

## INSIDE

- 2** Highlights from the Program Chair
- 3** Check. Change. Control. Helping African-Americans control hypertension
- 4** Insights from Early Career Day
- 5** AHA journals ranked at the top of their fields once again
- 6** JAMA now indexed by Thomson Reuters (formerly ISI)
- 7** Eat Less Salt offers recipes and tools to lower salt consumption
- 8** Heart-Check offers consumers a guide to quality heart, stroke care
- 9** Taking aim in the global fight against NCDs
- 13** Teaching Gardens planting seeds for healthy change
- 15** Hands-Only CPR kiosk teaches travelers lifesaving skill
- 18** Training students in CPR saves lives

## Guideline discussions, 20 LBCTs highlight Sessions' return to Dallas

**R**oughly 20 years ago, a newly minted MD from the University of Massachusetts Medical School roamed the halls of Scientific Sessions for the first time.

He absorbed lectures about his specialty, interventional cardiology. He befriended peers and leaders from his field and beyond. He enjoyed it all so much that he returned as a poster presenter – spending weeks preparing, getting multiple critiques by senior colleagues as well as the practical advice to carry extra glue sticks just in case his printouts started peeling from the boards.

As his career progressed – from junior investigator to senior investigator, then to a leader in academic medicine – Robert Harrington, MD, FAHA, FACC, not only kept coming to Sessions, he became one of the planners. And this year, his first as Chair of the Committee on Scientific Sessions Program, he's proud to say that he and his colleagues have put together an event that will enhance Sessions' reputation as the premier gathering of cardiovascular thought in the United States.

More than 18,000 attendees from more than 105 countries will roam the halls of the Dallas Convention Center from Saturday through Wednesday. Another 1.5 million professional attendees are expected to be involved virtually, absorbing groundbreaking insights, lectures from prestigious speakers and thought-provoking discussions about basic,



credit: Matt Pasant

translational, clinical and population science.

"That's what I think makes Sessions a unique meeting, that breadth of science being presented," said Harrington, Chair of the Department of Medicine at the Stanford University School of Medicine. "Science is moving more and more toward being a team-based activity and understanding how to connect clinical observation and apply it is facilitated by getting all these different types of scientists together."

The amount of science is staggering:

- 4,176 abstracts, plus 30 late-breaking basic science abstracts

- 758 sessions – 443 original research, 315 invited
  - Of those original research sessions, 306 are posters, 128 are oral, five are Late-Breaking Clinical Trials and four are Clinical Science Special Reports
  - 20 Late-Breaking Clinical Trials will be presented, along with 19 Special Reports

"The quality and volume of the science offered at Scientific Sessions this year is remarkable – even by the extraordinarily high standards of this meeting," said AHA President Mariell Jessup, MD, FAHA, and CSSP Chair

SCIENTIFIC SESSIONS continued on page 16

## Get With The Guidelines targets AFib patients

**T**here's a new tool for more effective treatment of the growing number of patients with atrial fibrillation.

The American Heart Association recently launched Get With The Guidelines®-AFIB, which facilitates healthcare providers' application of evidenced based therapies in the care of patients hospitalized for treatment of atrial fibrillation. The program provides clinical decision support and real-time reporting to assist hospitals in tracking their performance related to several key metrics.

The program is the fifth and latest module in Get With The Guidelines, which is the largest national hospital-based quality improvement program for cardiovascular disease. It identifies gaps in treatment and attempts to prevent complications and reduce risks by

ATRIAL FIBRILLATION continued on page 14



## Carrying FAHA designation special

**K**iran Musunuru has a long list of accomplishments for someone who's only 37 – an MD, PhD and MPH. But the title he holds most dear? FAHA.

Musunuru, who splits his time between cardiology, working as a research scientist and teaching genetics and biochemistry to undergraduates at Harvard University, earned his FAHA during last year's Scientific Sessions. It was an accomplishment he had sought since joining the American Heart Association as a Premium Professional Member in 2006.

"FAHA really takes something extra," Musunuru said. "It really signifies the highest level of commitment to the ultimate mission of the American Heart Association."

### Origins of FAHA

The American Heart Association was founded in

For the complete list of FAHAs, see pages 10-11.

1924 by six cardiologists. It's not clear, however, exactly when fellowship programs began.

For many years, fellows were elected by individual scientific Councils. Honorees were designated either Fellows or Associate Fellows of a particular Council.

In 2000, the AHA's Science Advisory Coordinating Committee authorized the Council on Clinical Cardiology to conduct a pilot program designating elected



Kiran Musunuru, MD, PhD, MPH, FAHA

FAHA continued on page 12

## TODAY AT SESSIONS

Don't miss today's highlighted presentations and events. For a complete schedule, see the Final Program or view it online at [scientificsessions.org](http://scientificsessions.org).

### 9–11:45 a.m.

*Early Career: Opening General Session*  
Ballrooms C1 & C2

### 9:15–9:45 a.m.

*2013 Awards for Lifetime Achievement in Cardiac Resuscitation Science and Trauma Resuscitation Science*  
Trinity Ballroom, Omni Dallas Hotel

### 2:15–3:30 p.m.

*Samuel A. Levine Young Clinical Investigator Award Finalists*  
Room C140

### 2:30–4 p.m.

*ReSS Best of the Best Oral Abstract Presentations*  
Trinity Ballroom, Omni Dallas Hotel

### 3:45–5 p.m.

*Laennec Young Clinician Award Finalists*  
Room C140

### 5–6:30 p.m.

*Early Career Reception*  
Hall F lobby

### 5:15–6:45 p.m.

*ReSS Poster Session and Reception*  
Dallas Ballroom D-H, Omni Dallas Hotel

### 7–9 p.m.

*AHA Cardiovascular Evening Symposium: Diabetes and Cardiovascular Disease: Current Controversies*  
Dallas Ballroom BC, Omni Dallas Hotel

# Highlights from the Program Chair

By Robert Harrington, MD, FAHA, FACC, Committee on Scientific Sessions Program Chair

## The American Heart Association

is proud to welcome you to Dallas, home of our headquarters, for the 2013 Scientific Sessions. AHA staff and leadership have worked tirelessly since the conclusion of last year's meeting in Los Angeles to make sure you feel right at home for the next five days.

No matter where we convene, the annual Scientific Sessions is always home to the latest and greatest in cardiovascular medicine and research, and this year is certainly no exception. Featuring 5,000 presentations, 4,000 abstracts and 1,000 invited faculty, the 2013 program covers seven multidisciplinary cardiovascular cores, including 26 specialized programming tracks.

Today, we start things off with a full day of programming devoted to our Early Career attendees. In many ways, the EC program is one of the real highlights of the meeting, as it truly represents “the future.”

By design, the morning EC sessions are broad to provide invaluable insights into general career development themes. Part one of the Early Career Opening General Session, for example, will cover topics such as how to get published in the top journals; the role that AHA can play in early career development; how to find research funding; and tips for navigating and getting the most out of the Scientific Sessions.

Part two of the morning session will feature a distinguished lineup of some of

cardiovascular science's top researchers, who will discuss new research paradigms and opportunities for both clinical and basic science investigators.

