dyslipidemia, glucose intolerance, hypertension, subclinical inflammation and prothrombotic state. This multiplex risk factor predicts major adverse cardiovascular events independent of traditional risk factors and confers an approximately seven-fold increased risk of diabetes.

Despite the mountain of evidence suggesting an impending public health crisis, the metabolic syndrome remains under-recognized, under-diagnosed and under-treated. Recently, we considered the reasons for this detection and treatment gap and suggested a simplified, practical approach to the metabolic syndrome.<sup>1</sup>

#### **Less Emphasis on Clinical Definition**

The utility of the metabolic syndrome lies in the emphasis on an underlying dysmetabolic phenotype and the attention it calls to co-existing cardiovascular risk factors. Much of the debate surrounding the metabolic syndrome has been driven by imperfections in the clinical definitions and resulting confusion about how to apply the syndrome in clinical practice.<sup>2</sup>

#### **Simplified Approach Needed**

Recognizing the widespread failure to fully address the risk associated with the metabolic syndrome, we adapted our Center's "ABCDE" approach<sup>3</sup> into a simplified treatment algorithm.

#### Assessment:

- Diagnosis of metabolic syndrome is critical (ICD9 277.7).
- Followed by calculation of 10-year risk using traditional scoring tools.

#### Aspirin:

 Most patients with metabolic syndrome and 10-year risk >6% should be treated with 81 mg/d of aspirin.

#### Blood Pressure:

- Target blood pressure should be <130/80 mmHg.
- Beta blockers and thiazides should be avoided as initial agents, as they may worsen insulin resistance.
- ACE-I and ARBs may modestly improve glycemic control and should be the initial drugs selected.

#### **Cholesterol:**

- Statins, which lower innate inflammation as well as LDL-C, are first-line therapy.
- · Patients with metabolic syndrome likely

have residual risk after LDL-lowering due to small, dense lipoprotein phenotype, increased triglyceride rich lipoproteins, decreased HDL-C and elevated non-HDL-C (collectively called "atherogenic dyslipidemia").

 Non-HDL-C should be the second cholesterol target, and target levels should be achieved with intensification of statin therapy and then addition of fenofibrate or extended release niacin.

#### **Diabetes Prevention:**

• Lifestyle modification is always first-line therapy for metabolic syndrome.

Current clinical definitions choose risk factors that are readily measurable, correlate with insulin resistance and can be integrated with guidelines for primary prevention. We find available definitions to be equally useful for identifying the metabolic syndrome phenotype, yet each suffers from exclusion of some features of the disease — such as inflammation — and somewhat arbitrary dichotomization of risk variables.

We believe that undue importance has been placed on the exact definition. The resulting debate has caused physicians to miss opportunities for early identification of the disease process and comprehensive preventive intervention. Therefore, a broad approach should be taken in identifying the metabolic syndrome phenotype, combining current definitions with the identification of related conditions such as subclinical inflammation, family history, fatty liver disease, polycystic ovarian syndrome and sleep-disordered breathing.

#### **More Emphasis on Lifetime** Cardiovascular Risk

The metabolic syndrome should be considered a tool for identifying patients who have an increased lifetime risk of cardiovascular disease. The syndrome is not designed to be a precise risk-scoring instrument. Despite this, the metabolic

syndrome can identify a population of lower-risk patients at greater cardiovascular risk than predicted by traditional risk factors.

Therefore, we believe that the metabolic syndrome is best used as a tool for adjusting the risk calculated by instruments, such as the Framingham

Risk Score. One approach is to broaden the intermediate risk category from the 10 percent to 20 percent 10-year risk to 6 percent to 20 percent when the metabolic syndrome is present, thus allowing earlier, more aggressive treatment.



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- 2. MJ Blaha and TA Elasy. Clinical use of the metabolic syndrome: why the confusion? Clin Diabetes. 2006;24:125-131.
- 3. TJ Gluckman, et al. A practical and evidence-based approach to cardiovascular disease risk reduction. Arch Intern Med 2004;164(14):1490-1500.
- · Metformin has insulin-sensitizing effects and has been shown to delay diabetes in several large clinical trials.

