Heart Rhythm 2007

Heart Rhythm Daily

Saturday • May 12, 2007 • Denver, CO

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INSIDE THIS ISSUE

DAY AT A GLANCE

Saturday

Ongoing
Registration, Exhibition, Debates, Scientific Sessions, Posters

8:00 a.m.–9:30 a.m.
Special Session: Case-based Tutorials, Core Curricula, Featured Symposia

8:00 a.m.–9:30 a.m.
Special Session: Highlights of Heart Rhythm 2007

8:00 a.m.–9:30 a.m.
Special Session: Douglas P. Zipes Lectureship—Silvia Priori, MD, PhD

10:30 a.m.–11:30 a.m.
Special Session: AFib Summit Highlights

1:00 p.m.–5:15 p.m./
1:00 p.m.–7:30 p.m.
Special Session: ABIM Board Recertification Prep Courses

Please note: All events will take place in the convention center, unless otherwise noted.

SAVE PACe: Dual Chamber Minimal Ventricular Pacing Effective

Use of dual chamber minimal ventricular pacing resulted in a 40% reduction in the relative risk of developing persistent atrial fibrillation in the SAVE PACe trial, presented by Michael O. Sweeney, MD, from Brigham and Women's Hospital in Boston.

The trial, which compared dual chamber minimal ventricular pacing with conventional dual chamber pacing (DDDR), was stopped early by the Data Monitoring Committee when the trial met its primary endpoint: time to development of persistent AF.

It is the first prospective study to demonstrate that prevention of ventricular desynchronization using new dual chamber minimal ventricular pacing algorithms can reduce the risk of developing persistent AF compared with DDDR.

SAVE PACe enrolled 1,065 patients (51% women) with sinus node dysfunction, intact AV conduction, and normal QRS duration; patients were randomized to DDDR or to the new dual chamber pacing that uses new algorithms (Search AV and MVP) designed to prioritize intrinsic AV conduction, preserve ventricular conduction, and prevent ventricular desynchronization.

Michael O. Sweeney, MD, presented results of SAVE PACe, a late-breaking trial, on Friday.

Sweeney reported that 68 patients in the DDDR group developed persistent AF vs. 42 patients in the dual chamber minimal ventricular pacing group. Patients in the new dual chamber pacing group also had a lower risk of invasive ablative procedures and hospitalizations for heart failure, and less ventricular pacing.

Multidisciplinary Study of ARVD

Task force criteria for identification of arrhythmogenic right ventricular dysplasia (ARVD) may need revision, given the results of a late-breaking study presented here yesterday.

Frank I. Marcus, MD, of the

(LATE-BREAKERS, *see page 3)*

Society Recognizes Distinguished Contributors

The Heart Rhythm Society's Distinguished Awards recognize those who have made important contributions through science, education, service and pioneering in cardiac pacing and electrophysiology.

This year's winners: Distinguished Scientist Award, D. George Wyse, MD, PhD, FHRS; Distinguished Teacher Award, Paul A. Levine, MD, FHRS; Distinguished Service Award, Michael E. Cain, MD, FHRS; and Pioneer in Cardiac Pacing and Electrophysiology, David G. Benditt, MD, FHRS.

D. George Wyse, MD, PhD, FHRS

The Distinguished Scientist Award recognizes "an individual who has made major contributions to the advancement of scientific knowledge" in the field of cardiac pacing and electrophysiology.

Dr. Wyse is Emeritus Professor at University of Calgary, Alberta, Canada. Wyse played an integral role in the Cardiac Arrhythmia Suppression Trial (CAST), the Antiarrhythmics Versus Implantable Defibrillators (AVID) Trial and the Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) trial.

Wyse has acted as a consultant to several public research funding agencies and has produced over 300 articles in his active research career. He was also the founding coordinator of the Medical Research Council of Canada's Program Grant in Cardiac Electrophysiology at the University of Calgary.

"Dr. Wyse's common sense and understanding of the big picture have made his scientific contributions applicable to countless patients," said Stephen C. Hammill, MD, Chair of the Awards Subcommittee.

Paul A. Levine, MD, FHRS

The Distinguished Teacher Award honors an individual who has "demonstrated outstanding skills as a teacher" in electrophysiology and pacing.

Levine has had an eminent career at Boston University, where he was director of the pacing program and electrocardiogram lab until 1989, when he became Vice President for Medical Services of at St. Jude Medical's Cardiac Rhythm Management Division (originally Siemens Pacesetter).