The afternoon Early Career program is organized around council activity, with sessions designed to provide insights into what's hot in particular fields. Afternoon sessions will also introduce attendees to important topics such as keys to academic success and advice for getting started as an Early Career investigator.

While today's primary focus is the Early Career attendee, the presentations hit upon topics relevant to a much broader audience. Topics such as mentorship, grant writing and journal submissions are just a few examples. I encourage attendees at all stages of their careers to attend these worthwhile sessions.

In addition to today's great EC programming, we have made a concerted effort to promote networking among attendees throughout the day. This evening's Laennec Clinician awards, which highlight the exciting work of Early Career attendees, is another great networking opportunity.

The day's programming concludes with the first of three evening symposia sched-



Robert Harrington, MD, FAHA, FACC

uled over the course of the meeting. These symposia are excellent opportunities to continue each day's learning activities in the more informal setting of a dinner program. The programming for each is selected and planned by CSSP and consistent with the high standards of the meeting.

Tonight's offering, “Diabetes and Cardiovascular

Disease: Current Controversies,” will be held from 7–9 p.m. at the Omni Dallas Hotel. The symposium will cover topics including the most appropriate hyperglycemic agent(s) for a variety of patient types; the causes and effects of noncompliance with glycemic control agents; the current evidence guiding treatment selection for patients with diabetes and multivessel CAD; and the most appropriate approach – medical therapy, PCI or surgery – to manage stable coronary artery disease in patients with diabetes.

Again, welcome to the 2013 American Heart Association Scientific Sessions, the premier cardiovascular research and instructional meeting in the world. We're happy to have you here and look forward to an educational, enlightening and enjoyable week. ▼

## Don't miss this new session!

Clinical Practice Guidelines  
for Prevention: Next Steps



Wednesday, Nov. 20, 9 AM–11:20 AM  
Omni Dallas Hotel, Dallas Ballroom D-H



## Learn at Heart

with the Professional Education Center

The American Heart Association and the American College of Cardiology are excited to provide a series of new cardiovascular prevention guidelines for the assessment of cardiovascular risk, lifestyle modifications that reduce risk, management of elevated blood cholesterol, and management of increased body weight in adults.

To support the implementation of these guidelines, the American Heart Association is making a series of web tools available for download now:

- Narrated slidesets on the content of each guideline available at [learn.heart.org](http://learn.heart.org)
- The new Pooled Cohort Equations CV Risk Calculator available at [my.americanheart.org/cvriskcalculator](http://my.americanheart.org/cvriskcalculator)

Visit the Professional Education Center.

[learn.heart.org](http://learn.heart.org)

## EARLY CAREER PROGRAM SATURDAY, NOV. 16

SESSION NUMBER	SESSION TITLE	LOCATION	TIME
EC.21	Peripheral Vascular Disease – Fellows in Training Workshop	Ballroom A1	8 a.m.–5:20 p.m.
EC.02	Early Career Opening General Session – Part 1	Ballrooms C1 & C2	9–10 a.m.
EC.03	Early Career Opening General Session – Part 2: New Paradigms and Opportunities in Cardiovascular Research for Clinical and Basic Science Researchers	Ballrooms C1 & C2	10–11:45 a.m.
EC.08	Cardiac Electrophysiology Sessions for AHA Early Career Day – Part 1: Considering Electrophysiology as a Specialty	Room D227	1–1:45 p.m.
EC.12	How to Thrive as an Early Career Academic Cardiovascular Specialist <i>Planned by the Council on Clinical Cardiology</i>	Room C140	1–2 p.m.
EC.07	Challenges at the Start of Your Cardiac Surgical Practice <i>Planned by the Council on Cardiovascular Surgery and Anesthesia</i>	Room C150	1–2:30 p.m.
EC.11	Mission Possible: Keys to Early Career Academic Success – Part 1 <i>Planned by the Council on Basic Cardiovascular Sciences</i>	Room C143	1–2:40 p.m.
EC.04	Training and Funding: How to Get Started as an Early Career Investigator <i>Planned by the Quality of Care and Outcomes Research/Epidemiology and Prevention/Lifestyle and Cardiometabolic Health Councils</i>	Room D223	1–2:45 p.m.
EC.13	Choosing Your Path <i>Planned by the Council on Cardiovascular Disease in the Young</i>	Room C144	1–3 p.m.
EC.06	How to Build a Roadmap for Your Career in Functional Genomics and Translational Biology <i>Planned by the Council on Functional Genomics and Translational Biology</i>	Room D163	1–3 p.m.
EC.01c	Developing a Career in Physical Activity Research: Is Funding Available?	Room C146	1–3:45 p.m.
EC.10	Cardiac Imaging Boot Camp <i>Planned by the Council on Cardiovascular Radiology and Intervention</i>	Room D170	1–5 p.m.
EC.09	Interventional Cardiology Fellows Program	Room D226	1–5 p.m.
EC.05	Mechanisms and Models of Early Career Success in Cardiovascular and Stroke Nursing Science <i>Planned by the Council on Cardiovascular and Stroke Nursing</i>	Room D168	1–5 p.m.
EC.14	Cardiac Electrophysiology Sessions for AHA Early Career Day – Part 2: My Story—A Panel Discussion on the Different Types of EP Career Options	Room D227	1:45–3 p.m.
EC.17	How to Develop a Successful Research Career <i>Planned by the Epidemiology and Prevention/Lifestyle and Cardiometabolic Health Councils</i>	Room D223	3–4:20 p.m.
EC.16	Mission Possible: Keys to Early Career Academic Success – Part 2 <i>Planned by the Council on Basic Cardiovascular Sciences</i>	Room C143	3–4:45 p.m.
EC.18	Hottest of the Hot in FGTB Research <i>Planned by the Council on Functional Genomics and Translational Biology</i>	Room D163	3–5 p.m.
EC.15	Starting a Successful Career in Quality of Care and Outcomes Research <i>Planned by the Council on Quality of Care and Outcomes Research</i>	Room D222	3–5 p.m.
EC.19	Cardiac Electrophysiology Sessions for AHA Early Career Day – Part 3: Early Career EP Clinical Session	Room D227	3:15–5 p.m.

## Check. Change. *Control.* helping African-Americans control hypertension

**A**frican-Americans can learn how to prevent and manage hypertension with Check. Change. *Control.*, a community program launched by the American Heart Association this year. The evidence-based program uses volunteer health mentors to motivate participants to self-monitor their blood pressure and to upload and track their readings in Heart360®, the AHA's free Web-based tool.

About 43 percent of African-American men and 47 percent of African-American women have high blood pressure, according to the AHA's High Blood Pressure Statistical Fact Sheet 2013 Update. By comparison, about one-third of white men and women have hypertension.

The AHA initially provided grants of \$20,000 to the top 18 markets to implement the pilot. The program has since expanded to 90 programs in 60 markets, including Los Angeles, Houston and Philadelphia. The goal is to enroll 30,000 African-Americans by the end of 2014. About 13,000 African-Americans and participants of other ethnicities have signed up so far.

As of August, more than 30,000 readings had been uploaded by nearly 9,400 participants. The results show an overall decrease in blood pressure, especially for those who started out

with high blood pressure and uploaded at least two readings per month for four consecutive months. Those participants saw a 27/10.5 drop in blood pressure.

