# Daily Saturday, November 7 Saturday, November 7 Carry Saturday, November 7

# INSIDE

- Today's highlights from the Program Chair
- IOM report reinforces AHA strategies to improve cardiac arrest survival
- Session will examine use of digital technology in resuscitation
- AHA-funded network boosts blood pressure research

# New resuscitation guidelines update CPR chest pushes

# **The American Heart Association's**

updated resuscitation guidelines, published in *Circulation* in October, refine how fast and how deep chest compressions should be during CPR.

The new rate of chest compressions is 100 to 120 per minute, compared to "at least 100" in previous guidelines. For adolescents and adults, a rescuer should push down at least 2 inches, but no more than 2.4 inches on the chest,

compared to "at least 2 inches" in previous guidelines.

The changes are based on a large study published in the journal *Critical Care Medicine* in April. Data from the prospective, observational



Clifton Callaway, MD

study showed that as compressions surpassed 120 per minute, rescuers didn't push as hard on the chest, decreasing blood circulation.

At 100 to 119 compressions per minute, only 35 percent of compressions didn't go deep enough.

"Compressing more than 120 times per minute is pretty difficult and most people will naturally compress 100 to 110 times per minute," said Clifton Callaway, MD, chair of the AHA's Emergency Cardiovascular Care Committee.

The upper limit for compression depth came from a smaller study published in the journal *Resuscitation* in 2013 that suggested that injuries were possible with chest compressions beyond 2.4 inches.

However, "people should not be afraid of

CPR GUIDELINES continued on page 10



# Program innovations designed to increase interactivity at Scientific Sessions

or the thousands of doctors, researchers and other healthcare professionals attending the American Heart Association's Scientific Sessions, plotting each day is akin to picking from an all-you-can-eat buffet at a five-star restaurant.

No matter what you like, there's plenty to choose from — and the quality will be top notch

"There's something for everybody — really, more than you can handle," said

Frank W. Sellke, MD, FAHA, and the Chairman of the Committee on Scientific Sessions Program (CSSP). "It's a great problem to have."

Consider this small sample of options:

- Interested in learning more about the finer points of how clinical trials work, from start to finish? There's a full-day event organized by Elliott Antman, MD, FAHA, and Robert Harrington, MD, FAHA, the pair who combined to oversee the last four Sessions.
- Interested in the growing field of
- vascular medicine? How about arrhythmia? You could delve into either subject so deeply that you might think you're attending a convention devoted to it.
- Held an artificial heart or an LVAD lately? If not, check out the Simulation Zone, which features everything from those hands-on demonstrations to computerized challenges offering case-based situations for non-scientists and practitioners.

SCIENTIFIC SESSIONS continued on page 12

# ILCOR releases advisory statement on temperature management after cardiac arrest

# In an advisory statement published in

October by the Advanced Life Support Task Force of the International Liaison Committee on Resuscitation (ILCOR), therapeutic hypothermia has been renamed "targeted temperature management."

The new wording is a more concise formulation of the underlying concept of controlling core temperature to achieve specific therapeutic outcomes, said Michael Donnino, MD, lead author of the advisory statement. The new wording covers any form of temperature control within cardiac arrest.

"The statement recommends that you perform targeted temperature management for patients who suffer cardiac arrest," said Donnino, associate professor of medicine at Harvard Medical School and director of the Center for Resuscitation Science at Beth Israel Deaconess Medical Center in Boston.

Scientific Sessions attendees can expect repeated reference to the ILCOR



advisory statement during the Resuscitation Science Symposium (ReSS) Saturday and Sunday. The symposium will also explore the latest research in targeted temperature management and related topics in resuscitation.

A Saturday session titled "Therapeutic Hypothermia: My Target Temperature is ..." will highlight the latest clinical

research on the therapeutic effects of

ILCOR continued on page 10

# **TODAY AT SESSIONS**

Don't miss today's highlighted presentations and events. For the complete schedule, download the Mobile Meeting Guide, see the Final Program or view the online program at scientificsessions.org.

### 8:15-9:15 a.m

IOM Report on Cardiac Arrest Valencia Ballroom – W415AB

### 9 a.m.-12 p.m.

Early Career: Opening General Session

Chapin Theater

### 9:15-10:00 a.m.

2015 Awards for Lifetime Achievement in Cardiac Resuscitation Science and Trauma Resuscitation Science Valencia Ballroom – W415AB

# 10:15-11:30 a.m.

ReSS Best of the Best Oral Abstract Presentations and Presentation of the Best Abstract Awards for Cardiac and Trauma Resuscitation Science

Valencia Ballroom – W415AB

# 1-2:30 p.m.

ReSS Poster Session

Valencia Ballroom - W415AB

### 2-3:15 p.m.

Samuel A. Levine Young Clinical Investigator Award Finalists Sunburst – W340B

# 3–5 p.m.

Laennec Young Clinician Award Finalists

Sunburst - W340A

# 5-6:30 p.m.

Early Career Reception

# SCIENTIFIC SESSIONS BY THE NUMBERS





More than 17,000 cardiovascular professionals



1.5 million



Global presence from more than

e 100 countrie



programming new tracks, including tracks:
Clinical Trialists, Health Tech and Workplace Health



5,000 presentations



1,500 invited faculty

4,000 abstract presentations, all from world leaders in cardiovascular disease



Science and Technology Hall exhibits will be open Sunday through Tuesday with more than 200 exhibitors showcasing the latest cardiovascular technology and resources. Don't miss the hands-on activities in the new Simulation Zone.

# HIGHLIGHTS FROM THE PROGRAM CHAIR

By Frank W. Sellke, MD, FAHA, Committee on Scientific Sessions Program Chair

# **Welcome to the American Heart**

Association's Scientific Sessions, the premier cardiovascular science meeting in the world. This year's meeting looks to be one of the best ever.

The Committee on Scientific Sessions Program, along with Vice Chair Eric D. Peterson, MD, MPH, and the AHA staff have done a truly outstanding job arranging the meeting content in an all-new format, focusing on 30 areas of interest (tracks) within basic, clinical and population science. We have also added new educational and simulation programs alongside the usual outstanding scientific, clinical and translational lectures and poster presentations.

Saturday's highlights include the Early Career Day Program (9 a.m. to 5 p.m.) with specialty science breakouts, including the Peripheral Vascular Disease FIT Workshop. The program concludes with a reception from 5 to 6:30 p.m. Whatever their field or interest, young investigators can attend a number of outstanding programs and learn new techniques and cutting-edge science, and network with both young and established colleagues.

The Resuscitation Science Symposium begins Saturday and continues through Monday. The ReSS Symposium will begin with introductions at 8 a.m. followed by the ReSS Plenary Session and the long-awaited IOM Report on Cardiac Arrest, which will be presented from 8:15 to 9:15 a.m. The Samuel A. Levine Young Clinical Investigator Award Finalists will present from 2 to 3:15 p.m. and the Laennec Young Clinical Award Finalists will present from 3 to 5 p.m.

This year, we have outstanding plenary and special sessions covering all areas of clinical cardiovascular science. One of the highlights of every Scientific Sessions is the Late-Breaking Clinical Trials. This year, we had a record number of late-breaking submissions, contributing to the excellent content of the meeting. Sunday's LBCT highlights include the presentation of trials examining new therapies

for systolic and diastolic heart failure, and the effects of remote management on outcomes after discharge.

Mandav's LRCT presentations will feature

Monday's LBCT presentations will feature trials looking at decreasing the global burden of disease, novel findings from next-generation registries and cutting-edge technologies in EP. Monday's presentations also include a special program on the recent NIH-funded SPRINT Trial. It will examine the effects of level of control of hypertension on cardiovascular outcomes, and the two-year follow-up of the Ischemic Mitral Regurgitation Trial, sponsored by the NIH Cardiothoracic Surgery Network.

During Tuesday's LBCT presentations, we will hear the results of trials on acute coronary syndrome and PCI. It will include follow-up of the DAPT study and Pegasus-TIMI trials, and clinical science special reports on managing risk factors for CAD, including follow-up of the JUPITER and ACCORDIAN trials. Wednesday we will hear about novel



Frank W. Sellke, MD, FAHA

therapies for common problems.

In addition, we are fortunate to have surgical pioneer Alain Carpentier, MD, PhD, presenting the Lasker Lecture and NHLBI Director Gary H. Gibbons, MD, presenting a special lecture on precision medicine, both on Monday. We have continued to expand the meeting's basic and clinical science content with moderated

poster presentations, including increased interactions with poster professors in all sessions. This will allow optimal interaction and networking.

Other outstanding sessions include more than 20 joint programs with international societies, and Best Of Sessions from other cardiovascular meetings. There are special focus sessions on nursing science, clinical trials, and lifelong CHD and heart health in the young. Finally, Frontiers in Science programs include the Arrhythmia Research Summit and the Program on Vascular Disease.

Program additions include a health-tech session and a Genomic Boot Camp.