Levine maintains appointments

(Distinguished, *see page 4)*

Visit us at Booth #245

Theodore Chow, M.D., FACC
Electrophysiologist, The Ohio Heart & Vascular Center; Director, Electrophysiolgy Research for Carl & Edyth Linder Clinical Trials Center

Medicare has issued a National Coverage Decision covering Spectral Analytic Method™ Microvolt T-Wave Alternans™ (MTWA) testing broadly for the evaluation of patients at risk for sudden cardiac death. "I recommend MTWA testing of primary prevention ICD candidates (LVEF ≤ 35%) when:

- **The patient is reluctant to undergo ICD implantation without additional proof of risk;**
- **The patient has a borderline LVEF for ICD qualification; or**
- **The time horizon for ICD benefit is reduced, for example by significant co-morbidities or advanced age.**

Since the great majority of sudden cardiac deaths occur in patients with LVEF above 35%, MTWA testing is also appropriate in my opinion for evaluating these patients when a clinical suspicion for risk is present, for example, syncope or non-sustained ventricular arrhythmias, particularly in those with LV dysfunction and prior myocardial infraction."

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Gavel Passes to New Leadership at 2007 President's Reception

Incoming President Bruce D. Lindsay, MD, FHRS, officially took office Friday at the Annual Heart Rhythm Society President's Reception, along with the other members of the Society's new leadership.

"I will work to fulfill the mission of the Heart Rhythm Society by working closely with our capable staff," Lindsay said. "If each incoming President sets a new agenda for the organization, the organization tends to zigzag. The role of the President is to provide guidance to the committees and the Board of Trustees as we try to achieve the organization's goals."

Bruce D. Lindsay, MD, FHRS

Lindsay said he plans to focus on budgetary concerns, reimbursement issues, health policy initiatives, and educational programs. He said it is important for the Society to take action regarding the revision of The Centers for Medicare & Medicaid Services codes.

"There are other technologies coming down the line that could be affected by this," he said. "We need appropriate guidelines for coding and reimbursement."

Lindsay said he will also strive to ensure that Society members are getting as much as possible from the dues they pay to the organization.

Lindsay is the Director of the Clinical Electrophysiology Laboratory and a Clinical Professor of Medicine at the Washington University School of Medicine in St. Louis. He is also Director of the Electrophysiology Unit at Barnes-Jewish Hospital.

President Dwight W. Reynolds, MD, FHRS, passed the gavel to Incoming President Bruce D. Lindsay, MD, FHRS, at a ceremony Friday night.

Other officers

Also assuming their new posts as 2007 HRS officers:

N.A. Mark Estes, III, MD, FHRS is President-Elect. He is a Professor of Medicine at Tufts University School of Medicine and Director of the Cardiac Arrhythmia Center at New England Medical Center in Boston.

The position of 1st Vice President will be held by Richard L. Page, MD, FHRS. Page holds the Robert A. Bruce Endowed Chair in Cardiovascular Research and is head of the Division of Cardiology at the University of Washington Medical Center in Seattle.

Douglas L. Packer, MD, FHRS, vacated his position as Treasurer for the Society to assume the responsibilities of 2nd Vice President. Packer is a Professor of Medicine at The Mayo Clinic College of Medicine in Rochester, MN, with a primary specialty in cardiovascular disease.

Susan L. Song, RN, BSN, FHRS will serve as Secretary through May 2009. She is Device Coordinator at Keck School of Medicine, University of Southern California in Los Angeles. She has been a member of the Society since 1980 and has served on many committees. Previously a Trustee for the Society, John P. DiMarco, MD, PhD, FHRS, will serve as Treasurer. He is Professor of Internal Medicine and Director of Electrophysiology Service at the Division of Cardiovascular Medicine at the University of Virginia Health System.

New members of the Board of Trustees include John D. Day, MD; Leonard I. Ganz, MD; and Cynthia M. Tracy, MD. In addition, Gordon F. Tomaselli, MD, FHRS, was reappointed for a second term of two years.

For more on Dr. Lindsay's objectives, please see page 6.

(**LATE-BREAKERS,** continued from page 1)

University of Arizona, said the goal of his study is to establish a North American registry of newly diagnosed patients based on standardized diagnostic test criteria. A second goal is to determine the genetic background of ARVD, a disease involving the right ventricular myocardium.