American Heart Association volunteer Patricia Lane, MBA, BSN, RN, administrative director of neurosciences at Bon Secours Richmond Health System, facilitates the program in Richmond, Va. It was the mentorship component that convinced her to get involved. Overall, the program has about 1,500 volunteer health mentors, which include both healthcare professionals and people without medical experience.

"Everyone always talks about education, which is of course important. But with the mentors, there's accountability," Lane said. "There's that person there to make sure you check it, change it and control it. That's how you really become hardwired for those lifestyle changes."

Each program engages participants with strategies unique to the community. Programs include faith-based, corporate, healthcare and community models. Zumba classes have been a



Patricia Lane, MBA, BSN, RN

particularly successful strategy in Richmond, Lane said. A few dozen participants gather twice a week for a 45-minute class. They get their blood pressure checked before each class.

Program participants without access to a blood pressure monitor were given one.

"We made sure they knew how to use it, how to read it and what to do with it afterward,"

said Lane, who also participates in the program. Every Friday at 2 p.m., an alarm on her phone reminds her to take her blood pressure.

"There are people walking around who have no idea they have high blood pressure," Lane said. "And they don't know it means they are at higher risk for stroke and heart disease. Once they know their numbers and understand their numbers, they can do something about it."

Healthcare professionals interested in becoming a volunteer health mentor should contact local AHA offices. Local AHA staff can also provide information about enrollment events, where they can be connected with a mentor. For more information, visit [heart360.org](http://heart360.org). ▼

## MEMBER SPOTLIGHT

### Peter W. Wilson, MD

*Professor of Medicine in the Cardiology Division, Professor of Public Health at the Rollins School of Public Health, and Director of Epidemiology and Genomic Medicine at the Atlanta VA Medical Center*



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

I have been attending AHA meetings since around 1980. I have been a professional member for close to 30 years.

### Why did you join?

I joined because my research has focused on preventive cardiology. The fall Scientific Sessions and the spring EPI/NPAM meeting are the key meetings that I have attended over the years.

### Are you involved in any AHA councils?

Yes, I am a Fellow of NPAM, now called the Lifestyle and Cardiometabolic Health Council, and a Fellow of the EPI Council. I am currently chair of the Lifestyle and Cardiometabolic Health Council.

### What do you enjoy most about these roles?

Council activities and their committees are the gears of the American Heart Association. They keep the engine going. Volunteers are the fuel and oil that keeps the AHA moving forward.

### How else are you involved with AHA?

I have worn a variety of AHA hats. I have represented the AHA at a smoking tax legislation meeting at the Georgia State House, participated in local AHA fundraising walks in Atlanta and attended Lobby Day in Washington, D.C. I also have sat on a committee that reviews the AHA scientific publications that are proposed and published in the AHA journals.

### Why is membership valuable to you?

AHA membership opens doors to getting involved. When positions on committees are open, the AHA first turns to the current members to "get the job done." There are a lot of tasks that need to be organized in order for the large AHA meetings to take place. Position papers have to move forward and other activities to be coordinated. The AHA members contribute a great deal to make those things happen.

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

Volunteer your time and efforts to the AHA. Get involved. There are all sorts of opportunities. We have a common goal to reduce the burden of cardiovascular disease and each volunteer is highly valued. ▼

## CAREER PROGRESSION: JORDAN MILLER, PhD

At Scientific Sessions past, Jordan Miller, PhD, noticed that poster exhibits often were overshadowed in prestige and attendance by oral presentations taking place simultaneously in different areas.

"Even the most brilliant physicians and scientists can't be in two places at once, and that problem is amplified at meetings that are this large," he said.

After Miller became a member of the ATVB Council's Committee for Scientific Sessions Programming (CSSP), it was clear that this concern was widespread throughout the Council, and the ATVB CSSP chairs – Drs. William Chilian and Greg Shelness – have continually championed changes to help improve Scientific Sessions. This year, under the leadership of Drs. Robert Harrington and Kenneth Bloch (Chair and Vice Chair, respectively of the full CSSP encompassing all councils), many of the changes discussed at the ATVB Council's CSSP meeting and elsewhere were implemented at Scientific Sessions.

"The amount of concomitant programming between posters and oral presentations is reduced this year," said Miller, who serves on the ATVB Council's CSSP and is chair of the council's Early Career Committee. "There are also 'poster professors,' who will give guided tours of each session and engage presenters. We're hoping this leads to a significant increase in attendance for the poster presentations,

Each day in this spot, we will profile an investigator in various career stages, from early career to distinguished veteran.

which is what a large number of young investigators are assigned."

Miller – a 38-year-old researcher in the Division of Cardiovascular Surgery and an assistant professor at the Mayo Clinic in Rochester, Minn. – is only a few years removed from being an early career investigator himself.

He joined the AHA in 2001 and became more involved with the organization and the ATVB Council in 2005, when he moved from the University of Wisconsin to the University of Iowa for postdoctoral training.

He remembers being in awe at his first Scientific Sessions, in 2005.

"You'd look at it and say, 'Gosh, it's sensory overload,'" he said. "I also noticed after my first few years that there was a progressive reduction of the visibility and attendance of young researchers, particularly in ATVB."

Those experiences helped convince him that he wanted to do whatever he could to help the cause of young investigators. He said his three primary mentors – Drs. Michael Joyner, Jerome Dempsey and Donald Heistad – "ingrained in me that if you get the chance to give young people the opportunities to do something great, a lot of them will."

To that end, he helped organize the

ATVB Early Career Competition, which highlights work by outstanding young investigators and has created more interest in Scientific Sessions among early career members in the council.

"While I don't think the AHA will ever become an excessively early-career-centric organization, we provide balance to the equation," Miller said. "If we can contribute to something the American Heart Association is doing, terrific. If we disagree with the direction of something, we've been put in position to be listened to by ATVB and AHA leadership. It's been all I've hoped for."

Miller also is chair of the ATVB Council's Communications Committee.

"The biggest question is: How do you get young people to become members and keep them as active and engaged members in the ATVB council?" he said. "You want them to get involved so they feel they have an active voice in the American Heart Association."

He and other committee leaders recently turned to social media to get more young investigators involved. "And also to reach out to the mid-career and senior, too," he said. "It's not just about the young people, it's about everybody." ▼



# Inspiring Possibility: One investigator's insights from Early Career Day at Scientific Sessions

**A** November trip to Chicago served as the culmination of an elective cardiology sub-internship I would later recognize as a turning point in my medical training. It was my first time attending the American Heart Association Scientific Sessions, and in 2006, I anticipated discussions of drug-eluting stent safety, and results from the Open Artery Trial (OAT) assessing late angioplasty for occluded infarct-related arteries. Actually, the highlight for me took place just prior to the opening plenary session, as I watched Professor Eugene Braunwald address a crowd of trainees with a precursor to his lecture on "Adventures in Cardiovascular Research."