#### **Diet Therapy:**

- Weight Loss
- The Mediterranean Diet rich in omega-3 fatty acids, fruits, vegetables, nuts and fiber — appears to offer specific benefits to insulin-resistant patients with metabolic syndrome.
- · Low-glycemic-load diets appear to improve insulin sensitivity and many metabolic syndrome risk factors.

· Omega-3 fatty acid supplementation, which lowers triglycerides, dampens inflammation and reduces thrombosis, can be considered.

#### **Exercise:**

- Improved fitness and reduced fatness improve all features of the metabolic syndrome.
- There are no clear guidelines for quantity of exercise, as there is a dose-response relationship between vigorous activity and risk factor improvement.
- · Pedometers can motivate; aim for 10,000 steps/d.

#### ACCEL **GISSI-HF: Rosuvastatin** Shows No Effect on **Clinical Outcomes**

iven that coronary artery disease (CAD) is the prevalent etiology of heart failure (HF), researchers are evaluating strategies known to prevent CAD to determine if they have similar preventive effects in patients with symptomatic heart failure. Both the lipid-lowering and pleiotropic effects of statins are effective in CAD prevention and treatment. Numerous studies have suggested that statins could be useful therapy for HF patients and offer clinical benefits such as a reduction in cardiovascular (CV) mortality.

Therefore, the Gruppo Italiano per lo Studio della Sopravvivenza nell'Insufficienza cardiaca (GISSI) investigators randomized HF patients, irrespective of left ventricular systolic function, to rosuvastatin 10 mg (n = 2,285) or placebo (n = 2,289) with a median 3.9-year follow-up. Primary endpoints for GISSI-HF were time to death or CV-related hospitalization.

According to Gianni Tognoni, M.D., who co-chaired the GISSI-HF Steering Committee, when the trial was first proposed, interest was so high that 357 centers participated.

There was little difference in the primary endpoints: there were 657 deaths in the rosuvastatin group and 644 among placebo patients (29% vs. 28%) while 1,305 rosuvastatin patients were hospitalized as opposed to 1,283 placebo patients (57% vs. 56%). Similar results were reported for secondary endpoints as well.

The findings mirror those of the Controlled Rosuvastatin in Multinational Trial in Heart Failure (CORONA) study. Although GISSI-HF and CORONA had different inclusion criteria, both reported no significant benefit in terms of CV-related events despite significant reductions in low-density lipoprotein cholesterol and C-reactive protein with active treatment.

"What has been important to confirm in order to set apart our discussion was safety," said Tognoni, who is of the Consorzio Mario Negri Sud. After close monitoring, rosuvastatin 10 mg was safe and well-tolerated with no statin-related effect on renal or muscle function.

In applying GISSI-HF to clinical practice, Tognoni noted that CAD patients receive statins to hit specific targets, but "heart failure is a different world. There is no reason why statins should be considered for treating heart failure." Even with a primary indication for lipid reduction, he said, the safest course for a patient currently on statins who develops heart failure would be to stop statins and instead apply "the full spectrum of treatment that is available for heart failure patients."



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# Salary Not the Bottom Line with Job Offers

Part 2: Culture and Contracts

alary is important, but it's not the most important thing, says Kenneth T. Hertz, C.M.P.E. The most important thing for any physician starting out is the culture of a practice. If your core values aren't consistent with those of the practice, no matter how good the salary might be, it's not going to work out.

In a two-part interview, Hertz, who is a principal at the Medical Group Management Association (MGMA), discussed



salary trends and shared this advice and more for young cardiologists who are making a choice on their first job.

"Part 1 Salary the Trends" is in the Winter 2009 *Fellows in Training News*. In Part 1, Hertz reviews recent salary data from MGMA and discusses expec-

Hertz tations based on regions and need. Part 1 and Part 2 are both available at *www.acc.org/membership/Fellows.* 

#### **Getting the Most Out of an Interview**

We have all probably heard this advice about job interviews, but it bears repeating. Job interviews are two-way discussions. They want to know you better, but you are there to find out about them also. Once you've got an interview, come prepared to ask questions that will give you answers about their culture.