The study has analyzed and classified 108 probands, or index patients. Data and diagnostic test results - including 12-lead ECG, signal averaged ECG, and 24 hour Holter monitor - were sent from 17 enrolling centers in the United States and Canada. Imaging studies included a 2D echo, cardiac MRI, and right ventricular angiogram. All tests were subsequently interpreted blindly by experts in core labs.

The high rate of difference in classification by the core laboratories of the right ventricular images by echo, MRI, and angiography was an unexpected finding, Marcus said, and was the impetus for his recommendation to revise the task force criteria. "Genetic identification reveals limitations of the task force criteria," Marcus added. The task force is scheduled to meet at the conclusion of Heart Rhythm 2007.

CONVERT study

Episodic amiodarone therapy pericardioversion was no more effective than continuous amiodarone therapy for rhythm control in the CONVERT study. Isabelle C. Van Gelder, MD, of the University Hospital Maastricht in the Netherlands, said both strategies were effective but more adverse events occurred in the episodic therapy group.

The trial enrolled 206 patients with recurrent AF who were given a 600-mg loading dose of amiodarone daily for four weeks, followed by 200 mg daily. The patients randomized to the episodic group discontinued amiodarone treatment one month postcardioversion and then restarted the therapy pericardioversion if AF recurred.

Patients randomized to the continuous group continued the amiodarone therapy.

At the median follow-up of 1.8 years, there was no significant difference between the two groups in sinus rhythm control; the number of amiodarone-related events was comparable. There were more recurrences of AF and CV in the episodic treatment group and more disease-related events, including hospitalization for heart failure. Quality of life was similar.

J-Rhythm study

If quality of life is a top consideration, a pharmacologic rhythm control strategy for treatment of paroxysmal AF may be more effective than a rate control strategy, said Satoshi Ogawa, MD, PhD, of the Cardiovascular Institute in Tokyo, in a presentation Friday.

The randomized multicenter comparative study evaluated 823 patients with paroxysmal AF. Patients were randomized to either a pharmacological rate or a rhythm control strategy. Both groups continued antithrombotic therapy. Follow-up was a mean of 586 days.

Ogawa said that sinus rhythm was maintained more frequently in the rhythm control group and resulted in a significantly better event-free survival than the rate control strategy. There was, additionally, a significant difference in quality of life scores for those treated with the rhythm control strategy.

ICE-CHIP trial

Sanjeev Saksena, MD, reported results of ICE-CHIP, the first prospective open label, multicenter trial to compare intracardiac echocardiography to transesophageal echo (TEE) in visualization of septal and left atrial pathology that may predispose patients to stroke.

The Euro-American trial included 95 patients with AF; all patients imaged by both modalities for a blinded comparison. All patients underwent an invasive catheterization procedure, including right heart catheterization, and all had undergone a TEE within the previous 48 hours.

Saksena reported a number of differences between the two modalities. One finding was that ICE more readily identified left atrial thrombi, whereas TEE was more effective for left atrial appendage.

(**Distinguished,** continued from page 1)

at Loma Linda University, where he is a Clinical Professor of Medicine, and at the University of California Los Angeles, where he is a Clinical Associate Professor of Medicine. He is actively involved in the teaching programs at both institutions.

Levine is internationally recognized as a leading expert in pacemakers and ICDs and is a featured speaker at many international forums and symposia. He has written a number of books on cardiac pacing as well as many peer-reviewed journal articles and book chapters.

"Dr. Levine is truly known as a teacher's teacher," Hammill said.

Michael E. Cain, MD, FHRS

The Distinguished Service Award recognizes an individual who "has made outstanding contributions to the Heart Rhythm Society."

Cain recently moved to Buffalo to become the Dean of the School of Medicine and Biomedical Sciences at University of Buffalo. Previously, he was the Lewin Professor of Medicine and Director of the Cardiovascular Division at Washington University in St. Louis. He has been a member of the Heart Rhythm Society since 1985. In 1998, he was elected to the Board of Trustees and subsequently served as Secretary, Chair of the 2002 Annual Scientific Sessions and President from 2003 to 2004. He also served as Chair of the Positioning Task Force, which led to the Society's new name and logo.