Now a cardiology fellow at Brigham and Women's Hospital, I have since had the privilege of interacting with Dr. Braunwald at our own Fellows' Reports. I have heard him retell the story of the advent of transbronchial and later transeptal cardiac catheterization; of defining the natural history of severe calcific aortic stenosis prior to the adoption of widespread surgical intervention; of the dramatic discovery of "functional aortic stenosis" (now known as hypertrophic obstructive cardiomyopathy) in a young patient in the operating theater; of the realization that carotid sinus stimulation not only alleviated



Written by Viviany R. Taqueti, MD, a member of the American Heart Association's Membership & Communications Committee, Clinical Cardiology Council; this viewpoint is adapted from her volunteer activities with AHA's *Connections* newsletter.

angina, but normalized ST segment elevation in a patient in the throes of MI, leading to a revolutionary idea in thrombolysis.

The narratives are extraordinary. Speaking in a low rumble, he is crystal clear, careful to identify events by the proper chronology, and to give credit to co-investigators he mentions by full names. He refers to his colleagues and their collective scientific legacies as his intellectual offspring. He emphasizes the importance of focusing on big questions and the act of choosing a mentor as the single most consequential career decision one can make. He peppers his stories with personal anecdotes of unlikely collaborations started at the taxi stand, or over dinner at the local housing complex of the former National Heart Institute. And then he goes on to summarize "10 tips for a successful career in translational research."

Effortlessly, he continues to command a crowd, bringing together generations that include visiting students and longtime disciples. We listen in silence, amazed and delighted by the old stories. In them, cardiology as we know it comes to life. In our minds, we contrast the world he depicts with the more familiar hospital wards and research laboratories of today. He recounts how, at my age, he became Chief of Cardiology, and not long thereafter, Chair of Medicine. He talks of the nonexistence of investigational review boards or of informed consent. At its simplest, there was an observation. And from that careful observation, there were possibilities.

Bearing witness to these stories is invaluable. For me, these experiences provide context for what we set out to do every day in academic cardiology. There is little more powerful than hearing Dr. Braunwald tell of a difficult time, then watch him light up as he describes how a perceived mistake blossomed into discovery. It provides a humanizing and inspiring complement to reading about his latest successful randomized clinical trial.

As many of us wrestle with the future of academic research in an era of constraints, his words provide perspective. Trainees of my generation grew up with the idealism of the academic physician-scientist as the "triple threat" master clinician, scientist and educator. Listening to Dr. Braunwald, I am reminded that this construct is actually relatively new, matured over the last half-century with the advent of hypothesis-driven research. This opened up an already rich world of clinical observations to even richer possibilities afforded by the ready path from bench to bedside, and back.

These days, it can be difficult to maneuver the wards or labs of academic institutions without daily reminders of the growing demands and all-consuming complexities inherent in modern clinical care, scientific research, and post-graduate training. In an increasingly scrutinized clinical environment that values volume, and in the future, outcomes; an increasingly competitive research environment that rewards big science while remaining vulnerable to political volatility; and an increasingly strained training environment that defaults to longer, specialized tracks while simultaneously limiting hours and hands-on experience, many are questioning the viability of the path to "triple threat."

But as Dr. Braunwald notes, much as the concept of the academic physician-scientist evolved before, it is evolving

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# AHA journals ranked at top of their fields once again

**A**merican Heart Association journals celebrated another notable year, marked by top rankings in their fields, new digital offerings, and improved features and benefits.

“Our main objective remains constant: providing the most important evidence-based information and expert perspective in cardiology today,” said *Circulation* Editor-in-Chief Joseph Loscalzo, MD, PhD, FAHA.

*Circulation* continued its top ranking in the Peripheral Vascular Disease and the Cardiac & Cardiovascular Systems subject categories (2012 *Journal Citation Reports*®, Thomson Reuters, 2013). It ranks No. 1 for Impact Factor, 5-Year Impact Factor, *Article Influence*® Score, and *Eigenfactor*® Score.

*Arteriosclerosis, Thrombosis, and Vascular Biology (ATVB)*, *Circulation Research*, *Hypertension*, and *Stroke* each claimed the No. 1 spot in its respective immediate field of study.

The *Circulation*-branded journals — *Circulation: Arrhythmia and Electrophysiology*, *Circulation: Cardiovascular Genetics*, *Circulation: Cardiovascular Imaging*, *Circulation: Cardiovascular Interventions*, *Circulation: Cardiovascular Quality and Outcomes*, and *Circulation: Heart Failure* — remained among the leading cardiology journals. Most are ranked as the top journal in their subspecialty area, and all are among the top 15 in the Cardiac & Cardiovascular Systems subject category. For more details on rankings for AHA journals, visit [www.ahajournals.org/site/misc/Impact\\_Factor.xhtml](http://www.ahajournals.org/site/misc/Impact_Factor.xhtml).

AHA journals' apps are available as free downloads at the iTunes App Store, including free sample issues for each journal.

## EARLY CAREER DAY

continued from previous page

again. The profound, perhaps inevitable changes underway are providing new opportunities for creative thinking, including better utilization of available resources by forging new collaborations to approach existing challenges. As he hints, the thrombocardiologist of the 20th century is becoming the diabetocardiologist of the 21st, and so on. Opportunity is here, and those that persevere in novel ways, guided by an inner compass grounded in promoting health and healing patients, will make important contributions.

And therein lies the value of activities like Early Career Day. It is through these kinds of programs that I have had the opportunity to interact informally with the greats of our profession, to hear from thought leaders in unconventional forums as they share a bit about their experiences as they happened, with sometimes surprising results. These reflections are critical for fostering context and confidence, a sense of possibility, particularly beyond the confines of any one local institution. It is easy to underestimate the impact this can have on trainees.

Back at McCormick Place later that Saturday, I watched with pride as the second-year fellow with whom I had worked as a medical student presented the case of a patient with an unusual manifestation of amyloid heart disease for the Laennec Clinical Cardiology award; that fellow would later become my attending and research collaborator. It was the first time I felt I was part of a cardiology community. And it was inspirational. ▼

The initial free trial periods have expired for the Wolters Kluwer Health apps, with full content now limited to member and non-member subscribers. To claim access to the iPad editions of the journals to which you subscribe, visit [www.ahajournals.org/site/misc/ipadapps.xhtml](http://www.ahajournals.org/site/misc/ipadapps.xhtml) for instructions. *JAHA* — *Journal of the American Heart Association* is always accessible for free.

The AHA Scientific Statements and Guidelines for 2012, collectively published in January as a free iPad supplement, also include the AHA/ASA “Heart Disease and Stroke Statistics—2013 Update.” The supplement is free through any of the 11 AHA journal apps produced by Wolters Kluwer Health. If you don't have an iPad, you can access all AHA Statements and

Guidelines at [my.americanheart.org/statements](http://my.americanheart.org/statements).

At [www.ahajournals.org](http://www.ahajournals.org), AHA/ASA members have online access to full content, depending on membership level. Anyone can access tables of contents and article abstracts, sign up for electronic table of contents alerts and RSS feeds, and read Editor's Picks.

The six *Circulation*-branded journals successfully transitioned to digital-only publications in January, allowing them to publish an average of 30 percent more content than when launched in 2008. Authors also benefit from no color charges within articles.

The AHA journals further support their global author community with services aimed at improving the publication

experience. Benefits include unparalleled global reach and exposure in academic, research and healthcare institutions; potential inclusion in the AHA's Science News media release program that generates nearly 10 billion media impressions annually; and robust multi-channel marketing generating more than 24 million global market impressions each year.