And to help you better organize your time at the meeting, the Mobile Meeting Guide app has been improved.

Whatever your interest or specialty, this year's program encompasses a wide array of programs to enhance your clinical education and scientific knowledge. We welcome you to Scientific Sessions, and are confident you will have a great experience.

# EARLY CAREER PROGRAM SATURDAY, NOV. 7

SESSION NUMBER	SESSION TITLE	LOCATION	TIME
EC.02	PVD FIT—Session 1: Venous Disease	Room W315AB	9–11:15 a.m.
EC.01	Early Career Opening General Session	Chapin Theater	9 a.m.–12 p.m.
EC.03	PVD FIT—Session 2: Cerebrovascular Disease and Stroke	Room W315AB	11:15 a.m.–12 p.m.
EC.19	Cardiac Electrophysiology Sessions for AHA Early Career Day: Considering Electrophysiology as a Specialty – Part 1	Room W312AB	1–1:45 p.m.
EC.12	Proper Mentorship and Guidance—Steps to Success in Academia – Part 1 (Planned by the Council on Basic Cardiovascular Sciences and Arteriosclerosis, Thrombosis and Vascular Biology)	Room W303	1–2:45 p.m.
EC.16	The Future of Clinical Cardiology: How to Develop a Roadmap for Success (Planned by the Council on Clinical Cardiology)	Room W224GH	1–3 p.m.
EC.18	The Many Paths to Success in Pediatric Cardiology (Planned by the Council on Cardiovascular Disease in the Young)	Room W110A	1–3 p.m.
EC.23	Genome Editing Boot Camp (Planned by the Council on Functional Genomics and Translational Biology)	Room W224EF	1–3 p.m.
EC.14	Tricks and the Trade: Pearls and Pitfalls for Early Career Scientists in the 3CPR Specialties – Part 1 (Planned by the Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation)	Room W312C	1–3:15 p.m.
EC.07	Everything You Wanted to Know About Developing a Career in Cardiovascular Surgery and Anesthesia (Planned by the Council on Cardiovascular Surgery and Anesthesia)	Room W311EF	1–4:45 p.m.
EC.22	Building a Research Career: Pathway to Success (Planned by the Council on Cardiovascular and Stroke Nursing)	Room W224AB	1–5 p.m.
EC.24	Introduction to Cardiac Imaging (Planned by the Council on Cardiovascular Radiology and Intervention)	Room W307AB	1–5 p.m.
EC.08	Precision Medicine and Big Data Methods: Applications and Methods for New Investigators (Planned by the Councils on Epidemiology and Prevention, and Lifestyle and Cardiometabolic Health and Quality of Care and Outcomes Research)	Room W209AB	1–5:20 p.m.
EC.04	PVD FIT—Session 3: Diseases of the Aorta and Major Branches	Room W315AB	1:20-2:30 p.m.
EC.20	Cardiac Electrophysiology Sessions for AHA Early Career Day—My Story: A Panel Discussion on the Different Types of EP Career Options – Part 2	Room W312AB	1:45–2:50 p.m.
EC.05	PVD FIT—Session 4: Lower Extremity Peripheral Artery Disease	Room W315AB	2:30–4 p.m.
EC.06	PVD FIT—Session 5: Launching the Academic Vascular Career	Room W315AB	4–4:45 p.m.
EC.13	Proper Mentorship and Guidance—Steps to Success in Academia – Part 2 (Planned by the Council on Basic Cardiovascular Sciences and Arteriosclerosis, Thrombosis and Vascular Biology)	Room W303	3–5 p.m.
EC.15	Emerging Science: Updates from the 3CPR Early Career Committee – Part 2 (Planned by the Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation)	Room W312C	3:30–4:50 p.m.
EC.17	Everything an Early Career Functional Genomics Physician Scientist Needs to Know (Planned by the Council on Functional Genomics and Translational Biology)	Room W224EF	3–5 p.m.
EC.21	Cardiac Electrophysiology Sessions for AHA Early Career Day—Early Career EP Clinical Session – Part 3	Room W312AB	3–5 p.m.

# IOM report reinforces AHA strategies to improve cardiac arrest survival

he latest Institute on
Medicine (IOM) report on
cardiac arrest will sound
familiar to AHA members
who work in cardiac arrest.
The IOM's findings on the burden of
cardiac arrest, the need for additional
research, its call for a national
cardiac arrest registry and strategy
recommendations to improve patient
care echo work the AHA has done and
plans to do in the future.

"The IOM report resonated very strongly with the work of the AHA, specifically the work of the Emergency Cardiovascular Care Committee and the Get With The Guidelines® program," said Robert Neumar, MD, PhD, professor and chair of emergency medicine at the University of Michigan Health System in Ann Arbor. Neumar chaired the AHA's response to the IOM's June report on "Strategies to Improve Cardiac Arrest Survival: A Time to Act."

The IOM report will be discussed in depth today during a one-hour session that begins at 8:15 a.m. in the Valencia Ballroom – W415AB.

One of the most important recommendations from the report is to establish a national cardiac arrest registry at the local, state and national levels, Neumar said.

"Having data on the incidence, system performance and outcomes is foundational to know where we are now, and also to measure any impact from the strategies proposed by the IOM or the AHA," he said. "If we can't measure where we are, we can't measure where we are going or the impact of our investments."

A second key recommendation is to foster a culture of action in response to cardiac arrest. Basic life support begins with recognizing cardiac arrest, calling 911, performing CPR and using an AED if one is available.

"Cardiac arrest is the most critically ill human condition that exists," Neumar said. "People need to understand that their individual actions can be the difference between life and death. Cardiac arrest is unique in health care in that we have put such importance on what bystanders can and must do to initiate that chain of survival."

A third key recommendation is increased support for cardiac arrest research. Despite the prevalence of cardiac arrest, support for research is disproportionate compared to cancer, stroke, myocardial infarction and other diseases, Neumar said.

"The IOM's call to action needs to be responded to," he said. "The AHA is willing to step up, even take the lead in much of the response. But we can't do



it alone. Improving outcomes requires the active support and involvement of other stakeholders, including government agencies and funding bodies, to implement these clearly defined strategies."

There are about 535,200 outof-hospital and 209,000 in-hospital cardiac arrests each year in the United

States. At a national level, only 25.5 percent of adults who suffer cardiac arrest in a hospital setting survive to discharge. For out-of-hospital cardiac arrest, only 10.6 percent of patients survive to hospital discharge.

Survival rates vary widely based on personal factors such as age, race, gender and health status. Survival rates also vary widely based on the characteristics of local emergency medical services and local health care systems. While some communities and hospitals have significantly improved cardiac arrest outcomes, there are pronounced variations and disparities in care. Local resources and personnel must provide appropriate, timely and high quality care in order to save more lives locally.  $\blacktriangledown$ 

# MEMBER SPOTLIGHT

Michelle M. Fennessy, PhD, RN

Assistant Professor at The Ohio State University, College of Nursing Columbus, Ohio

# How long have you been an AHA/ ASA Professional Member?

Four years at the professional level but I have been a general member of the AHA for 10 years.

# Why did you join?

I have always enjoyed the learning and networking that takes place within the American Heart Association. Membership offers so much in terms of online resources, networking and a highly regarded organization to showcase my research. I also like what the AHA promotes for health and wellness.

# **Are you involved in AHA councils?**

Yes, very much so! I am the current chair for the Council on Lifestyle and Cardiometabolic Health's Early Career Committee and also serve as the advocacy ambassador for the Council on Cardiovascular and Stroke Nursing (CVSN). I pay additional fees for my association with the Epidemiology and Prevention Council as well.

# What do you enjoy most about these roles?

As an advocacy ambassador, I have a platform to keep the CVSN council updated about future legislative and policy efforts within the AHA. I have also been a part of the AHA Lobby Day, which is both fun and rewarding on so many levels. Additionally, as chair of the Lifestyle Early Career Committee, I have the opportunity to work with some of the best scientists. Together, we discuss new ways to improve our meetings and help to bring important educational topics that early career scientists need to build their careers. It is an honor to serve in both roles and I consider it my way of giving back.

# How else are you involved with the AHA?

I contribute via annual donations and I support local AHA venues. Another great place to connect is via platforms like yourethecure.org, which uses grassroots efforts mixed with social media to garner support for research funding and future legislative efforts. We also have an early career Facebook page (https://www.facebook.com/groups/ahaearlycareer/) that includes all councils. It's a great place to connect for upcoming conferences, communicate about conference room accommodations or learn about career opportunities.

# Why is membership valuable to you?

It gives a lot of meaning to my work as a scientist, a professor and a concerned citizen. The AHA is such a great mix of science, policy, community and health. I value what the AHA has done for my career and I hope to pay this forward.

# What message would you like to convey to your colleagues about being an AHA member?

Please take a moment to join, get engaged in councils and community events, and enjoy the superb networking afforded by the AHA. ▼

# **CAREER PROGRESSION**

# ELVIN T. PRICE, PHARMD, PHD T

Growing up, as close relatives struggled with heart disease, Elvin T. Price saw firsthand that medications don't work for everyone.