Use the interview to drill down for details. If a practice says, "Don't worry, we all practice however we want," find out what that really means. Does it mean if you only want to work three days a week, you can do that? Does it mean you have control of your schedule and can decide to see only eight patients a day?

Also, be prepared to talk with everyone. Ask partners, employed physicians and other employees what they like and don't like about the practice, what they expect of the practice and what the practice expects of them.

Find out what's important to the people in the group. Is money all they talk about at board meetings, or do they talk about the group's strategic direction? Are they focused on patients, or are their own schedules and convenience more important? Ask employees whether the practice has fulfilled its promises to them. Were they disappointed or happy with what they found once they came on board?

Be sure to get a sense of how important work/life balance is to the practice, particularly if it is important to you. For doctors from the old school, work/life balance was not an issue — for them, work was life. Make sure you are compatible.

Finally, ask for a copy of the contract before your interview, so you can prepare questions. At the interview, go through the contract with the practice members.

#### How to Approach a Contract

Not everything needs to be written down in a contract, but be wary of vague assurances. If they say, "We're working on this bonus program for you, and we'll have it ready by the time you get here," or "We can't give you the details now, but don't worry; it will be okay," run the other way, says Hertz.

It might even be a good idea to have an attorney who specializes in health care law review the contract. Some parts of the contract may be boilerplate, but your attorney can ensure that the contract complies with state and federal law and is fair to both you and the practice.

You'll need to know what compensation model the practice uses — a guaranteed salary, an incentive model or some hybrid of the two.\* Clarifying expectations is also critical. Does the practice expect you to find your own patients, for example, or will it ensure you have the patients you need as you start out?

Finally, take what your friends say with a grain of salt, adds Hertz. Your friend tells you he's got an offer of \$600,000. Two years later, his compensation, which has shifted to a productivity model, has dropped to only \$275,000, and he doesn't like the people in his practice. Meanwhile, your starting salary of \$350,000 has nearly doubled, and you are happy with your practice colleagues.

<sup>\*</sup> See "Which Compensation Model Works Best for You?" Fellows in Training News, Winter 2009.

# ACC/ACCF Announces Slate of Officers and Trustees

Election of the 2009 – 2010 American College of Cardiology/American College of Cardiology Foundation (ACC/ACCF) Officers and Board of Trustees will occur during the Annual Business Meeting to be held at ACC.09, March 28 – 31, in Orlando.

#### President

#### Alfred A. Bove, M.D., Ph.D., F.A.C.C., of



Philadelphia, Pa., will be installed as president of the ACC/ACCF on March 30, 2009, at the 58th Annual Convocation of the ACC to be held in

Orlando. Bove, who is well known as the former editor in chief of ACC's Cardiosource - which he helped to develop – served as ACC President-Elect this past year and Vice President in 2007. He received his MD and PhD (Physiology) degrees from Temple University Medical School in 1966 and 1970. After a medical internship and residency at Temple Hospital and a post-doctoral fellowship at Temple and the Mayo Clinic, he served two years in the U.S. Navy as an undersea medical officer and then joined the cardiology staff at Temple in 1973. In 1981, he joined the Mayo Clinic Division of Cardiology and returned to Temple as the section chief in cardiology in 1986. In 1998, he accepted the position of Associate Dean for Practice Plan Affairs at Temple and in 1999 resigned as the section chief to assume full-time efforts as an associate dean. In 2001, he became an emeritus professor of medicine and returned as section chief at Temple in 2005. He retired from the U.S. Naval Reserve in 1998, after 33 years of service, including active duty at the Naval Medical Research Institute in 1971 and as a member of a mobile hospital staff in Operation Desert Storm in 1991.

Bove's research includes coronary endothelial function, myocardial function in valvular heart disease and heart failure, exercise physiology, diving and hyperbaric medicine and medical informatics. He has received numerous awards for his work in cardiovascular medicine and environmental medicine. He practices clinical cardiology with particular expertise in heart failure and heart transplantation, undersea medicine and sports medicine and has published extensively on these topics. His current research involves Internet-based medical information systems for management of chronic heart disease.