Visit the AHA HeartQuarters (booth 339) or Wolters Kluwer Health-Lippincott Williams & Wilkins (booth 1613) in the Science & Technology Hall to check out the AHA journals' apps and other new features; pick up a complimentary sample copy of any of the AHA's five print journals; and information for authors, members and subscribers. ▼

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IN THE TREATMENT OF ACUTE CORONARY SYNDROME

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# JAHA now indexed by Thomson Reuters (formerly ISI)

**J**AHA – *Journal of the American Heart Association* is now indexed in the Thomson Reuters (formerly ISI) Science Citation Index Expanded and will receive an Impact Factor in 2014. This is recognition of the stature of the journal and will make publication in *JAHA* more valuable to authors by further enhancing visibility and discoverability of all the articles published.

Coverage of *JAHA* will include all published content beginning with Volume 1, 2012.

Representing all 16 scientific councils, *JAHA* is the voice of the entire American Heart Association and American Stroke Association. The journal's mission is to provide a holistic approach to publishing that offers every AHA/ASA member the opportunity to share unique interests across all cardiovascular and cerebrovascular fields.

In less than two years, *JAHA* has accelerated scientific discovery and enriched education by providing free online access to, and unrestricted noncommercial reuse of, all published articles.

This year, *JAHA* is not only leading the Open Access movement in its field, but remains vigilant and committed to:

- **Quality Science:** *JAHA* underwent a rigorous evaluation of published content before being accepted by Thomson Reuters.
- **Compliance:** *JAHA* became fully compliant with new mandates from Research Councils UK and Wellcome Trust.
- **Expanded Reach:** Articles are now automatically deposited in PubMed Central (now PMC) on publication as required by the National Institutes of Health, Wellcome Trust and other funding agency mandates. This benefits authors and readers alike.

## Other Highlights and facts about *JAHA's* progress

- In 2012, more than 40 percent of submissions came from outside the United States, including 8 percent from Japan, 5 percent from the United Kingdom, 5 percent from Canada and 4 percent from Germany.
- Median time from submission to first decision is less than 25 days.
- Articles are posted online within four weeks of acceptance, after payment of the Article Publication Charge. As an Open Access journal, the payment of an Article Publication Charge is required prior to publication. AHA/ASA members are eligible for discounted Article Publication Charges.
- *JAHA* offers authors the ability to present all aspects of their work. There are no

restrictions on article length and there is unlimited use of color images and video.

- Immediately on publication, *JAHA* content is available in MEDLINE®/PubMed®/Index Medicus and PMC, the free full-text archive of PubMed, as well as 17 additional databases.
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You can pick up a free *JAHA* booklet with featured articles, information for authors, and more at AHA HeartQuarters (booth 339) and from Wiley (booth 1012). Visit online at [jaha.ahajournals.org](http://jaha.ahajournals.org). ▼

PAID

IN THE TREATMENT OF  
ACUTE CORONARY SYNDROME

## HELP MAKE AN IMPACT WITH BRILINTA

BEYOND 30 DAYS, BEYOND THE HOSPITAL,  
BETTER EFFICACY THAN CLOPIDOGREL

**AT 30 DAYS**, BRILINTA plus aspirin reduced the primary composite end point of cardiovascular (CV) death, myocardial infarction (MI),\* or stroke by 12% RRR† (ARR‡ 0.6%) vs clopidogrel plus aspirin.<sup>§1,2</sup>

**AT 12 MONTHS**, BRILINTA plus aspirin significantly reduced the primary composite end point by 16% RRR (ARR 1.9%) vs clopidogrel plus aspirin. The difference between treatments was driven by CV death and MI with no difference in stroke.<sup>§1</sup>

**IMPORTANT SAFETY INFORMATION ABOUT BRILINTA**  
**WARNING: BLEEDING RISK**

- BRILINTA, like other antiplatelet agents, can cause significant, sometimes fatal, bleeding
- Do not use BRILINTA in patients with active pathological bleeding or a history of intracranial hemorrhage
- Do not start BRILINTA in patients planned to undergo urgent coronary artery bypass graft surgery (CABG). When possible, discontinue BRILINTA at least 5 days prior to any surgery
- Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, percutaneous coronary intervention (PCI), CABG, or other surgical procedures in the setting of BRILINTA
- If possible, manage bleeding without discontinuing BRILINTA. Stopping BRILINTA increases the risk of subsequent cardiovascular events

**WARNING: ASPIRIN DOSE AND BRILINTA EFFECTIVENESS**

- Maintenance doses of aspirin above 100 mg reduce the effectiveness of BRILINTA and should be avoided. After any initial dose, use with aspirin 75 mg–100 mg per day

**CONTRAINDICATIONS**

BRILINTA is contraindicated in patients with:

- History of intracranial hemorrhage
- Active pathological bleeding such as peptic ulcer or intracranial hemorrhage
- Severe hepatic impairment because of a probable increase in exposure; it has not been studied in these patients. Severe hepatic impairment increases the risk of bleeding because of reduced synthesis of coagulation proteins
- Hypersensitivity (e.g. angioedema) to ticagrelor or any component of the product

# Eat Less Salt offers recipes and tools to lower salt consumption

**W**ith processed foods and restaurant meals contributing more than 75 percent of the sodium in our diet, *American Heart Association Eat Less Salt* can be a resource to help your patients reduce their sodium intake whether they're eating out or at home.

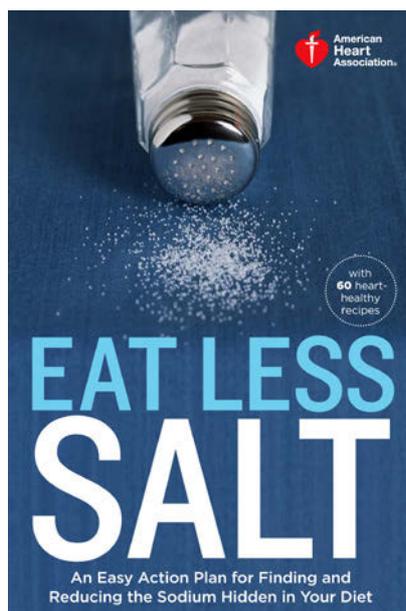
Far more than a cookbook, this is a healthy lifestyle book that offers easy, realistic advice for cutting down on sodium — from understanding nutrition labels to recognizing popular “salt traps.” It also provides tips for keeping sodium in check when eating out and encourages readers to watch the salt in foods such as processed cheese, seasoned bread crumbs, canned broth or vegetables, and even fresh poultry.

Experts agree that increasing awareness

is the first step to reducing sodium.

“Read the label, read the label, read the label,” said Rachel Johnson, PhD, MPH, RD, FAHA, chair of the American Heart Association's Nutrition Committee and professor of nutrition and medicine at the University of Vermont in Burlington. “The sodium has to be listed. Also, be careful when considering herb mixes because they may include salt.”

*Eat Less Salt* also



includes 60 new recipes for popular foods that are usually high in sodium. They include lower-sodium versions of take-out favorites such as beef and broccoli, hot and sour soup, chicken nuggets and pizza; classic comfort foods including country-fried chicken, lasagna, chili, chicken pot pie, potato salad and green bean casserole; and popular restaurant dishes such as tortilla soup, pad Thai,

enchiladas and chicken Parmesan.