"Watching my elders struggling motivated me to try to do something about it," said Price, assistant professor of pharmaceutical sciences at the University of Arkansas for Medical Sciences College of Pharmacy in Little Rock. "I've been interested in how drugs work and why they don't work in certain individuals for as long as I can remember."

Price realized how common cardiovascular disease is during pharmacy school at Florida A&M University in Tallahassee, where many classmates had similar family histories. Early research on heart disease risk factors also spurred his interest in the genetics and heritable risk in heart disease, which led to his interest in the pharmacogenetics of medication response.

While he was completing his PhD at the Center for Pharmacogenomics at the University of Florida, AHA's Scientific Sessions convened in nearby Orlando. Price applied for a minority travel grant, which allowed him to attend the meeting for the first time.

"That meeting helped me to grasp the translational nature of the science that

Each day in this spot, we will profile an investigator at a different career stage, from early career to distinguished veteran.

was presented at the American Heart Association," he said. "It was my first experience with an international crowd. It was really an eye-opening experience. I grasped how there was everything from basic science to clinical and translational science. I saw people from all over the world who were open to serving as mentors."

That first experience at Scientific Sessions opened several doors. Price pursued additional training in cardiovascular genetic epidemiology at Washington University School of Medicine's division of biostatistics in St. Louis, through a program with the National Heart, Lung, and Blood Institute. His mentors, active members of the AHA, secured two lectures for the group from former AHA President Donna Arnett, PhD, MSHP, BSN, FAHA.

"That experience gave me additional exposure on methods and different strategies researchers use," Price said. "It was really useful to see how epidemiologists approach genetic problems compared to pharmacists. It

really made me appreciate service in the AHA even more."

Today, Price is vice chair of the membership committee for the Functional Genomics and Translational Biology Council.

"It's a really cool council made up of individuals doing basic functional aspects with genetics, as well as genetic epidemiologists," he said. "The council sort of covers the translational divide that is influenced by genetics."

As vice chair of the membership committee, Price works to keep the council's membership diverse with individuals from different training backgrounds. The mentorship program matches junior faculty with mid- or senior-level faculty.

"Thanks to the council, I now have an international mentor with a phenomenal lab," Price said. "I've visited her department and given a guest lecture. It's an exciting council, and I enjoy serving as a part of the leadership." ▼

# AHA quality programs generate practice-changing research

esearch presented at Scientific Sessions, based on data collected through AHA registries that track cardiac events and patient outcomes from millions of providers and patients, could help transform the provision of cardiac care.

"Get With The Guidelines and Mission: Lifeline have, as their primary goal, the improvement of patient care and outcomes," said Deepak L. Bhatt, MD, MPH, executive director of interventional cardiovascular programs at Brigham and Women's Hospital Heart & Vascular Center and professor of medicine at Harvard Medical School in Boston.

Bhatt chairs the Quality Oversight Committee, a group of volunteers that oversees the AHA's quality improvement programs. Get With The Guidelines focuses on stroke, heart failure, resuscitation and atrial fibrillation. Mission: Lifeline links EMS providers and health systems to improve care for myocardial infarction. Both are designed to help healthcare professionals deliver evidence-based care that's focused on improving patient outcomes.

'The basic premise is that the more the quality



of healthcare improves, the more patient outcomes improve," Bhatt said. "All of the quality programs include registries that are intended to generate research, presentations and publications that change the way cardiac care is delivered. We are seeing research being presented this year that has the potential to dramatically improve the ways we deliver care and the outcomes our care produces."

On Monday, Shanshan Li, MD, MSc, ScD, an epidemiologist at the Harvard School of Public Health in Boston, will present new findings on sex- and race-related disparities in care, based on data from Get With The Guidelines-Coronary Artery Disease. Li will present the abstract, "Sex and Race Related Disparities in Care and Outcomes After Hospitalization for Coronary Artery Disease Among Older Adults," at 11:15 a.m. in W203.

Also on Monday, lead author Emily O'Brien, PhD, will present an abstract titled "Clinical Effectiveness of Statin Therapy After Ischemic Stroke: Primary Results from the PROSPER Study" at 9:30 a.m. in the Best of AHA Specialty Conferences section of Hall A2. The study examines the efficacy of statins in patients who have had ischemic stroke, using data from Get With The Guidelines-Stroke. O'Brien is a member of the Duke University Clinical Research Institute and an instructor in the Duke University School of Medicine in Durham, North Carolina.

"This is research from patients with strokes in the real world and what impact statins might have on outcomes patients have told us they care about most," Bhatt said. "They value time at home, which means discharge to a skilled nursing facility, and months of rehab may not be something they consider a desirable outcome."

On Tuesday, Jacob P. Kelly, MD, a fellow at the Duke Clinical Research Institute, will present a study titled "The Potential Impact of Expanding Cardiac Rehabilitation Coverage in Heart Failure: Insights From Get With the Guidelines-Heart Failure." This new analysis examines the impact of the recently expanded indications for cardiac rehabilitation. Kelly will present the study's findings at 6:30 p.m. in W300.

Mission: Lifeline is also generating new findings.

One of the key strategies to improve outcomes for ST-elevation myocardial infarction and out-of-hospital cardiac arrest is to provide appropriate care within recommended timeframes. This could mean bypassing a hospital in favor of a more distant facility.

"When you have a STEMI, what's best for the patient is to get to a center that can deliver primary PCI as rapidly as possible," Bhatt said. "When that means bypassing another hospital, that bypassed hospital has to cooperate even though doing the right thing may put them at an economic disadvantage. One of the real questions is whether appropriate state policies can encourage that kind of cooperation."

Jacqueline Green, MD, a cardiology fellow at the University of Michigan in Ann Arbor, worked with Mission: Lifeline data to examine the effects of a state bypass policy. She will present her findings at 9 a.m. Monday in the Special Focus section of Hall A2. The abstract is titled "Are State Policies that Permit Prehospital Bypass Associated with Better Treatment Patterns Among Patients with ST-Elevation Myocardial Infarction? A Report from AHA's Mission: Lifeline Program."

"This will be a very interesting analysis of how best to treat STEMI patients prior to their arrival to the hospital," Bhatt said. "Should they be bypassing smaller facilities that can't deliver primary PCI rapidly? And does it help to have state policies that encourage that kind of bypass? These are the sorts of questions our registries are uniquely positioned to address."

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# Session will examine use of digital technology in resuscitation

he widespread use of cell phones and other digital media tools is transforming the way critical information and patient care can be delivered. This is particularly true for resuscitation care.

"What's unique about resuscitation is that it relies on things being done quickly," said Raina Merchant, MD, MSHP, chair of the AHA's Emergency Cardiovascular Care Science Subcommittee. "With CPR in particular, the focus is on what citizens can do. Unlike conditions where EMS might be the primary provider, CPR for cardiac arrest is unique in that ordinary citizens can save a life. Digital media can add speed and aid in life-saving."

Merchant helped organize a session on digital media for this year's Resuscitation Science Symposium. The session, which begins at 4:15 p.m. Saturday in the Valencia Ballroom – W415AB, was designed to expose the boundaries that slow and impede the delivery of resuscitation care. Today's systems of care and medical response were created before the emergence of digital networks, 24/7 connectivity and the almost-instant availability of information on demand, Merchant noted.

The session will open with a first look at AED delivery by drone. The second presentation will examine a new technology known as PulsePoint.org. Volunteers sign up via cell phone with a standing offer to provide CPR should a cardiac arrest occur near their location. When a 911 operator identifies a likely cardiac arrest, an emergency notice is sent directly to volunteers who are near the incident.

"This is another shift in the way we think about our usual approach to cardiac arrest, similar to the drone concept of bringing an AED to the site of rescue," said Merchant, assistant professor of emergency medicine and director of the Social Media and Health Innovation Lab at the University of Pennsylvania in Philadelphia. "We should rely on EMS coming to the

OHCA and epinephrine timing

Researchers in Japan conducted a multicenter retrospective cohort study to evaluate the effectiveness of time to first epinephrine administration on neurological outcomes following out-of-hospital cardiac arrest. Results of the study will be released during an ReSS Oral Abstract Presentation at 5:30 p.m. Saturday in the Valencia Ballroom – W415.

patient but when there are so many potential rescuers near the site of a cardiac arrest, bystanders can also help quickly. This is a way to enlist willing bystanders who can potentially respond far faster than EMS, get hands on the chest and start CPR, or get an AED while EMS is still in transit."

A third presentation will look at the future of telemedicine. This relatively new channel has been shown to improve care in stroke and other conditions,



# SESSION PREVIEW

ReSS.08: Digital Media 4:15–5:30 p.m. Saturday Valencia Ballroom – W415Al

Photo credit: Allan Hunter Shoemake used with permissio from the Robert Wood, Johnson Foundation

Merchant said. It makes sense to expand a proven technology to emergent conditions to provide guidance and coaching to

responders on the scene.