#### Officer Recommendations

The Board of Trustees recommends that these Fellows become the 2009 – 2010 officers of the College.

#### **President-Elect**

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



Senior Advisor for Cardiovascular Disease for Northern California Kaiser and a clinical professor of medicine at the University of

California, San Francisco. He is a practicing interventional cardiologist with an active practice of consultative cardiology. His major interest in process measures and outcomes assessment in cardiovascular care has led to helping the creation and implementation of various cardiovascular guidelines for Northern California Kaiser. Prior to serving as ACC Vice President this past year, he was on the ACC Board of Trustees. He has also been ACC Governor of Northern California. In addition, Brindis has served as the chief medical officer and chair of the ACC National Cardiovascular Registry (NCDR®) Management Board. He received a national ACC Distinguished Fellow Award in 2007. Brindis graduated MIT in 1970, after which he obtained a Master's Degree in Public Health from UCLA in 1972. He graduated Emory Medical School Summa Cum Laude in 1977 with elected membership in Alpha Omega Alpha. All of his graduate medical training was performed at UCSF as a resident and chief resident in internal medicine and also as a cardiology fellow.

#### **Vice President**

#### David R. Holmes Jr., M.D., F.A.C.C., is



professor of medicine, Mayo Clinic College of Medicine and has Master's Faculty Privileges in Clinical Research at the Mayo Graduate School of

Medicine, Rochester, Minn. He also serves as a consultant in cardiovascular medicine. An invasive and interventional cardiologist, Holmes is chair of upcoming i2 Summit 2009 in Orlando and has played a major role in the development of all i2 Summit meetings. His professional experience and academic appointments have included director of electrophysiology and pacing and director of the cardiac catheterization laboratory, both at the Mayo Clinic. He has been active in many ACC activities, including serving as a member of the ACC Board of Trustees. Holmes has received numerous awards over the years, including the ACC Distinguished Scientist Award (Clinical Domain) in 2004. He has published extensively and serves on the editorial boards of many journals, including the *Journal of the American College of Cardiology*.

#### **Board of Trustees**

The Nominating Committee makes the following unanimous recommendations for Trustees of the College for a five-year term (2009-2014):

#### Gregory J. Dehmer, M.D., F.A.C.C., is professor



of medicine at the Texas A&M University College of Medicine and director of the cardiology division at the Scott & White Clinic in Temple, Texas. Dehmer

has served on the writing committees of several national guidelines, including ACC's interventional training programs standards, the ACC/American Heart Association (AHA) guidelines for coronary angiography and the ACC/AHA/Society for Cardiovascular and Angiography Interventions (SCAI) Expert Consensus Document for Cardiac Catheterization Laboratories. He is a member of the NCDR <sup>®</sup> management board and the editor in chief of the American College of Cardiology-CathKIT<sup>®</sup>, a quality improvement tool for cardiac catheterization laboratories developed jointly by ACC and SCAI.

#### Gerard R. Martin, M.D., F.A.C.C., is executive



director of the Center for Heart, Lung and Kidney Disease and chief of cardiology at Children's National Medical Center, Washington, D.C. He is

also co-director of the Children's National Heart Institute, Washington, D.C., and C. Richard Beyda Professor of Cardiology, George Washington University. Martin has been active in many ACC activities. In particular, he led the development and served as chair of the Adult Congenital and Pediatric Cardiology Section and Council, and he spearheaded the development of the Congenital Cardiology Solutions (CCS.08 and CCS.09) programs. He is also chair of the ACC IMPACT Registry<sup>™</sup> Steering Committee. He serves as ACC representative to Joint Council on Congenital Heart Disease, the American Board of Pediatrics and the American Board of Pediatrics Subspecialty Consortium. Martin served as ACC Governor for the District of Columbia, 2003 – 2006.

#### George P. Rodgers, M.D., F.A.C.C., is currently



president and chief medical officer of the Biophysical Corporation in Austin, Texas, a company dedicated to advancing clinical knowledge

through its research in the field of biomarkers. He practices clinical cardiology with Austin Heart, a premier cardiology group at which he was president from 1999 to 2004. Rodgers recently served as chair of the ACC Board of Governors for 2007 and is a member of the ACC/ACCF Executive Committee and ACC Board of Trustees. He serves on the Board of Governors Steering Committee, the ACC PAC committee, Fellowship Education Redesign Task Force, the International Governance Task Force and chairs the ACC Workforce Task Force.