“A big limiting factor to reducing sodium is that not enough people are cooking. So much of our salt is from prepared, processed and restaurant foods,” Johnson said. “Until we can further reduce the amount of sodium in our food supply, lower-salt recipes are so helpful.”

Considering that Americans consume an average of more than 3,400 milligrams of sodium daily — far more than the American Heart Association recommends — *Eat Less Salt* provides important health information. It explains how too much sodium can raise your blood pressure, putting you at risk for heart attack, stroke and other cardiovascular diseases.

*Eat Less Salt* was released in March and is available at [ShopHeart.org](http://ShopHeart.org), bookstores and other online book sellers. ▼

ADVERTISEMENT

## PROVEN SUPERIOR TO CLOPIDOGREL IN REDUCING CV DEATH AT 12 MONTHS

CV death secondary end point: RRR with BRILINTA plus aspirin was 21% (ARR 1.1%) vs clopidogrel plus aspirin.<sup>§1</sup>

### INDICATIONS

BRILINTA is indicated to reduce the rate of thrombotic CV events in patients with acute coronary syndrome (ACS) (unstable angina [UA], non-ST-elevation MI [NSTEMI], or ST-elevation MI [STEMI]). BRILINTA has been shown to reduce the rate of a combined end point of CV death, MI, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with PCI, it also reduces the rate of stent thrombosis.

BRILINTA has been studied in ACS in combination with aspirin. Maintenance doses of aspirin >100 mg decreased the effectiveness of BRILINTA. Avoid maintenance doses of aspirin >100 mg daily.



**BLEEDING AT 12 MONTHS, there was no significant difference in Total Major Bleeding (which includes Fatal and Life-threatening bleeding) for BRILINTA plus aspirin vs clopidogrel plus aspirin (11.6% vs 11.2%).**

**There was a somewhat greater risk of Non-CABG-related Major plus Minor Bleeding for BRILINTA plus aspirin vs clopidogrel plus aspirin (8.7% vs 7.0%) and Non-CABG-related Major Bleeding (4.5% vs 3.8%), respectively.**

**PLATO trial did not show an advantage for BRILINTA compared with clopidogrel for CABG-related Bleeding (Total Major 85.8% vs 86.9% and Fatal/Life-threatening 48.1% vs 47.9%, respectively).<sup>||1</sup>**

### WARNINGS AND PRECAUTIONS

- Moderate Hepatic Impairment: Consider the risks and benefits of treatment, noting the probable increase in exposure to ticagrelor
- Premature discontinuation increases the risk of MI, stent thrombosis, and death
- Dyspnea was reported in 14% of patients treated with BRILINTA and in 8% of patients taking clopidogrel. Dyspnea resulting from BRILINTA is self-limiting. Rule out other causes
- BRILINTA is metabolized by CYP3A4/5. Avoid use with strong CYP3A inhibitors and potent CYP3A inducers. Avoid simvastatin and lovastatin doses >40 mg
- Monitor digoxin levels with initiation of, or any change in, BRILINTA therapy

\*Excluding silent MI. †RRR=relative risk reduction. ‡ARR=absolute risk reduction. §The PLATO study compared BRILINTA (180-mg loading dose, 90 mg twice daily thereafter) and clopidogrel (300-mg to 600-mg loading dose, 75 mg daily thereafter) for the prevention of CV events in 18,624 patients with ACS (UA, NSTEMI, STEMI). Patients were treated for at least 6 months and up to 12 months. BRILINTA and clopidogrel were studied with aspirin and other standard therapies.

||PLATO used the following bleeding severity categorization: **Major Bleed-Fatal/Life threatening.** Any one of the following: fatal; intracranial; intrapericardial bleed with cardiac tamponade; hypovolemic shock or severe hypotension due to bleeding and requiring pressors or surgery; clinically overt or apparent bleeding associated with a decrease in hemoglobin (Hb) of more than 5 g/dL; transfusion of 4 or more units (whole blood or packed red blood cells [PRBCs]) for bleeding. **Major Bleed-Other.** Any one of the following: significantly disabling (eg, intraocular with permanent vision loss); clinically overt or apparent bleeding associated with a decrease in Hb of 3 g/dL; transfusion of 2 to 3 units (whole blood or PRBCs) for bleeding. **Minor Bleed.** Requires medical intervention to stop or treat bleeding (eg, epistaxis requiring visit to medical facility for packing).

### ADVERSE REACTIONS

- The most commonly observed adverse reactions associated with the use of BRILINTA vs clopidogrel were Total Major Bleeding (11.6% vs 11.2%) and dyspnea (14% vs 8%)
- In clinical studies, BRILINTA has been shown to increase the occurrence of Holter-detected bradyarrhythmias. PLATO excluded patients at increased risk of bradycardic events. Consider the risks and benefits of treatment

**Please see Brief Summary of Prescribing Information, including Boxed WARNINGS, on the adjacent pages.**

References: 1. Data on file, 1755503, AstraZeneca. 2. BRILINTA Prescribing Information, AstraZeneca.

# Heart-Check leads consumers to quality heart, stroke care

The American Heart Association is making it easier for patients to identify the best medical care for their heart health.

Building on the success of the Heart-Check mark that consumers have used to recognize heart-healthy food in the grocery store for 18 years, the AHA has launched a revamped interactive website that lets patients easily identify medical centers that have earned the Heart-Check hospital accreditation and/or certification.

Using the website, patients can identify accredited and certified hospitals for the type of care they're seeking, locate the nearest centers and learn what the accreditation means for patient care.

"Heart-Check lets individuals know that hospitals are ready and fully capable of providing high-quality heart disease

and stroke care," said Gregg C. Fonarow, MD, FAHA, FACC, chair of the Hospital Accreditation Science Committee and director of Ahmanson-UCLA Cardiomyopathy Center.

The AHA has granted accreditation and/or certification to more than 1,100 hospitals in the United States since the Hospital Accreditation program was launched in 2011.

The accreditation and certification program comprises several levels reflecting the expertise of the facility, including:

- Comprehensive Stroke Center Certification
- Primary Stroke Center Certification
- Advanced Certification in Heart Failure
- Heart Attack (STEMI) Receiving Center Accreditation
- Heart Attack (STEMI) Referring Center Accreditation

The hospital accreditation and certification

underscores the important decisions patients make about their health and the need for them to be better informed about which services meet AHA standards, Fonarow said.

"Better-informed choices and selecting hospitals where evidence-based therapies are more consistently applied can lead to better recoveries as well as a lower risk of having recurrent cardiovascular or stroke events and ending up back in the hospital," he said.

Fonarow said the Hospital Accreditation program is an important tool for patients.



Gregg C. Fonarow, MD, FAHA, FACC

But he cautioned that it shouldn't be the focus in an emergency situation.

"The time that someone is having an acute myocardial infarction or a stroke is not the time to go online and find a hospital with the Heart-Check mark," Fonarow said. "Those individuals need to call 9-1-1 and activate EMS for immediate care."