"The Heart Rhythm Society's Distinguished Awards recognize those who have made important contributions through science, education, service, and pioneering in cardiac pacing and electrophysiology."
—Stephen C. Hammill, MD,

After his presidency, Cain continued to serve HRS in many capacities. He was Chair of the Governance Committee, Presidents Council, International Advisory Council, and the 2005 Strategic Planning Conference. For the past two years he has served as the North American Co-chair of the International Coalition of Organizations of Pacing and Electrophysiology and is the current Chair of the Publications Committee.

"Michael Cain has worked tirelessly to improve our Society and ease the transition from the North American Society of Pacing and Electrophysiology to the Heart Rhythm Society," Hammill said.

David G. Benditt, MD, FHRS

The Pioneer in Cardiac Pacing and Electrophysiology Award honors an individual who "has made significant contributions to this field."

Early in his career, Benditt studied sinus node dysfunction, which led to the publication of a seminal article on the significance of secondary pauses after rapid atrial pacing. He went on to establish an internationally renowned program in cardiac electrophysiology at the University of Minnesota, where he is currently a Professor of Medicine and Co-director of the Arrhythmia Center.

Although Benditt has 200 publications to his credit, he is perhaps best known for his contributions to the understanding of syncope. In addition to pioneering the widespread introduction of the tilt table test to clinical practice, he has been a leader in understanding the indications and limitations of medication to treat vaso-vagal syncope. In addition, he was involved in the early introduction and development of rate responsive pacing, physiological pacing and transvenous defibrillation.

"Dr. Benditt's pioneering work in syncope highlights a career devoted to improving patient care," Hammill said.

Society Awards Full-Year Research Fellowships

The Heart Rhythm Society honored its Full-Year Research Fellowship Award winners during a breakfast reception yesterday.

The Society has awarded full-year research fellowships in cardiac electrophysiology since 1982. The fellowships are awarded "for the purpose of encouraging research training, either in basic or clinical electrophysiology."

The full-year fellowships are given to researchers early in their careers who seek to gain specialty education and experience. The fellowships are available to individuals who have earned a doctoral degree in medicine, philosophy, osteopathy, or science, or have received equivalent training in biomedical engineering.

Fellowship recipients are expected to use the full-year fellowships to advance their long-term goals in the field of cardiac pacing and electrophysiology.

Abstract presentations

The 2006-2007 HRS Research Fellowship recipients presented their scientific abstracts, covering a variety of areas. Presentations included: Morten B. Thomsen, PhD, "Altered Ion-Current Response to Catecholaminergic Stimulation in Myocytes After Induction of Cardiac Memory;" Kizana Eddy, MBBS, PhD, "Novel Biological Therapies Targeting Cardiac Arrhythmias;" Murali Chiravri, MD, PhD, "The Role of Islet-1 Precursors in the Development and Regeneration of the Cardiac Conduction System;" and Robert D. Winslow, MD, "Atrial Structure and Function Before and After Catheter Ablation for Atrial Fibrillation: A Magnetic Resonance Imaging Study."

Fellowships for 2007-2008

There were seven 2007-2008 fellowships also awarded at the reception. The awardees are: Masatoshi Yamazaki, MD; Michael J. Cutler; Vincent Y. See; Kamilla Kelemen, MD; Mihail G. Chelu, MD; Morton B. Thomsen, PhD; and Jorge E. Massare, MD.

These fellowships are made possible by the continuing support of Boston Scientifc Corporation, St. Jude Medical, Medtronic, Inc., and Biotronik, Inc.

The process for selecting the HRS 2008-2009 Fellowships will begin in August 2007. "Every year the Heart Rhythm Society Fellowships are an opportunity to promote research for promising individuals early in their careers," said Kristen Downey, Heart Rhythm Society Education Coordinator. "We encourage all eligible candidates to apply for this opportunity."

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Incoming President Discusses Society Goals for Coming Year

Incoming President Bruce D. Lindsay, MD, FHRS, eyes the coming year with optimism tempered by the realities of a challenging Society agenda as the Heart Rhythm Society moves into its 29th year.

Lindsay said he plans to focus on generating public awareness of sudden cardiac arrest, adoption of the guidelines on catheter ablation of atrial fibrillation, working with The Centers for Medicare & Medicaid Services (CMS) on coding issues and new technologies, and bringing added value and a robust education platform to a growing Society membership.

"My commitment is to fulfill the mission of the organization and move the Strategic Plan forward," Lindsay said. "It is not the President's job to set the agenda. It is the President's job to carry out the strategic mission of the organization." The Heart Rhythm Society accomplishes this objective primarily through its focus on educational programs, health policy/advocacy, the development of guidelines, and membership value.