The final presentation will look at the use of big data generated by social media channels such as Facebook and Twitter. Not only do these channels offer new

avenues to push information out to users, they are also an opportunity to mine rich new data sources that may help researchers understand the epidemiology of health conditions and assess the challenges and opportunities for intervention.

"This session is about taking the science that we know and asking how we can apply it in new ways in this new digital landscape," Merchant said. "We still need data, we still need trials. We still need to think about what environments these adjuncts might work in and when they are ready to replace current approaches. Unlike many plenaries, there may be more questions here than answers. That is the atmosphere where science really flourishes and exciting ideas happen."

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# Bugher Foundation trustee Dan Adams remembered as inspirational, creative force

an Adams, who oversaw a family foundation that blossomed into one of the nation's leading funders of stroke research, died on June 30. He was 75.

Adams died accompanied by his loved ones at an assisted living facility near his home in Greenwich, Connecticut. He had been diagnosed with acute myeloid leukemia

Although his professional specialty was corporate branding, Adams became a leader in the fight against stroke through his involvement in the Henrietta B. and Frederick H. Bugher Foundation. The Bugher Foundation has funded more than \$36 million in heart and stroke studies overseen by the

American Heart Association/American Stroke Association. This foundation is the most generous research donor in the AHA's history.

The Adams family has been intimately involved in the foundation since its inception. Dan's father, Nelson Adams, helped start the Bugher Foundation, and Dan's sons, Bryan and Bruce, are among the trustees. Interestingly,



the Adamses are not related to the namesake benefactors, nor are they connected to cardiovascular disease, except for their devotion through this foundation.

Formally known as the American Stroke Association-Bugher Centers of Excellence in Stroke Collaborative Research, its focus on recovery, resilience and prevention includes psychology, psychiatry and neuropsychology. This met Adams' oft-stated goal of "getting the mind into the mix."

"Through his compassionate leadership of the Bugher Foundation, Dan Adams and his family have supported stroke research in this country like no one else," said Ralph Sacco, a past president of the AHA/ASA who is chairman of neurology at the University of Miami Miller School of Medicine and director of the school's center in the current Bugher research project. "There are so many fellows, faculty, researchers and patients who are indebted to Dan and his family for their generosity and guidance of the Bugher Foundation in improving outcomes for patients with stroke and heart disease. I am incredibly grateful to have known and worked with Dan and I know his legacy will continue."

With nearly 30 years of funded research, the Bugher alumni club includes more than 200 researchers, many of whom have become leaders in the field. Perhaps the most prominent is Andrew Marks, creator of the first drug-eluting stent approved by the Food and Drug Administration in 2003.

The current Bugher-funded project involves teams of researchers at UCLA, the University of Colorado at Denver and the University of Miami. They are in the second of four years of studying a broad range of issues — including stroke in children, rehabilitation and recovery, neuropsychology and cognition — and are working together in a collaborative format championed by Adams.

"Dan meant so much to our organization," said Nancy Brown, chief executive officer of the AHA/ASA. "As an individual leader, he helped shape the future of the AHA in research, as a trustee of the Bugher Foundation he was inspirational to so many others and as a friend he was always gracious and compassionate. His presence and input will be greatly missed."

Survivors include Adams' wife, Suzanne, sons Bryan and Bruce, Bruce's wife, Lee, and Bruce and Lee's daughters, Margaret and Lucy. He was preceded in death by another son, Danny. V

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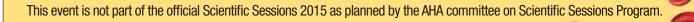
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# AHA/ASA journals provide instant feedback of online impact

ince 1950, the American Heart Association/American Stroke Association journals have accelerated advancements in patient care through scientific research. Here are some of the 12 journals' latest metrics:

**Recognition:** 364,700 total cites\* **Reputation:** 58.5 million article downloads†

Discoverability: 31 million online visits†

**Exposure:** 3.4 billion media impressions†

**Reach:** 12,500 institutions with

access†

**App-peal:** More than 138,000 iPad

app downloads†

In addition, Altmetric is now available on the journals' websites. It analyzes the online impact of journal content by tracking discussions on Twitter, Facebook, science blogs, mainstream news outlets and other sources. The data is available to authors and readers by clicking the "Metrics" link in the menu alongside each journal article. Visit www.ahajournals.org/site/altmetric.

"With Altmetric, the AHA/ASA journals can provide instant feedback as to how articles are received by the reading public. Seeing how articles are trending in the social media realm is appealing in this fast-paced environment," said Robert M. Carey, MD, MACP, FAHA, FRCPI, chair of the AHA Scientific Publishing Committee. "Combine the Altmetric feature with the robust metrics that we report, and the journals continue to look at measures of quality beyond the Impact Factor."

Another enhancement is the Open Access option that's now available for Original Research articles submitted to the journals. Visit www.ahajournals.org/site/openaccess for more information.

JAHA, the AHA/ASA's fully Open Access journal, represents the 16 AHA scientific councils. Submissions are encouraged from AHA/ASA members, and members are eligible for discounted article publication charges. Pick up a free JAHA booklet with featured articles, information about authors and more at AHA HeartQuarters (booth 859) or the Wiley exhibit (booth 950) in the Science & Technology Hall. You can also visit jaha.ahajournals.org.



ACCELERATING SCIENCE FOR EXTRAORDINARY IMPACT

# Join us for our Annual Awardee Group Photo at Scientific Sessions

- Photo taken with AHA President Mark Creager, MD, FAHA and other officers
- Monday, November 9 at 1:40 PM
- Level 3, Chapin Theater Lobby
- Participants will receive a special lapel pin!



Complimentary copies of the AHA's five print journals and information about all of the journals are also available in the Science & Technology Hall. You can view AHA/ASA journal apps and other new features in the hall. Stop by AHA HeartQuarters or the Wolters Kluwer exhibit (booth 951) for more information.

Many of the AHA/ASA journals have Facebook pages, tweets of the latest study results, connections via LinkedIn and blogs with readers about cases or recently published articles. For the latest, visit www.ahajournals.org/site/socialmedia. ▼

\*Total number of citations in 2014. Source: *Web of Science*<sup>TM</sup> (Thomson Reuters, 2015).
†Average per year based on 2014 metrics.

# AHA/ASA journals

- Arteriosclerosis, Thrombosis, and Vascular Biology
- Circulation
- Circulation Research
- Hypertension
- Stroke
- JAHA Journal of the American Heart Association
- Circulation: Arrhythmia and Electrophysiology
- Circulation: Cardiovascular Genetics
- Circulation: Cardiovascular Imaging
- Circulation: Cardiovascular Interventions
- Circulation: Cardiovascular Quality and Outcomes
- Circulation: Heart Failure

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# **ILCOR** continued from page 1

different target temperatures, as well as the need for individualized care and an examination of the role of hypothermia in trauma. The session begins at 2:30 p.m. in the Valencia Ballroom - W415AB.

An oral abstract session on Saturday will provide a glimpse of other target temperature management strategies, while a pair of concurrent oral abstract sessions on Sunday will explore the expanding world of targeted temperature management in clinical and trauma care.

All of these sessions draw from the research considered by the ILCOR task force when drafting its advisory statement. The group considered three questions, Donnino said. The first was whether some form of targeted temperature management

should be used in comatose post-cardiac arrest patients. The second and third questions involved appropriate targets and duration of the intervention when targeted temperature management is used.

The task force reached its conclusions based on systematic review and, as appropriate, meta-analyses for each of the three questions. Members completed a bias assessment for all studies included in the review and used GRADE methodology to evaluate the evidence and develop treatment recommendations.

The answer to the first question is yes — targeted temperature management is appropriate for essentially all adults suffering cardiac arrest who remain comatose after resuscitation and return to spontaneous circulation, Donnino said. The ILCOR statement expands the temperature management target to a consistent temperature within the range of 32°C to 36°C. Prior recommendations called for a target range between 32°C and 34°C.

"We also addressed how long to maintain target temperature management, the third question," Donnino said. "While there are no randomized data to answer that question definitively, we ultimately recommended at least 24 hours. That is consistent with the approximate times of the large randomized trials."

With regard to the timing of hypothermia, the task force recommended against the use of prehospital cooling with rapid infusion of large volumes of

cold IV fluid immediately after return to spontaneous circulation. The group concluded that other cooling strategies and cooling during cardiopulmonary resuscitation in the prehospital setting have not been studied adequately and further research is needed.

"This ILCOR advisory is the latest statement on targeted temperature control, not the last word. There has been and will continue to be additional research that affects future evaluations of these and other issues," Donnino said. "The ReSS offers cutting-edge research in resuscitation from experts around the world. This is the ideal symposium for all of those who are interested in the clinical, operational or research aspects of resuscitation." V

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# CPR GUIDELINES

continued from page 1

pushing hard," Callaway said. "Ribs bend with chest compressions and the 'injury' is usually very mild. It definitely is not life-threatening."