#### Stuart A. Winston, D.O., F.A.C.C., is a cardiac



electrophysiologist, Michigan Heart and Vascular Institute, St. Joseph Mercy Hospital, Ann Arbor, Mich. He has held numerous positions

there, including chief of cardiology and medical director. He is also a clinical instructor at the University of Michigan Medical School. Winston is co-chair, ACC Board of Governors' State Advocacy Work Group (2008 – 2009), was chair of the ACC Door-to-Balloon (D2B) Alliance Chapter Task Force in 2007 and a member of the steering committee for the D2B campaign. Winston's activities with the ACC Michigan Chapter have included being chair of the EP Advisory Committee and serving on the Guidelines Application in Practice (GAP) Advisory Committee for Southeastern Michigan GAP Expansion Project.

#### **Trustee Vacancies**

The Committee nominates John S. Rumsfeld,



M.D., Ph.D., F.A.C.C., to fill the vacancy created by Richard A. Chazal, M.D., F.A.C.C. who will resign his Trustee seat to assume the Treasurer

position. Rumsfeld's term would be from 2009 – 2012. He would then be eligible for a five-year reappointment. Rumsfeld is staff cardiologist and director, Cardiovascular Outcomes Research Group, Denver VA Medical Center and VA Eastern Colorado Healthcare System, and associate professor of medicine, University of Colorado Health Sciences Center, Denver, Colo. His ACC activities have included – Chief Science Officer, NCDR®, as well as numerous other NCDR activities; D2B Alliance Steering Committee and Evaluation Subcommittee; and member, International Business Development Task Force.

#### The Committee nominates Carole A. Warnes,



M.D., FA.C.C., to fill the vacancy created by James W. Fasules, M.D., F.A.C.C., who is resigning his Trustee seat to become ACC Senior Vice President

of Advocacy. Warnes' term would be from 2009 - 2011. She would then be eligible for a five-year reappointment. Warnes is professor of medicine, Mayo Clinic; consultant for cardiovascular diseases, pediatric cardiology and internal medicine; and director, Adult Congenital Heart Disease Clinic, Rochester, Minn. She was chair of the writing committee for the recently released ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease. She is a member of the ACC Education Oversight Committee and the Lifelong Learning Portfolio Work Group. Warnes has been an active member of the Adult Congenital and Pediatric Cardiology Section and Council.

# Surgeons and Cardiologists: Collaboration for the Patient

ontinued innovations in intervention along with an explosion of new technologies and new developments in cardiac surgery are affecting the cardiovascular specialist's practice model. The choices are many. When are less invasive strategies appropriate? When is surgery still the best option? As a result, we see decision-making and performance of a wide array of cardiovascular interventions in cath labs and operating rooms by care teams comprising clinical cardiologists, interventional cardiologists, cardiac surgeons and mid-level practitioners.

"Although for decades, cardiologists and cardiac surgeons worked side-by-side, sometimes they appeared to be worlds apart. But, it is changing," E. Murat Tuzcu, M.D., F.A.C.C., program co-director of the Surgeon and Cardiologists Collaboration: A Patient-Centered Approach to Emerging Technologies and Appropriate Use Criteria conference (Feb. 27 – 28).

Our program "recognizes that surgeons and interventional cardiologists treat the same patient population but with different tools, and increasingly, a collaborative approach is necessary to achieve optimal patient outcome," adds program co-director **John G. Byrne, M.D., F.A.C.C.** 

Find more information at www.acc.org/education/programs.

## Fasules Takes ACC Advocacy Position

**Im Fasules, M.D., F.A.C.C.**, has joined the ACC staff as the new Senior Vice President of Advocacy. Fasules is a professor of pediatric cardiology at the University of Arkansas for Medical Sciences and director of cardiology clinics at Arkansas Children's Hospital. He has also been a member of the ACC Board of Trustees and a Past Chair of the Board of Governors.