Education

Lindsay wants to ensure that the Society's educational programs are continually focusing on cutting edge information and providing members with the latest and best in the field.

"We need to take a hard look at our educational programs — at our annual meeting and other programs we offer — to make sure they are top quality," Lindsay said. "We are a technology-driven industry and meetings are therefore more dependent on technology and more expensive to hold. We need to assess whether we are allocating enough resources for our programs to be the top in the field."


Bruce D. Lindsay, MD, FHRS

The Society also plans to evaluate educational programs that may not be as effective or compelling as they once were. "In any meeting, some topics generate a lot of excitement, and some have lost their luster," he said. "It's time to consider whether we need to replace these programs with something else."

Health policy/advocacy

Lindsay believes the membership may not be aware of all the Society projects that serve the interests of both physicians and patients.

"CMS decided to revise a number of codes regarding ambulatory monitoring; this includes Holter monitors and event monitors," he said. "There are also codes related to Internet-based follow-up of ICDs and pacemakers, and there are some new technologies in development that could affect coding."

Lindsay said the Heart Rhythm Society decided to take the initiative to work with these particular codes. "CMS said it was going to make some changes, and we could either lead the way or they would do it themselves," he said. "We decided that as an organization, it is the Society's responsibility to take on these challenges."

Another important focus on health policy is the Sudden Cardiac Arrest initiative. The purpose of this initiative is to increase public awareness about risk factors for sudden cardiac death, treatments that reduce this risk, and the need for increased funding to improve the understanding of the cascade of pathophsiolgic events that result in cardiac arrest.

"High-risk" patients account for the minority of sudden cardiac death, and accurate identification of the high-risk patient is difficult. The Heart Rhythm Society supports improved identification of high-risk patients who would benefit from treatment and basic research that explains why "low-risk" patients account for the majority of sudden cardiac arrest victims.

Lindsay also looks forward to the Heart Rhythm Society Consensus Statement on the Surgical and Catheter Ablation of Atrial Fibrillation. This document is the result of the collaboration of many preeminent clinicians, led by Hugh Calkins, MD. The consensus statement addresses all aspects of surgical and catheter ablation, including guidelines for patient selection, methods, avoidance of complications, follow-up care, and trial design.

"This is a comprehensive document," Lindsay said. "It was an international collaborative effort with representation from the American Heart Association, the American College of Cardiology, and European societies."

Membership value

Lindsay, sensitive to the dues-paying membership, said that a fiscally responsible budget has always been a priority for the Heart Rhythm Society.

"We need to continuously reexamine our budget and our process to ensure a responsible budget that gives members the most value for the dues they pay," he said. "We need to look at the services the Society provides to make sure they are cost-effective and that we are reaching members in the areas they need." This includes clinicians who are physicians, allied professionals, and basic scientists, he added.

Lindsay said he looks forward to working with members and society leaders to meet the challenges of the year ahead.

"I have come to appreciate that physicians such as myself are volunteers, and while we put a lot of time and effort into supporting the goals of the Society, we can never do that completely on our own," he said. "We have a highly capable senior staff, and we are lucky to have such a great team in the Society to help us achieve those goals."

Advanced Ablation Course Offers Intensive Training

Education offered by the Heart Rhythm Society does not end at the conclusion of Heart Rhythm 2007 Scientific Sessions. In October, participants can attend the Advanced Ablation Course, which offers additional training in the evolving areas of catheter ablation for complex supraventricular and ventricular arrhythmias.

The course will take place October 14 through October 17 at the Westin Hotel in Chicago. William G. Stevenson, MD; Douglas L. Packer, MD; and David J. Wilber, MD, act as course Co-directors. The course will focus on multimodality ablation for atrial fibrillation and will include comprehensive information about new techniques and technologies.

This intensive four-day course is an opportunity to see first-hand new approaches, techniques, and cutting edge technologies in catheter ablation, including ablation for atrial fibrillation.

The latest methods and techniques for diagnosis and ablation coupled with anatomic insights will be taught using:

- didactic sessions
- case-based workshops
- automated audience response system that provides immediate feedback
- hands-on sessions

For more information on the ablation course, contact the Heart Rhythm Society at (202) 464-3400 or e-mail at info@hrsonline.org.