The new resuscitation guidelines also reemphasize the value of breaths during CPR by people willing and able to deliver them. Callaway expects conventional CPR with breaths as compared to Hands-Only CPR will be a topic of discussion among experts as new research emerges.

But for those untrained or unable to give the breaths, "it's better to give compressions than not do anything at all," Callaway said.

The AHA's resuscitation guidelines have been updated every five years through a partnership involving more than 250 international experts from the AHA and six other resuscitation councils that form the International Liaison Committee on Resuscitation (ILCOR). At an AHA-hosted ILCOR conference in January, seven expert panels reached consensus on hundreds of resuscitation topics based on research published since the 2010 guidelines.

More than 326,000 people experience cardiac arrest outside of a hospital each year and about 90 percent of them die, often because bystanders don't know how to start CPR or are afraid they'll do something wrong.

Guidelines recommend that CPR be given immediately after someone collapses and continue until a defibrillator is ready to use, emergency medical services take over or a victim starts moving. **T** 



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# **Unofficial Satellite Events**

# SATURDAY, NOV. 7

# 8:30-11:30 a.m.

Industry-supported Symposium Managing the Challenging HoFH Patient: Academic Insights and Practical Approaches for a Severe Dyslipidemia, an NLA Masters Summit

Sponsored by National Lipid Association Supported by Aegerion Pharmaceuticals and Amgen Inc.

Rosen Shingle Creek Hotel, Sebastian K Registration: www.lipid.org/NLAMastersSummit

University/Nonprofit Symposium Acute Coronary Syndrome in Younger Women: Unique Risks, Etiologies, Treatments and Opportunities Sponsored by Mayo Clinic Division of Cardiovascular Diseases

Supported by Mayo Clinic Division of Cardiovascular Diseases

Rosen Centre Hotel, Grand A Ballroom

University/Nonprofit Symposium Management of Hypertrophic Cardiomyopathy for the Clinical Cardiologist

Sponsored by Washington University School of Medicine - Continuing Medical Education Supported by Washington University and Barnes-Jewish Heart & Vascular Center

Rosen Centre Hotel, Grand Ballroom B Registration: BarnesJewish.org/orlando2015

# **SUNDAY, NOV. 8**

# 7–9 p.m.

University/Nonprofit Symposium

Cardio-Oncology: A New Era, An Evolving Discipline

Sponsored by Mayo Clinic Division of Cardiovascular Diseases Supported by Mayo Clinic Division of

Rosen Centre Hotel, Grand A Ballroom Registration: 6:30-7 p.m.

Industry-supported Symposium New Tools for Managing Hyperkalemia: Cases in Heart Failure and Renal Disease

Sponsored by ZS Pharma Supported by ZS Pharma

Rosen Centre Grand Ballroom D

# 7-9:15 p.m.

Industry-supported Symposium **Optimizing LDL-Targeted Cardiovascular Risk Reduction** 

Jointly Provided by the University of Massachusetts Medical School and CMEducation Resources, LLC Supported by an Independent Educational Grant from Sanofi and Regeneron Pharmaceuticals

Hyatt Regency Orlando, Plaza Ballroom D-G Registration: www.reg-LDL.com

Industry-supported Symposium AF Spotlight: Using NOACs Safely Sponsored by Postgraduate Institute for Medicine and Medtelligence

Supported by Boehringer Ingelheim

Pharmaceuticals, Inc. and Daiichi Sankyo, Inc. Hyatt Regency Orlando, Windermere Ballroom W,

Convention Level Registration: http://events.medtelligence.net/ha2015.html

Industry-supported Symposium

Repatha™ (evolocumab): Product Overview Sponsored by Amgen

Supported by Amaen

Hyatt Regency Orlando, Windermere X Room

# MONDAY, NOV. 9

Industry-supported Symposium Considerations in the Clinical Use of Non-Warfarin Oral Anticoagulation in Thrombosis

This activity is provided by Global Education Group. Paradigm Medical Communications, LLC is the educational partner.

Supported by an educational grant from Daiichi Sankyo, Inc.

Rosen Centre Hotel, Ballroom: Executive H Registration: 6:30 p.m.; www.paradigmmc.com/422

# 7-9 p.m.

Industry-supported Symposium **Anticoagulation Management and Evolving** Standards of Care

Sponsored by Boehringer Ingelheim Pharmaceuticals, Inc Supported by Boehringer Ingelheim Pharmaceuticals, Inc Hyatt Regency Orlando, Orlando Ballroom Registration/dinner: 7-7:20 p.m. Program: 7:20-9 p.m.

Industry-supported Symposium

An Expert Forum: Hot Topics in Stable Ischemic Heart Disease Management Sponsored by Voxmedia

Supported by Gilead Sciences Medical Affairs Rosen Centre Hotel, Grand Ballroom C Registration: 6:30 p.m.;

www.symposiareg.com/21513

Industry-supported Symposium **Secondary Prevention of** Atherothrombotic Events - Current Insights on Advancing Science

Continuing medical education activity is provided by Vindico Medical Education Supported by an educational grant from Merck & Co., Inc.

Hyatt Regency Orlando, Plaza International Ballroom H, Convention Level Registration: 6:30 p.m.; www.vindicocme.com/110915

Industry-supported Focus Group **VisualSonics Focus Group** 

Sponsored by VisualSonics Supported by VisualSonics

Hyatt Regency Orlando, Bayhill 17/18 Registration: www.visualsonics.com

# 7-10 p.m.

Industry-supported Symposium

Hyperkalemia and Health Outcomes

Sponsored by ReardenCME Supported by Relypsa Inc

Hyatt Regency Orlando Registration: www.HyperKvClinic.org

# 7-10 p.m.

Focus Group

# **SHAPE Trial Advisory Meeting**

Sponsored and supported by SHAPE Society for Heart Attack Prevention and Eradication Rosen Plaza Hotel

Registration: www.shapesociety.org

# **TUESDAY, NOV. 10**

### 6:30-8:30 a.m.

Industry-supported Symposium

Challenges in Cholesterol Management — What Your Patients Might Not Be Telling You: A Town Hall Symposium

Jointly provided by University of Louisville and Global Academy for Medical Education

Supported by an educational grant from Pfizer, Inc.

Hyatt Regency Orlando, Ballroom N Registration: tinyurl.com/cholesterolmanagement

### 7-8:30 a.m.

Convention Level

Industry-supported Symposium A 3-D View Statin Therapy — Only Part of a Comprehensive Approach to Dyslipidemia Management

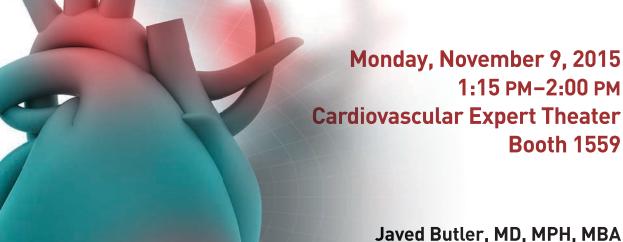
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Theater Presentations do not qualify for Continuing Medical Education (CME) credit.

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# SCIENTIFIC SESSIONS continued from page 1

Scientific Sessions is widely regarded as the premier gathering of cardiovascular thought leaders in the United States. Organizers take great pride in upholding that reputation, so they've spent countless hours over the last year evolving, improving and refining the program to ensure its depth and breadth. Now comes the fun part: seeing it all play out over the next four days in Orlando.

"All over the globe, cardiovascular physicians, scientists and other related professionals build their calendars around AHA Scientific Sessions because of its extensive offerings, including Late-Breaking Clinical Trials, novel research discoveries and programs tailored for

every cardiovascular specialty interest," said AHA President Mark Creager, MD, FAHA. "It is a particular treat to listen to experts discuss the latest developments in their field. The knowledge gained at Scientific Sessions makes us all better at our jobs, whether it's caring for patients or going back to the laboratory. The innovative programming at this year's meeting will highlight a great learning experience. I am anticipating another outstanding Scientific Sessions."

Plenary sessions and Late-Breaking Clinical Trials are foundational items on the agenda. Those remain among Sellke's favorites because of the rigorous review required for each speaker and subject to make it to the stage. He becomes even more enthusiastic in describing the 2015 innovations.

"This is NOT the same old Sessions," said Sellke, the chief of cardiothoracic surgery at Brown Medical School and the Lifespan Hospitals in Providence, Rhode Island. "If you haven't been for five years, I don't think you'd be able to recognize it."

For instance, you can now be in two places at once.

Technology makes it possible to virtually attend any session at any time. If you're coming out of one session and there's not enough time to get across the convention center, you can still "attend" the next session on your list via

mobile phone, tablet or computer. And if you aren't sure how to hook up such a connection, well, there's another session that can help solve that problem.

"Some of us are not up to speed on the newest technological advances," Sellke said. "This will give attendees an opportunity to kind of catch up and to get the most out of the meeting."