For more information regarding the American Heart Association's Hospital Accreditation/Certification

programs, or the Heart-Check mark, please visit [www.heart.org/accreditation](http://www.heart.org/accreditation) or [www.heart.org/myhospital](http://www.heart.org/myhospital). ▼

PAID

## BRILINTA® (ticagrelor) Tablets

### WARNING: BLEEDING RISK

- BRILINTA, like other antiplatelet agents, can cause significant, sometimes fatal bleeding [see WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS].
- Do not use BRILINTA in patients with active pathological bleeding or a history of intracranial hemorrhage [see CONTRAINDICATIONS].
- Do not start BRILINTA in patients planned to undergo urgent coronary artery bypass graft surgery (CABG). When possible, discontinue BRILINTA at least 5 days prior to any surgery [see WARNINGS AND PRECAUTIONS].
- Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, percutaneous coronary intervention (PCI), CABG, or other surgical procedures in the setting of BRILINTA [see WARNINGS AND PRECAUTIONS].
- If possible, manage bleeding without discontinuing BRILINTA. Stopping BRILINTA increases the risk of subsequent cardiovascular events [see WARNINGS AND PRECAUTIONS].

### WARNING: ASPIRIN DOSE AND BRILINTA EFFECTIVENESS

- Maintenance doses of aspirin above 100 mg reduce the effectiveness of BRILINTA and should be avoided. After any initial dose, use with aspirin 75-100 mg per day [see WARNINGS AND PRECAUTIONS and CLINICAL STUDIES (14) in full Prescribing Information].

### BRIEF SUMMARY of PRESCRIBING INFORMATION:

For full Prescribing Information, see package insert.

### INDICATIONS AND USAGE

#### Acute Coronary Syndromes

BRILINTA is a P2Y<sub>12</sub> platelet inhibitor indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction). BRILINTA has been shown to reduce the rate of a combined endpoint of cardiovascular death, myocardial infarction or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with PCI, it also reduces the rate of stent thrombosis [see Clinical Studies (14) in full Prescribing Information]. BRILINTA has been studied in ACS in combination with aspirin. Maintenance doses of aspirin above 100 mg decreased the effectiveness of BRILINTA. Avoid maintenance doses of aspirin above 100 mg daily [see Warnings and Precautions and Clinical Studies (14) in full Prescribing Information].

#### DOSAGE AND ADMINISTRATION

Initiate BRILINTA treatment with a 180 mg (two 90 mg tablets) loading dose and continue treatment with 90 mg twice daily. After the initial loading dose of aspirin (usually 325 mg), use BRILINTA with a daily maintenance dose of aspirin of 75-100 mg. ACS patients who have received a loading dose of clopidogrel may be started on BRILINTA. BRILINTA can be administered with or without food. A patient who misses a dose of BRILINTA should take one 90 mg tablet (their next dose) at its scheduled time.

#### CONTRAINDICATIONS

**History of Intracranial Hemorrhage** BRILINTA is contraindicated in patients with a history of intracranial hemorrhage (ICH) because of a high risk of recurrent ICH in this population [see Clinical Studies (14) in full Prescribing Information].

**Active Bleeding** BRILINTA is contraindicated in patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage [see Warnings and Precautions (5.1) and Adverse Reactions (6.1) in full Prescribing Information].

**Severe Hepatic Impairment** BRILINTA is contraindicated in patients with severe hepatic impairment because of a probable increase in exposure, and it has not been studied in these patients. Severe hepatic impairment increases the risk of bleeding because of reduced synthesis of coagulation proteins [see Clinical Pharmacology (12.3) in full Prescribing Information].

**Hypersensitivity** BRILINTA is contraindicated in patients with hypersensitivity (e.g., angioedema) to ticagrelor or any component of the product [see Adverse Reactions (6.1) in full Prescribing Information].

#### WARNINGS AND PRECAUTIONS

##### General Risk of Bleeding

Drugs that inhibit platelet function including BRILINTA increase the risk of bleeding. BRILINTA increased the overall risk of bleeding (Major + Minor) to a somewhat greater extent than did clopidogrel. The increase was seen for non-CABG-related bleeding, but not for CABG-related bleeding. Fatal and life-threatening bleeding rates were not increased [see Adverse Reactions (6.1) in full Prescribing Information]. In general, risk factors for bleeding include older age, a history of bleeding disorders, performance of percutaneous invasive procedures and concomitant use of medications that increase the risk of bleeding (e.g., anticoagulant and fibrinolytic therapy, higher doses of aspirin, and chronic nonsteroidal anti-inflammatory drugs [NSAIDs]). When possible, discontinue BRILINTA five days prior to surgery. Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, PCI, CABG, or other surgical procedures, even if the patient does not have any signs of bleeding. If possible, manage bleeding without discontinuing BRILINTA. Stopping BRILINTA increases the risk of subsequent cardiovascular events [see Warnings and Precautions (5.5) and Adverse Reactions (6.1) in full Prescribing Information].

**Concomitant Aspirin Maintenance Dose** In PLATO, use of BRILINTA with maintenance doses of aspirin above 100 mg decreased the effectiveness of BRILINTA. Therefore, after the initial loading dose of aspirin (usually 325 mg), use BRILINTA with a maintenance dose of aspirin of 75-100 mg [see Dosage and Administration and Clinical Studies (14) in full Prescribing Information].

**Moderate Hepatic Impairment** BRILINTA has not been studied in patients with moderate hepatic impairment. Consider the risks and benefits of treatment, noting the probable increase in exposure to ticagrelor.

**Dyspnea** In PLATO, dyspnea was reported in 14% of patients treated with BRILINTA and in 8% of patients taking clopidogrel. Dyspnea was usually mild to moderate in intensity and often resolved during continued treatment, but occasionally required discontinuation (0.9% of patients taking BRILINTA versus 0.1% of patients taking clopidogrel). If a patient develops new, prolonged, or worsened dyspnea during treatment with BRILINTA, exclude underlying diseases that may require treatment. If dyspnea is determined to be related to BRILINTA, no specific treatment is required; continue BRILINTA without interruption. In the case of intolerable dyspnea requiring discontinuation of BRILINTA, consider prescribing another antiplatelet agent. In a substudy, 199 patients from PLATO underwent pulmonary function testing irrespective of whether they reported dyspnea. There was no significant difference between treatment groups for FEV<sub>1</sub>. There was no indication of an adverse effect on pulmonary function assessed after one month or after at least 6 months of chronic treatment.

**Discontinuation of BRILINTA** Avoid interruption of BRILINTA treatment. If BRILINTA must be temporarily discontinued (e.g., to treat bleeding or for elective surgery), restart it as soon as possible. Discontinuation of BRILINTA will increase the risk of myocardial infarction, stent thrombosis, and death.

**Strong Inhibitors of Cytochrome CYP3A** Ticagrelor is metabolized by CYP3A4/5. Avoid use with strong CYP3A inhibitors, such as atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin and voriconazole [see Drug Interactions (7.1) and Clinical Pharmacology (12.3) in full Prescribing Information].

**Cytochrome CYP3A Potent Inducers** Avoid use with potent CYP3A inducers, such as rifampin, dexamethasone, phenytoin, carbamazepine, and phenobarbital [see Drug Interactions (7.2) and Clinical Pharmacology (12.3) in full Prescribing Information].