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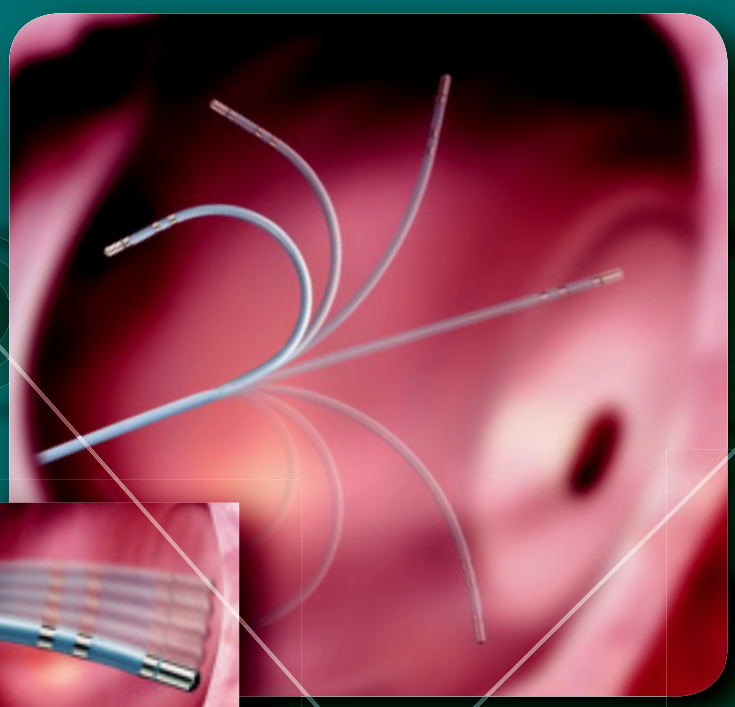

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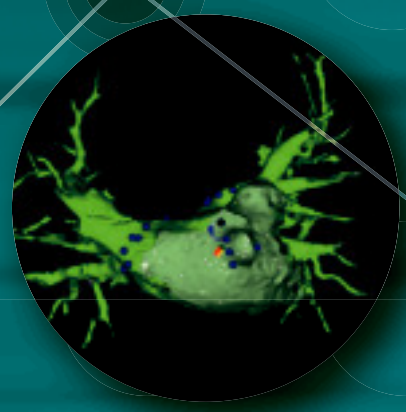

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SCA 360° Raises Awareness of Dangerous Heart Condition

Sudden cardiac arrest (SCA), a leading cause of cardiovascular death in the United States, remains misunderstood, and many patients are not aware of the condition or that they may be at risk.

"SCA is one of the most common reasons that people die in the United States today, yet people confuse it with events such as myocardial infarction, or they believe bypass surgery, stents or angioplasty can reduce their risk," said Bruce L. Wilkoff, MD, Director of Cardiac Pacing and Tachyarrhythmia Devices at The Cleveland Clinic. "SCA is not related to coronary disease or bypass. It is an electrical problem; it is a heart rhythm problem."

SCA, which kills more than 250,000 individuals annually, is a priority for the Society. In response to the issue, HRS developed the SCA 360° initiative to help build awareness of the condition.

Educating the public

The SCA 360° initiative is a comprehensive series of programs to build awareness, educate health care professionals with general cardiologists being the primary target audience, and to increase understanding of SCA. One facet of this is public education through informational brochures, advancing health care provider knowledge of risk factors, and establishment of resource centers.

Wilkoff said it is important for patients to ask their doctors what they can do to assess and reduce their risks.

"Patients with heart failure or who have had a heart attack are at greater risk," he said. "Also, some patients with genetic diseases — not congenital malformations but genetic codes that cause the electrical system to work differently — may be at risk," he explained.

One way of gauging a patient's risk for SCA is to evaluate their ejection fraction, Wilkoff said.

"Normal ejection fraction is 50% to 55%," he said. "If a patient's ejection fraction has decreased to 35% or below, it is clear that these patients have a substantially increased risk of SCA. At the very least, these patients should be evaluated for SCA."

> **"SCA is not related to coronary disease or bypass. It is an electrical problem; it is a heart rhythm problem."**
>
> —Bruce L. Wilkoff, MD

Although there are identifiable risk factors, Wilkoff said patients generally do not discuss SCA with their doctors.

"Physicians have been treating these problems with effective therapies for years," he said, "but if patients don't know they're at risk, they won't get the treatment they need."