Getting the most out of the meeting is the de facto mission statement behind every tweak the CSSP made.

Using feedback from attendees and presenters, and adding their own observations, these dedicated AHA volunteers focus on making sure everyone who takes the time and effort to be here gets what they need and want.

That leads to one of the most prominent changes, one that can be described quite bluntly: fewer boring lectures.

Oral sessions have been reduced from 10–15 minutes with a five-minute discussion to seven minutes or less of oration with the rest of the time going to discussion. The aim is generating more audience involvement, which in turn should yield a greater exchange of information

"Rather than doze off while someone is talking, you're actually involved in discussions," Sellke said.

A bigger change is that the number of oral presentations is going way down. Going way up is the number of poster presentations — and, in another major shift, they'll all be moderated.

Novel as this may sound, it's actually an expansion of an existing concept: the "Poster Professor."

This began a few years ago as a way for a presenter of a research poster, usually someone early in their career, to work one-on-one with a senior member of their field. The duo would discuss the science involved in the research featured on the poster, as well as the intricacies of sharing their work in this prestigious setting. The session proved so popular that the CSSP expanded it last year. Now it's growing again, so much that Sellke believes there eventually could be year-round tutorials to train "professors."

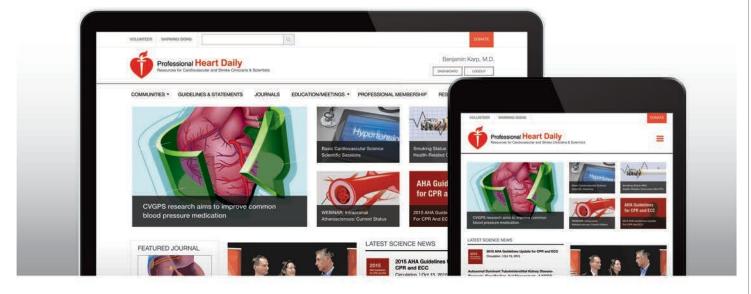
"It used to be that poster presenters sat around and hoped that people came to see them," Sellke said. "Now there's going to be an active exchange of information. First the presenter gives a couple-minute presentation of his poster, followed by a Q&A led by the professor and others in the audience. It's great for the effectiveness of exchanging information, and also for networking. This is a major change for the better."

Digital posters also will be more common. Some will be presented on big-screen TVs, accommodating — or perhaps luring — bigger crowds while also expanding the discussion accessible to someone who prefers to sit or stand outside the cluster around the presenters.

The Simulation Zone is brand new, and might be worth a look for even the most knowledgeable veteran for the simple reason that there's likely to be a lot of people there having fun.

Lines may form around the machines offering activities that test diagnosis skills. A cousin, of sorts, to the popular "Case Theater" series — which features real cases on video that are started

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and stopped for discussion and debate — these are made for one person at a computer.

"You might see a picture of a diseased organ and lab data, and you have to come up with a diagnosis or conclusion or a treatment paradigm," Sellke said. "Residents and medical students can benefit. It can also be used for postgraduate education for practicing physicians."

Then there are the hands-on activities, which could take on a show-and-tell vibe, even among experienced cardiologists. As Sellke notes, it's rare for anyone other than a surgeon to actually hold these devices and get a feel for them, to look inside and study all the various components.

"You don't pass around an LVAD or artificial heart in the ER before you put it in," Sellke said. "It's sterile and packaged, so even the people who are there see it but don't touch it. Our concern is we may have more interest than the space allotted can handle."

Frequent attendees of Sessions may have become accustomed to plotting their calendars around seven "cores." Even that has received a makeover.

Groupings are now based on science types: Basic Science, Clinical Science and Population. There are also groupings for "Frontiers in Science" and "Special Focus." All told, there are 30 tracks you can follow under these various umbrellas.

"Frontiers in Science" — with separate ones for vascular medicine and arrhythmias — are the deep dives that could feel like a meeting within the meeting. Sellke describes these offerings as a way of "getting a large amount of information in a very consolidated amount of time."

"Special Focus" areas include Nursing Research Science and the Resuscitation Science Symposium, events that have



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# **Call for Peer Reviewers**

AHA is recruiting reviewers for upcoming study sections. Our reviewers are basic, clinical and population investigators who possess the following minimum qualifications:

- Minimum Assistant Professor (or equivalent) career level
- Current or recent independent peer reviewed funding, typically at national level
- Consistent record of peer reviewed publications within the past five years
- Knowledge of the AHA and commitment to its mission
- AHA Professional Membership is highly desired

If you would like to become a reviewer, please contact Sue Hageman at susan.hageman@heart.org

long piggybacked with Sessions. Newcomers are "Lifelong CHD and Heart Health in the Young" and the Antman-and-Harrington-led event called "Clinical Trialists."

"If you want to know about every aspect of clinical trials — from setup to executing, monitoring, working with the FDA, analysis and more — then go to this session," Sellke said. "You can't cover everything in four hours, but I'm sure it's going to cover as much as possible, with input from international experts.

"It's not just for young members. I think they'll have an interest, but I would love to be there for this entire event, too. I've been involved in these my whole career, so I'm no novice, and I know I can learn a lot from these panelists."

Sellke attended his first Sessions in 1988. He was a cardiac surgery resident, and his boss recommended that he attend to present his work. He enjoyed it so much that he's returned every year since, usually presenting multiple abstracts. In fact, his lab at Brown is making six presentations this year.

Two years ago, Sellke joined the CSSP as an at-large member. A few months later, an illness forced the vice chair to step aside and Sellke took over that spot. He spent about 10 months watching Harrington prepare for the 2014 Sessions, and has spent the last year preparing for this weekend,

along with help from the rest of the CSSP team, his predecessors and AHA staff.

"It's really been a high point in my career," said Sellke, who also will oversee planning of the 2016 Sessions in New Orleans.

Considering how many hours he's carved from his life, personally and professionally, there must be something special about Sessions that drives Sellke.

"What I love is that there's so much going on," he said. "You've got the best clinical information, the best basic science, the best opportunities for networking, amazing plenary sessions and excellent Late-Breaking Clinical Trials. Now we're trying to make it the best for education and maintenance of certification and simulation training."

PAID ADVERTISEMENT

# Sanofi and Regeneron Expert Lectures Series

Join us at **Booth 1328** to learn about PCSK9 inhibition and the unmet need in patients with poorly controlled LDL-C

# Nov 8th

12:00 PM - 12:30 PM **Efficacy, Safety, and Tolerability With PCSK9 Inhibition** 

Harold Edward Bays, MD, FTOS, FACC, FACE, FNLA

3:15 PM - 3:45 PM Efficacy, Safety, and Tolerability of PCSK9 Inhibition in Special Populations

Michael Koren, MD, FACC

Nov 9th

1:00 PM - 1:30 PM Efficacy, Safety, and Tolerability With PCSK9 Inhibition

Norman Lepor, MD, FACC

Nov 10th

10:30 AM - 11:00 AM Efficacy, Safety, Tolerability, and Dosing Options With PCSK9 Inhibition

Paul Thompson, MD

# Visit the Cardiovascular Expert Theaters Lectures sponsored by Sanofi/Regeneron

Nov 8th Booth 1559

11:15 AM - 12:00 PM PCSK9 Inhibition: Long-term Safety and Efficacy

Michael Davidson, MD

Nov 9th Booth 1601

12:00 PM - 12:45 PM PCSK9 Inhibition: Efficacy and Safety With Two Dosing Options

Yehuda Handlesman, MD, FACP, FACE, FNLA

**LDL-C =** low-density lipoprotein cholesterol; **PCSK9 =** proprotein convertase subtilisin/kexin type 9.





# AHA-funded network boosts blood pressure research

esearchers from four institutions are delving into the causes and possible cures for high blood pressure as part of the American Heart Association's new Strategically Focused Research Network on hypertension.

High blood pressure is a leading risk factor for death worldwide, responsible for roughly 7.5 million deaths, according to a 2009 report from the World Health Organization. It's also a risk factor for heart disease, the world's leading cause of death.

The new studies seek to change how the condition is diagnosed and treated and to better understand its molecular basis. Scientists also hope to improve its treatment in young people and provide a new predictor of preeclampsia to help pregnant women get better care.

The network will include investigators from the University of Alabama at Birmingham, Medical College of Wisconsin, Cincinnati Children's Hospital and the University of Iowa.

The AHA will support the Strategically Focused Research Network on hypertension with an investment of \$15 million over four years, beginning this year.

"The four successful centers are all international leaders in the field of hypertension," said Christopher Wilcox, MD, director of the Center for Hypertension, Kidney and Vascular Research at Georgetown University.

"The proposed research entails a vibrant mix of basic studies to better understand the

causes and consequences of hypertension, and population studies to assess their impact in the U.S. population," said Wilcox, who serves as chair of the AHA's Hypertension Council.

At the University of Alabama at Birmingham, researchers want to change how high blood pressure is diagnosed and treated. They will study whether nighttime hypertension can be treated through sodium reduction and how salt consumption leads to high blood pressure at night.