At a time when health system reform tops the national agenda and the ACC agenda, Fasules brings to the College a profound depth of knowledge about health policy and our legislative system. He has been extremely active in advocacy activities, serving on the board of ACC's Political Action Committee and as a leader of

the Advocacy Committee. Fasules held a Robert Wood Johnson Health Policy Fellowship in Washington, D.C., in 1998. During the fellowship, he served as health legislative assistant in the office of **Sen. J.D. Rockefeller IV** (D-W.V.), staffing Sen. Rockefeller on

the Medicare Commission.

In his new position with the ACC, Fasules will provide strategic direction and management oversight for ACC's legislative policy, regulatory affairs, payer advocacy, PAC, grassroots and state government functions. He will lead our efforts to achieve health system reform based on quality and patient value. The balance he brings as a member, practicing cardiologist and experienced advocate creates a powerful combination for ACC.

### In Memoriam: Henry McIntosh, M.D., M.A.C.C.

ACC Past President Henry McIntosh, M.D., M.A.C.C., passed away on Dec. 26 at the age of 89.

McIntosh served in countless

leadership roles at the ACC and the American Heart Association over the years, including the ACC presidency in

1974. He spearheaded prevention initiatives and became an outspoken critic of the cigarette industry. He was deeply involved in the ACC Florida Chapter — the first of the ACC Chapters.



Dr. McIntosh served his country

and his patients with exceptional valor. He was a captain in the U.S. Parachute Infantry Office of Strategic Services during World War II and parachuted behind enemy lines in France. He was the recipient of the Silver Star, Croix de Guerre and two Bronze Stars. Later, Dr. McIntosh received a Presidential Citation from President Reagan for his work to develop Heartbeat International, a philanthropy that provides lifesaving pacemakers to needy patients around the world. The ACC is honoring Dr. McIntosh with a memorial contribution to one of his most enduring achievements, Heartbeat International.

### ACC introduces Cardiosource Journal Scan

ACC members will soon find the new **Cardiosource Journal Scan** — formerly Cardiosource Review Journal — showing up in their inboxes every week. The new e-journal will feature leading headlines from the most recent, clinically relevant medical journal articles. Headlines will be categorized by specialty and links to the full articles will be included under the headlines.





### **Cardiology Opportunities**

Covenant Medical Group is seeking board certified/board eligible cardiologists to join our group. The ideal candidates should have experience and a Texas license. Both positions offer strong practice growth, financial opportunity and draw from a population base of 1.2 million.

Covenant Medical Group (CMG) is seeking Interventional cardiologist with excellent clinical skills to join outstanding BC cardiologists and share call once a week with 6 cardiologists. This very active practice is affiliated with Covenant Health System Heart Center. The Heart Center is a state of the art facility and houses 85 beds and 8 catheterization labs for cardiac care.

Position is located in Lubbock, Texas where our physicians enjoy all the benefits of metropolitan living: entertainment and recreation, an international airport and a major Big 12 University (Texas Tech University), but with the friendliness and convenience of a smaller city. Covenant Medical Group is affiliated with Covenant Health System in Lubbock, Texas. CMG is a multi-specialty group with more than 200 physicians across West Texas and Eastern New Mexico. We offer a competitive salary and excellent benefit package that includes medical/dental insurance, life insurance, vacation/holidays, retirement plans, reimbursement for CME and other benefits.

CV should include salary requirements and can be forwarded to Covenant Medical Group, Attn: Kelly Reeves, 3420 22<sup>nd</sup> Place, Lubbock, Texas, 79410 or faxed to 806-723.7476. For telephone inquiries call 806-725-7875.