SCA Coalition

At a press conference on Thursday, more than 25 leading heart advocacy groups announced the formation of the Sudden Cardiac Arrest (SCA) Coalition – the first coalition dedicated to advancing increased research, awareness, and educational efforts to address SCA.

The Coalition will urge Congress and the federal agencies involved in national health policies and programs to devote more resources to greater public awareness of SCA, research, and access to life-saving therapies.

Over the next year, the SCA Coalition will encourage the introduction and passage of an Omnibus bill that, if passed, will provide the Department of Health and Human Services with the resources and the imperative to develop and implement a comprehensive education and research program for SCA.

ICD Registry™: Two New Initiatives Advance Goal of Improving Patient Care

Two new initiatives for the ICD Registry™ effort will be launched at Heart Rhythm 2007. The first initiative is to convene both physicians and allied professionals to begin revisions and enhancements targeted to the development of Version 2.0 of the ICD Registry™ data elements and definitions.

"This event marks the beginning of a 12-month effort to assess the current data elements and definitions of the baseline ICD Registry™," said Joel Harder, Manager of Quality Improvement and Outcomes for the Heart Rhythm Society. "The goals of this initiative are to delete data elements that are not useful, add new data elements that are needed, and make minor modifications to data definitions to assure clarity."

New customer service initiatives will be integrated into this effort, such as a new phone system that will improve the speed in providing answers to hospital participants on their concerns. Hospital participants will be asked to complete a questionnaire to provide feedback and ideas for this process at Heart Place.

Workgroup

In addition, a workgroup will meet to implement the new Longitudinal ICD Registry™ study design submitted to the Centers For Medicare & Medicaid Services in April 2007 and approved May 4.

"Although not at the power of a clinical trial, the intent is to define the frequency and appropriateness of ICD device firing therapy and the absolute rates of survival," said Stephen Hammill, Chair of the ICD Registry™ Steering Committee.

The five-year prospective study requires up to 350 physicians randomly selected in the ICD Registry™. Approximately 3,500 Medicare primary prevention patients meeting predetermined criteria will be followed for three years, and routine follow-up data will be entered into the online tool. An adjudication committee will evaluate the data from a device firing. The primary endpoint will be the first delivery of an appropriate shock or ATP. Participating physicians will be reimbursed for their participation and also will be provided an outcomes report at the end of the study.

Interested participants

Hospital participants who are interested in being involved in the study should contact their Registry Site Manager and answer "yes" to the question, "Would you be willing to participate in any future research study with the ICD Registry?"

Although that does not guarantee participants' hospitals a slot in the study, it helps the Yale study design coordinators know that the organization is interested in receiving an invitation to participate.

Questions should be directed to Joel Harder, who will be at the ICD Registry™ Booth at Heart Rhythm Place for more information.

Calling All Allied Professionals!

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Device Track Sessions

8:00 a.m.–9:30 a.m. Remote Monitoring: Meeting Workflow Challenges

10:30 a.m.–12:00 p.m. Pharmocology for AF: Considerations for the Advance Practitioner

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Advocacy at Forefront of Health Policy Committee Agenda

The Heart Rhythm Society's Health Policy Committee (HPC) recently undertook a number of advocacy issues addressing heart rhythm topics from the perspective of reimbursement, post-market surveillance, and improvements to the Food and Drug Administration.

Refining coding system

The HPC is taking major steps in the area of reimbursement and coding, according to Bruce Wilkoff, MD, Health Policy Chair. In conjunction with the American Medical Association and the American College of Cardiology, the Society will be suggesting a new coding structure for the monitoring of pacemakers, implantable defibrillators, biventricular devices, and Holter monitors.

It is the HPC's responsibility to ensure appropriate reimbursement and coding for heart rhythm specialists and to ensure patient access to these treatments, according to Amy Melnick, Vice President of Health Policy.

"When there are new procedures in our field, we make sure there are appropriate clinical practice guideline codes available," she said. "Currently, we are looking to refine and create new codes for patients with implanted pacemakers and defibrillators."

Wilkoff said the HPC addressed the coding issues at the Heart Rhythm 2007 Town Hall Meeting, which was devoted to the larger topic of remote monitoring.

"We discussed the legal and financial issues involved," he said.

Focus on remote monitoring

Wilkoff said the topic of remote monitoring is a top priority for the Health Policy Committee.

"This is an important initiative for us," he said. "We focused our entire Town Hall Meeting on remote monitoring of patients with implantable devices and diagnostic wearable devices," he added.