Researchers at the Cincinnati Children's Hospital hope to improve how blood pressure is managed through lifestyle to limit the need for medication in children.

Another goal is to reduce the number of young people who need echocardiograms and to identify genes that influence the development of blood pressure-related organ damage.

Scientists at the Medical College of Wisconsin said the lack of understanding about the molecular basis for hypertension is a big obstacle to examining new approaches for controlling it. To learn more, researchers there will look at how

University of California Los Angelas

University of California Los Angelas

University of Alabama, Morehouse School

University of Medicial University of Medicial University of Medicial University of Morehouse School

University of Texas Southwestern

American Heart Stroke Research Network

Association Association Strategically Focused Hypertension Research Network

Strategically Focused Disparities in CVD Research Network

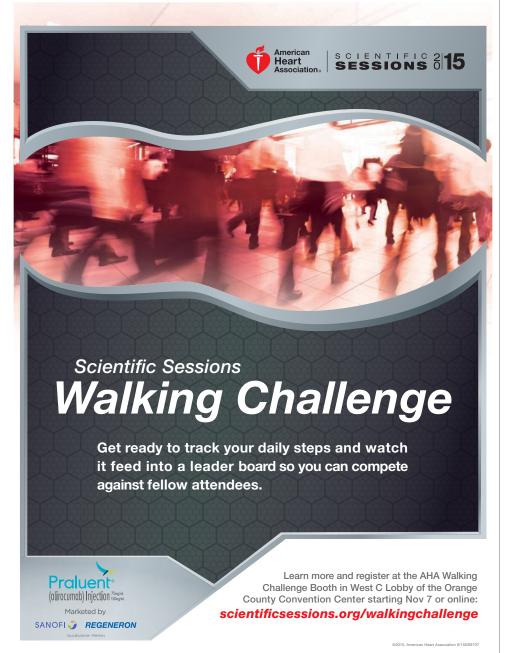
epigenetic changes throughout the entire human genome in people and animals with hypertension to identify new approaches for controlling high blood pressure.

At the University of Iowa, investigators aim to find a reliable, early predictor of preeclampsia to help doctors in areas with lower levels of obstetric care identify the highest-risk patients as early as the sixth week of pregnancy. Preeclampsia is associated with future

cardiovascular disease in both women and their children.

The research networks in Wisconsin and Iowa are supported by special funding from the AHA's Midwest Affiliate.

About 80 million U.S. adults have been diagnosed with high blood pressure. At 50, life expectancy is about five years longer for people with normal blood pressure than for hypertensive people, according to the AHA.





# PAID ADVERTISEMENT

### Corlanor® (ivabradine)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

### Please see package insert for full Prescribing Information 1. INDICATIONS AND USAGE

Corlanor is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction  $\leq 35\%,$  who are in sinus rhythm with resting heart rate  $\geq 70$ beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

# 4. CONTRAINDICATIONS

- Corlanor is contraindicated in patients with
- Acute decompensated heart failure
- Blood pressure less than 90/50 mmHg
   Sick sinus syndrome, sinoatrial block, or 3<sup>rd</sup> degree AV block, unless a functioning demand pacemaker is present

  Resting heart rate less than 60 bpm prior to treatment [see
- Warnings and Precautions (5.3)
- Severe hepatic impairment [see Use in Specific Populations (8.6)]
  • Pacemaker dependence (heart rate maintained exclusively by
- the pacemaker) [see Drug Interactions (7.3]]
  Concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors [see Drug Interactions (7.1)]

# 5. WARNINGS AND PRECAUTIONS

5.1 Fetal Toxicity

Corlanor may cause fetal toxicity when administered to a pregnant woman based on findings in animal studies. Embryo-fetal toxicity and cardiac teratogenic effects were observed in fetuses of pregnant rats treated during organogenesis at exposures 1 to 3 times the human exposures (AUC<sub>0.24th</sub>) at the maximum recommended human dose (MRHD) [see Use in Specific Populations (8.1)]. Advise females to use effective contraception when taking Corlanor [see Use in Specific Populations (8.3)].

### 5.2 Atrial Fibrillation

Corlanor increases the risk of atrial fibrillation. In SHIFT, the rate of atrial fibrillation was 5.0% per patient-year in patients treated with Corlanor and 3.9% per patient-year in patients treated with placebo [see Clinical Studies (14]]. Regularly monitor cardiac rhythm. Discontinue Corlanor if atrial fibrillation develops.

### 5.3 Bradycardia and Conduction Disturbances

Bradycardia, sinus arrest, and heart block have occurred with Corlanor. The rate of bradycardia was 6.0% per patientyear in patients treated with Corlanor (2.7% symptomatic; 3.4% asymptomatic) and 1.3% per patient-year in patients treated with placebo. Risk factors for bradycardia include sinus node dysfunction, conduction defects (e.g., 1st or 2nd degree atrioventricular block, bundle branch block), ventricular dyssynchrony, and use of other negative chronotropes (e.g., digoxin, diltiazem, verapamil, amiodarone). Concurrent use of verapamil or diltiazem will increase Corlanor exposure, may themselves contribute to heart rate lowering, and should be avoided [see Clinical Pharmacology (12.3]]. Avoid use of Corlanor in patients with  $2^{\rm nd}$  degree atrioventricular block, unless a functioning demand pacemaker is present [see Contraindications (4) and Dosage and Administration (2)

# 6. ADVERSE REACTIONS

Clinically significant adverse reactions that appear in other sections of the labeling include:

- Fetal Toxicity [see Warnings and Precautions (5.1)]
   Atrial Fibrillation [see Warnings and Precautions (5.2)]
   Bradycardia and Conduction Disturbances [see Warnings and
- Precautions (5.3)

**6.1 Clinical Trials Experience**Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In the Systolic Heart failure treatment with the I, inhibitor ivabradine Trial (SHIFT), safety was evaluated in 3260 patients treated with Corlanor and 3278 patients given placebo. The median duration of Corlanor exposure was 21.5 months.

The most common adverse drug reactions in the SHIFT trial are shown in Table 2 [see also Warnings and Precautions (5.2), (5.3)].

Table 2. Adverse Drug Reactions with Rates ≥ 1.0% Higher on Ivabradine than Placebo occurring in > 1% on ivabradine in SHIFT

_	Ivabradine N=3260	Placebo N=3278
Bradycardia	10%	2.2%
Hypertension, blood pressure increased	8.9%	7.8%
Atrial fibrillation	8.3%	6.6%
Phosphenes, visual brightness	2.8%	0.5%

<u>Luminous Phenomena (Phosphenes)</u>

Phosphenes are phenomena described as a transiently enhanced brightness in a limited area of the visual field, balos image decomposition (stroboscopic or kaleidoscopic effects), colored bright lights, or multiple images (retinal persistency). Phosphenes are usually triggered by sudden variations in light intensity. Corlanor can cause phosphenes, thought to be mediated through Corlanor's effects on retinal photoreceptors [see Clinical Pharmacology (12.1)]. Onset is generally within the first 2 months of treatment, after which they may occur repeatedly. Phosphenes were generally reported to be of mild to moderate intensity and led to treatment discontinuation in < 1% of patients; most resolved during or after treatment.

**6.2 Postmarketing Experience**Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to their frequency reliably or establish a causal relationship to drug exposure.

The following adverse reactions have been identified during post-approval use of Corlanor: syncope, hypotension, angioedema, erythema, rash, pruritus, urticaria, vertigo, diplopia, and visual impairment

# 7. DRUG INTERACTIONS 7.1 Cytochrome P450-Based Interactions

Corlanor is primarily metabolized by CYP3A4. Concomitant use of CYP3A4 inhibitors increases ivabradine plasma concentrations, and use of CYP3A4 inducers decreases them. Increased plasma concentrations may exacerbate bradycardia and conduction disturbances.

The concomitant use of strong CYP3A4 inhibitors is contraindicated [see Contraindications (4) and Clinical Pharmacology (12.3]]. Examples of strong CYP3A4 inhibitors include azole antifungals (e.g., itraconazole), macrolide antibiotics (e.g., clarithromycin, telithromycin), HIV protease inhibitors (e.g., nelfinavir), and nefazodone.

Avoid concomitant use of moderate CYP3A4 inhibitors when using Corlanor Examples of moderate CYP3A4 inhibitors include diltiazem, verapamil, and grapefruit juice [see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)].

Avoid concomitant use of CYP3A4 inducers when using Corlanor. Examples of CYP3A4 inducers include St. John's wort, rifampicin, barbiturates, and phenytoin [see Clinical Pharmacology (12.3]].