#### **This Month in**

#### December 30, 2008 / January 6, 2009

- A Big Promise from the Very Small: Identification of Circulating ES-like Pluripotent Cells in Patients with Acute Myocardial Infarction
- Declining In-Hospital Mortality and Rising Heart Failure Incidence in Elderly Patients With First Myocardial Infarction
- Rising Post-MI Heart Failure Incidence in the Elderly Patients. A Call for Actions

#### January 13

- Utilization and Impact of Pre-hospital Electrocardiograms for Patients with Acute ST-Segment Elevation Myocardial Infarction: Data from the NCDR ACTION Registry
- Leptin and Coronary Heart Disease: Prospective Study and Systematic Review
- Depression and Cardiovascular Healthcare Costs among Women with Suspected Myocardial Ischemia: Prospective Results from the Women's Ischemia Syndrome Evaluation (WISE)

#### **January 20**

- Contraceptive Hormone Use and Cardiovascular Disease
- Routine Intra-operative Completion Angiography after CABG and "One-Stop" Hybrid Revascularization: Results from a Fully Integrated Hybrid Cath Lab/OR
- Surgeons and Interventional Cardiologists in a Collaborative Environment

#### January 27

- Meta-analysis of the Relationship Between Non-High Density Lipoprotein Cholesterol Reduction and Coronary Heart Disease Risk
- Meta-analysis of the Relationship Between Non-High Density Lipoprotein Cholesterol Reduction and Coronary Heart Disease Risk
- Utility of the Seattle Heart Failure Model in Patients with Advanced Heart Failure

- The Interventional Cardiologist and Structural Heart Disease: The Need for a Team Approach
- TTE Heart Failure Index: Development of an Echocardiographic Risk-Stratification Index to Predict Heart Failure in Patients with Stable Coronary Artery Disease: The Heart and Soul Study

# ventions

- Incomplete Revascularization in the Era of Drug-Eluting Stents: Impact on Adverse Outcomes
- In-Hospital and 1-Year Outcomes among PCI Patients with Chronic Kidney Disease in the Era of Drug-Eluting Stents: A Report from the EVENT Registry

## **Educational Programs Calendar**

January 12 – 16, 2009 40th Cardiovascular Conference at Snowmass John H.K. Vogel, M.D., M.A.C.C., F.S.C.A.I.	Snowmass, Co
January 30 – 31, 2009 2009 Heart of Women's Heath Suzanne Hughes, M.S.N., R.N. Rita F. Redberg, M.D., M.Sc., F.A.C.C.	Atlant CME CE
January 30 - February 1, 2009 <b>28th Annual Perspectives on New Diagnostic and Therapeutic</b> <b>Techniques in Clinical Cardiology (ACCF Co-Sponsored)</b> C. Richard Conti, M.D., M.A.C.C. Jamie B. Conti, M.D., F.A.C.C.	Lake Buena Vista, Fla CME CE
February 13 - 15, 2009 <b>The Clinical Practice of Peripheral Arterial Disease:</b> <b>Key Components for Cardiovascular Specialists</b> Michael R. Jaff, D.O., F.A.C.C. Christopher J. White, M.D., F.A.C.C.	Washington, D.C CME CE
February 16 – 20, 2009Kohala Coa <b>24th Cardiovascular Conference in Hawaii</b> John H.K. Vogel, M.D., M.A.C.C., F.S.C.A.I.	ast, Big Island, Hawa CME
February 16 - 20, 2009 <b>31st Annual Cardiology at Big Sky</b> Kim A. Eagle, M.D., F.A.C.C. Sidney Goldstein, M.D., F.A.C.C.	Big Sky, Montan.
February 27 - 29, 2009 Surgeon-Cardiologist Collaboration: A Patient Centered Approach to Emerging Technologies and Appropriateness Criteria John G. Byrne, M.D., F.A.C.C. E. Murat Tuzcu, M.D., F.A.C.C.	Washington, D. (
March 28, 2009 Cardiovascular Care 2009: Armed Forces, Public Health Service and Veterans Affairs Combined Cardiology Symposium Jeffrey J. Cavendish, M.D., F.A.C.C.	Orland CME
March 28, 2009 Clinical Pharmacology in the Management of Cardiovascular Disease Janet B. Long, M.S.N., A.C.N.P., F.A.H.A.	Orland Pharm cme ce
April 16 - 18, 2009 The 36th Interpretation and Treatment of Cardiac Arrhythmias: Arrhythmia Management for the Clinician (ACCF Co-Sponsored) Peter R. Kowey, M.D., F.A.C.C.	Philadelphi.
May 7 - 9, 2009 <b>31st Annual Recent Advances in Clinical Nuclear Cardiology</b> <b>and Cardiac CT Featuring Case Review with the Experts</b> Daniel S. Berman, M.D., F.A.C.C. Guido Germano, Ph.D., M.B.A., F.A.C.C. Jamshid Maddahi, M.D., F.A.C.C.	Washington, D.C CME CE
May 29 - 30, 2009 Emergency CV Care 2009 Christopher B. Granger, M.D., F.A.C.C. James G. Jollis, M.D., F.A.C.C. Mayme Lou Roettig, R.N., M.S.N.	Chicag CME CE
May 29 - 31, 2009 7th Annual Cardiovascular Magnetic Resonance Imaging: State-of-the-Art Updates and Comparisons with Computed Tomography W. Gregory Hundley, M.D., F.A.C.C.	Washington, D.C.