In September, the committee composed recommendations for device performance of pacemakers and ICDs related to post-market surveillance, Melnick said. She explained that the recommendations involve data communication, device malfunction, and the role of the clinician regarding the devices.

"We are now working to implement these recommendations," she said. "We submitted testimony to the FDA about improvements to the post-market surveillance network, and we are working with Congress to advocate for resources and change in this area."

Coalition for a stronger FDA

The HPC also partnered with the Coalition for a Stronger FDA, joining other agencies that work with the FDA to improve its efficiency.

"The focus of the Coalition is to improve, enhance, and increase appropriations for the FDA so that the agency can do its job better," Melnick said.

Wilkoff said the FDA has addressed the issue of remote monitoring by collaborating with the agencies involved to formulate a "sentinel network" for implantable devices.

"The FDA plans to design a Sentinel Network to provide a way of detecting problems with implantable devices and, hopefully, with drugs as well," he said.

Focus on sudden cardiac awareness

The Heart Rhythm Society has launched a coalition of more than 25 organizations dedicated to the advocacy of legislation to raise awareness of SCA prevention, education, treatment, and research.

According to Wilkoff, "This needs federal attention now, and the Society is in the position to lead this exciting coalition."

Society Expands IBHRE Exam Prep Courses

The International Board of Heart Rhythm Examiners (IBHRE), formerly NASPExAM, is expanding efforts to better meet the needs of members.

The IBHRE, a standard of excellence for cardiac arrhythmia professionals, administers the exam that is recognized as the highest benchmark of professional competency in cardiac pacing, defibrillation, and electrophysiology.

In an effort to further promote the time-honored and well-regarded IBHRE exam, the Heart Rhythm Society introduced the IBHRE Online Exam Prep Course for the Physician last year. This year, the Society introduced an additional course, IBHRE Online Prep Course for the Associated Professional/Cardiac Pacing, to complement the exam for associated professionals.

"The online prep course is an excellent resource and study tool for those preparing for the exam," said Sheri A. Sesay-Tuffour, Executive Director of the IBHRE. "With 200 questions to work with, it provides an authentic, in-depth experience that is similar to the live exam experience."

Preparatory modules

Sesay-Tuffour said the online prep courses offer a practice module and a timed module. The practice module allows the candidate to gain a thorough understanding of exam questions at their own pace, with feedback and analysis of answers.

"The practice module helps to assess your knowledge base within specific exam content areas," she said. "This method of study is important in broadening your understanding of cardiac arrhythmia practice standards."

Participants have unlimited use of the practice modules for the 12 months prior to the exam and can choose 100 practice questions to work through, Sesay-Tuffour said.

The timed module simulates a real-time test, and there is only one opportunity to use this feature, she said. "Participants do a final preparatory run through a new set of 100 timed exam questions different from those in the practice module," Sesay-Tuffour explained. "This is as close to taking the actual test as they will get." The prep courses are parallel to the actual exam, with questions comparable to those used in past examinations, she added.

Role of the IBHRE

As an independent body of the Heart Rhythm Society, the IBHRE is "uniquely positioned" to provide those who take the exam with the means to academically or professionally advance in heart rhythm management, Sesay-Tuffour said.

The IBHRE has offered examinations to physicians and associated professionals for more than 20 years. The IBHRE offers three exams: The Examination of Special Competency in Cardiac Pacing and Cardioversion Defibrillation for the Physician; The Examination of Special Competency in Cardiac Pacing and Cardioversion Defibrillation for the Associated Professional; and The Examination of Special Competency in Cardiac Electrophysiology for the Associated Professional.

In 2008, IBHRE will introduce computer-based testing, Sesay-Tuffour said. IBHRE launched a computer-based schedule at the Heart Rhythm 2007 Scientific Sessions.

Sesay-Tuffour said the IBHRE administers rigorous exams — the average pass rate is 60% — that raise the level of professionalism and credibility in cardiac pacing.

"The exams are not easy, but examinees understand that the knowledge they acquire through testing is critical for optimal patient care. The successful examinee holds the internationally accepted IBHRE recognition with a higher level of proficiency to perform device-related therapies," Sesay-Tuffour said.

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[1] *LATITUDE Patient Management system: LATITUDE Active Monitoring™ alerts physician of potential loss of life-saving therapy.* Data on file. C7-322-0407.