# 7.2 Negative Chronotropes

Most patients receiving Corlanor will also be treated with a betablocker. The risk of bradycardia increases with concomitant administration of drugs that slow heart rate (e.g., digoxin, amiodarone, beta-blockers). Monitor heart rate in patients taking Corlanor with other negative chronotropes

7.3 Pacemakers
Corlanor dosing is based on heart rate reduction, targeting a heart rate of 50 to 60 beats per minute [see Dosage and to be Administration (2)]. Patients with demand pacemakers set to a rate  $\geq$  60 beats per minute cannot achieve a target heart rate < 60 beats per minute, and these patients were excluded from clinical trials [see Clinical Studies (14]). The use of Corlanor is not recommended in patients with demand pacemakers set to rates  $\geq$  60 beats per minute.

# 8. USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy Risk Summary

Based on findings in animals, Corlanor may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies of Corlanor in pregnant women to inform any drug-associated risks. In animal reproduction studies, oral administration of ivabradine to pregnant rats during organogenesis at a dosage providing 1 to 3 times the human exposure (AUC $_{0.24\mathrm{m}}$ ) at the MRHD resulted in embryo-fetal toxicity and teratogenicity manifested as abnormal shape of the heart, interventricular septal defect, and complex anomalies of primary arteries. Increased postnatal mortality was associated with these teratogenic effects in rats. In pregnant rabbits, increased post-implantation loss was noted at an exposure (AUC<sub>0-24in</sub>) 5 times the human exposure at the MRHD. Lower doses were not tested in rabbits. The background risk of major birth defects for the indicated population is unknown. The estimated background risk of major birth defects in the U.S. general population is 2 to 4%, however, and the estimated risk of miscarriage is 15 to 20% in clinically recognized pregnancies. Advise a pregnant woman of the potential risk to the fetus.

Clinical Considerations
Disease-associated maternal and/or embryo/fetal risk

Stroke volume and heart rate increase during pregnancy, increasing cardiac output, especially during the first trimester. Pregnant patients with left ventricular ejection fraction less than 35% on maximally tolerated doses of beta-blockers may be particularly heart-rate dependent for augmenting cardiac output. Therefore, pregnant patients who are started on Corlanor, especially during the first trimester, should be followed closely for destabilization of their congestive heart failure that could result from heart rate slowing

Monitor pregnant women with chronic heart failure in 3rd trimester of pregnancy for preterm birth.

# Animal Data

In pregnant rats, oral administration of ivabradine during the period of organogenesis (gestation day 6-15) at doses of 2.3, 4.6, 9.3, or 19 mg/kg/day resulted in fetal toxicity and teratogenic effects. Increased intrauterine and post-natal mortality and cardiac malformations were observed at doses  $\geq$  2.3 mg/kg/day (equivalent to the human exposure at the MRHD based on AUG<sub>0.24hr</sub>). Teratogenic effects including interventricular septal defect and complex anomalies of major arteries were observed at doses  $\geq$  4.6 mg/kg/day (approximately 3 times the human exposure at the MRHD based on AUC  $_{\!0.24hr}$  ).

In pregnant rabbits, oral administration of ivabradine during the period of organogenesis (gestation day 6-18) at doses of 7, 14, or 28 mg/kg/day resulted in fetal toxicity and teratogenicity. Treatment with all doses  $\geq$  7 mg/kg/day (equivalent to the human exposure at the MRHD based on  $AUC_{0-24 \rm ln}/$  caused an increase in post-implantation loss. At the high dose of 28 mg/kg day (approximately 15 times the human exposure at the MRHD based on AUC<sub>0-24m</sub>), reduced fetal and placental weights were observed, and evidence of teratogenicity (ectrodactylia observed in 2 of 148 fetuses from 2 of 18 litters) was demonstrated.

In the pre- and postnatal study, pregnant rats received oral administration of ivabradine at doses of 2.5, 7, or 20 mg/kg/day from gestation day 6 to lactation day 20. Increased postnatal mortality associated with cardiac teratogenic findings was observed in the F1 pups delivered by dams treated at the high dose (approximately 15 times the human exposure at the MRHD based on AUC<sub>0-24hr</sub>).

### 8.2 Lactation

Risk Summary
There is no information regarding the presence of ivabradine in human milk, the effects of ivabradine on the breastfed infant, or the effects of the drug on milk production. Animal studies have shown, however, that ivabradine is present in rat milk [see Data]. Because of the potential risk to breastfed infants from exposure to Corlanor, breastfeeding is not recommended.

Data
Lactating rats received daily oral doses of [14C]-ivabradine (7 mg/kg) on post-parturition days 10 to 14; milk and maternal plasma were collected at 0.5 and 2.5 hours post-dose on day 14. The ratios of total radioactivity associated with  $\Gamma^{4}$ C]ivabradine or its metabolites in milk vs. plasma were 1.5 and 1.8, respectively, indicating that ivabradine is transferred to milk after oral administration.

# 8.3 Females and Males of Reproductive Potential

# Contraception

Corlanor may cause fetal harm, based on animal data. Advise females of reproductive potential to use effective contraception during Corlanor treatment [see Use in Specific Populations (8.1)].

# 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

# 8.5 Geriatric Use

No pharmacokinetic differences have been observed in elderly (≥ 65 years) or very elderly (≥ 75 years) patients compared to the overall population. However, Corlanor has only been studied in a limited number of patients ≥ 75 years of age.

# 8.6 Hepatic Impairment

No dose adjustment is required in patients with mild or moderate hepatic impairment. Corlanor is contraindicated in patients with severe hepatic impairment (Child-Pugh C) as it has not been studied in this population and an increase in systemic exposure is anticipated [see Contraindications (4) and Clinical Pharmacology (12.3]]

8.7 Renal Impairment No dosage adjustment is required for patients with creatinine clearance 15 to 60 mL/min. No data are available for patients with creatinine clearance below 15 mL/min [see Clinical Pharmacology (12.3)].

# 10. OVERDOSAGE

Overdose may lead to severe and prolonged bradycardia. In the event of bradycardia with poor hemodynamic tolerance, temporary cardiac pacing may be required. Supportive treatment, including intravenous (IV) fluids, atropine, and intravenous beta-stimulating agents such as isoproterenol, may be considered.

This Brief Summary is based on the Corlanor  $\!\!^{\circledcirc}$  Prescribing Information v1, 04/15

# *A*MGEN

Corlanor® (ivabradine) Manufactured for: Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 Patent: http://pat.amgen.com/Corlanor/

Add Corlanor® to maximally tolerated doses of beta-blockers and help give appropriate patients with stable, symptomatic chronic heart failure...

# MORE HOME. LESS HOSPITAL.



Learn how you can **DO MORE with Corlanor**® to reduce the risk of hospitalization for worsening heart failure<sup>1</sup>

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# **Indication**

Corlanor® (ivabradine) is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction  $\leq 35\%$ , who are in sinus rhythm with resting heart rate  $\geq 70$  beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

# **Important Safety Information**

- **Contraindications:** Corlanor® is contraindicated in patients with acute decompensated heart failure, blood pressure < 90/50 mmHg, sick sinus syndrome, sinoatrial block, 3<sup>rd</sup> degree atrioventricular block (unless a functioning demand pacemaker is present), a resting heart rate < 60 bpm prior to treatment, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker), and concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors.
- Fetal Toxicity: Corlanor® may cause fetal toxicity when administered to a pregnant woman based on embryo-fetal toxicity and cardiac teratogenic effects observed in animal studies. Advise females to use effective contraception when taking Corlanor®.
- Atrial Fibrillation: Corlanor® increases the risk of atrial fibrillation. The rate of atrial fibrillation in patients treated with Corlanor® compared to placebo was 5% vs. 3.9% per patient-year, respectively. Regularly monitor cardiac rhythm. Discontinue Corlanor® if atrial fibrillation develops.

- Bradycardia and Conduction Disturbances: Bradycardia, sinus arrest and heart block have occurred with Corlanor®. The rate of bradycardia in patients treated with Corlanor® compared to placebo was 6% (2.7% symptomatic; 3.4% asymptomatic) vs. 1.3% per patient-year, respectively. Risk factors for bradycardia include sinus node dysfunction, conduction defects, ventricular dyssynchrony, and use of other negative chronotropes. Concurrent use of verapamil or diltiazem also increases Corlanor® exposure, contributes to heart rate lowering, and should be avoided. Avoid use of Corlanor® in patients with 2<sup>nd</sup> degree atrioventricular block unless a functioning demand pacemaker is present.
- Adverse Reactions: The most common adverse reactions reported at least 1% more frequently with Corlanor® than placebo and that occurred in more than 1% of patients treated with Corlanor® were bradycardia (10% vs. 2.2%), hypertension or increased blood pressure (8.9% vs. 7.8%), atrial fibrillation (8.3% vs. 6.6%), and luminous phenomena (phosphenes) or visual brightness (2.8% vs. 0.5%).

Please see Brief Summary of full Prescribing Information on adjacent page.

 $\textbf{Reference: 1.} \ \, \textbf{Corlanor}^{\circledcirc} \ \, \textbf{(ivabradine)} \ \, \textbf{Prescribing Information, Amgen.}$ 



Cardiovascular



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