For a complete listing of upcoming events and to register online, go to www.acc.org/education/programs/programs.htm



#### The XIENCE<sup>™</sup> V Everolimus Eluting Coronary Stent on the MULTI-LINK MINI-VISION<sup>®</sup> or MULTI-LINK

LY VISION<sup>®</sup> Delivery System

#### INDICATIONS

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

#### CONTRAINDICATIONS

The XIENCE V stent is contraindicated for use in patients:

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

#### WARNINGS

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

#### PRECAUTIONS

- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent is presently unknown.
- Risks and benefits should be considered in patients with severe contrast agent allergies.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Use fluoroscopy to avoid arterial damage.
- Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death.
- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the XIENCE V SPIRIT family of trials.
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.
- A patient's exposure to drug and polymer is proportional to the number of and total length of implanted stents. See *Instructions for Use* for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE V stent have not been established for subject populations with the following clinical settings:
- Patients with prior target lesion or in-stent restenosis related brachytherapy, patients in whom mechanical atherectomy devices or laser angioplasty devices are used simultaneously, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.5 mm or > 4.25 mm or lesion lengths > 28 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, chronic total occlusions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent acute myocardial infarction (AMII) or evidence of thrombus in target vessel, moderate or severe lesion calcification, multivessel disease, in-stent restenosis, and patients with longer than 24 months follow-up</li>

- Everolimus has been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA).
  Formal drug interaction studies have not been performed with the XIENCE V stent because of limited systemic exposure to everolimus eluted from XIENCE V.
- Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant patients was associated with increased serum cholesterol and triglycerides that in some cases required treatment.
- Non-clinical testing has demonstrated that the XIENCE V stent, in single and in overlapped configurations up to 68 mm in length, is MR Conditional. It can be scanned safely under the conditions in the *Instructions for Use.*
- The XIENCE V stent should be handled, placed, implanted, and removed according to the *Instructions for Use.*

#### POTENTIAL ADVERSE EVENTS

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

Abrupt closure, Access site pain, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobatt, chromium, nickel, tungsten, acrylic and fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriours, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery pasm, Coronary or stent thrombosis, Death, Dissection of the coronary artery by ass graft surgery, Fever, Hypotension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, kschemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia (due to vascular injury), Pseudoaneurysm, Renal Failure, Restenosis of the stented segment of the artery, Shock/pulmonary artery, Unstable or stable angina pectoris, Vascular complications including at the entry site which may require vessel repair, Vessel dissection

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

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

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





XIENCE V<sup>™</sup> is a trademark of Abbott Laboratories. TAXUS<sup>®</sup> is a registered trademark of Boston Scientific.

All illustrations are artist's renditions.

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# The leading edge of deliverability. Discover the XIENCE behind it.

Finally, a DES to help you navigate your most challenging cases. XIENCE V™ is built on the market-leading MULTI-LINK VISION® cobalt chromium

stent with the thinnest struts<sup>1</sup> for smooth and effortless deliverability.

<sup>1</sup>Manufacturer-reported strut thickness. Data on file at Abbott Vascular.

All illustrations are artist's renditions. Please see Brief Summary of IFU on the following page. For more information, visit our web site at www.XienceV.com.

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