#### ADVERSE REACTIONS

##### Clinical Trials Experience

The following adverse reactions are also discussed elsewhere in the labeling:

- Dyspnea [see Warnings and Precautions (5.4) in full Prescribing Information]

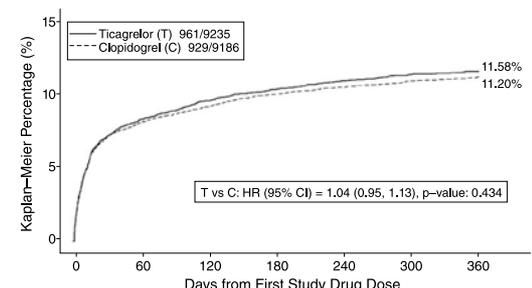
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. BRILINTA has been evaluated for safety in more than 10000 patients, including more than 3000 patients treated for more than 1 year.

**Bleeding** PLATO used the following bleeding severity categorization:

- **Major bleed – fatal/life-threatening.** Any one of the following: fatal; intracranial; intrapericardial bleed with cardiac tamponade; hypovolemic shock or severe hypotension due to bleeding and requiring pressors or surgery; clinically overt or apparent bleeding associated with a decrease in hemoglobin (Hb) of more than 5 g/dL; transfusion of 4 or more units (whole blood or packed red blood cells (PRBCs)) for bleeding.
- **Major bleed – other.** Any one of the following: significantly disabling (e.g., intraocular with permanent vision loss); clinically overt or apparent bleeding associated with a decrease in Hb of 3 g/dL; transfusion of 2-3 units (whole blood or PRBCs) for bleeding.
- **Minor bleed.** Requires medical intervention to stop or treat bleeding (e.g., epistaxis requiring visit to medical facility for packing).
- **Minimal bleed.** All others (e.g., bruising, bleeding gums, oozing from injection sites, etc.) not requiring intervention or treatment.

Figure 1 shows major bleeding events over time. Many events are early, at a time of coronary angiography, PCI, CABG, and other procedures, but the risk persists during later use of antiplatelet therapy.

Figure 1 Kaplan-Meier estimate of time to first PLATO-defined 'Total Major' bleeding event



Annualized rates of bleeding are summarized in Table 1 below. About half of the bleeding events were in the first 30 days.

Table 1 Non-CABG related bleeds (KM%)

	BRILINTA N=9235	Clopidogrel N=9186
Total (Major + Minor)	8.7	7.0
Major	4.5	3.8
Fatal/Life-threatening	2.1	1.9
Fatal	0.2	0.2
Intracranial (Fatal/Life-threatening)	0.3	0.2

As shown in Table 1, BRILINTA was associated with a somewhat greater risk of non-CABG bleeding than was clopidogrel. No baseline demographic factor altered the relative risk of bleeding with BRILINTA compared to clopidogrel. In PLATO, 1584 patients underwent CABG surgery. The percentages of those patients who bled are shown in Table 2. Rates were very high but similar for BRILINTA and clopidogrel.

# Taking aim in the global fight against NCDs

For the first time, governments worldwide will be accountable for progress against heart disease, stroke and other non-communicable diseases, thanks to an international plan to prevent and control NCDs.

As member of the Noncommunicable Disease Alliance (NCD Alliance), the American Heart Association advocated strongly to help develop the World Health Organization's global monitoring framework, which includes nine global prevention and control targets and 25 progress indicators. In May, U.N. member states unanimously adopted the framework and endorsed the WHO's Global NCD Action Plan.

The most ambitious target is the "25 by 25" goal, which calls for a 25 percent reduction in premature mortality from

NCDs by 2025. Other targets aim to combat physical inactivity, sodium intake, raised blood pressure, obesity, diabetes and other modifiable risk factors; to promote drug therapy to prevent heart attack and stroke; and to increase availability of medicines and technologies to treat NCDs.

More than 36 million people die worldwide each year from cardiovascular diseases, cancer, respiratory diseases, diabetes and



Ralph Sacco, MD, FAHA

other NCDs combined, according to the WHO. That number is expected to climb to 44 million by 2020.

Economically, the global burden of NCDs is projected to top \$47 trillion in treatment costs and lost wages over the next two decades, according to a 2011 study from the World Economic Forum and the Harvard School of Public Health. The annual global cost of cardiovascular diseases is estimated to increase from \$863 billion in

2010 to more than \$1 trillion by 2030.

Such data helped convince the U.N. to address what has become a global crisis. American Heart Association CEO Nancy Brown served as a representative for non-governmental organizations on the U.S. delegation at the 2011 summit on NCDs. It was only the second U.N. meeting ever to deal with health, the first targeting HIV/AIDS.

"The 2025 goals aren't meant to be easy," said AHA Past President Ralph Sacco, MD, FAHA, current co-chair of AHA's International Committee and chairman of neurology at the University of Miami Miller School of Medicine. "It's going to take a lot of collaborative, aggressive, preventive efforts. The AHA has been there from the start and is actively engaged in trying to get these targets reached, both domestically and internationally."

## ADVERTISEMENT

### BRILINTA® (ticagrelor) Tablets

2

Table 2 CABG bleeds (KM%)

	Patients with CABG	
	BRILINTA N=770	Clopidogrel N=814
Total Major	85.8	86.9
Fatal/Life-threatening	48.1	47.9
Fatal	0.9	1.1

Although the platelet inhibition effect of BRILINTA has a faster offset than clopidogrel in *in vitro* tests and BRILINTA is a reversibly binding P2Y<sub>12</sub> inhibitor, PLATO did not show an advantage of BRILINTA compared to clopidogrel for CABG-related bleeding. When antiplatelet therapy was stopped 5 days before CABG, major bleeding occurred in 75% of BRILINTA treated patients and 79% on clopidogrel. No data exist with BRILINTA regarding a hemostatic benefit of platelet transfusions.

**Drug Discontinuation** In PLATO, the rate of study drug discontinuation attributed to adverse reactions was 7.4% for BRILINTA and 5.4% for clopidogrel. Bleeding caused permanent discontinuation of study drug in 2.3% of BRILINTA patients and 1.0% of clopidogrel patients. Dyspnea led to study drug discontinuation in 0.9% of BRILINTA and 0.1% of clopidogrel patients.

**Common Adverse Events** A variety of non-hemorrhagic adverse events occurred in PLATO at rates of 3% or more. These are shown in Table 3. In the absence of a placebo control, whether these are drug related cannot be determined in most cases, except where they are more common on BRILINTA or clearly related to the drug's pharmacologic effect (dyspnea).

Table 3 Percentage of patients reporting non-hemorrhagic adverse events at least 3% or more in either group

	BRILINTA N=9235	Clopidogrel N=9186
Dyspnea <sup>1</sup>	13.8	7.8
Headache	6.5	5.8
Cough	4.9	4.6
Dizziness	4.5	3.9
Nausea	4.3	3.8
Atrial fibrillation	4.2	4.6
Hypertension	3.8	4.0
Non-cardiac chest pain	3.7	3.3
Diarrhea	3.7	3.3
Back pain	3.6	3.3
Hypotension	3.2	3.3
Fatigue	3.2	3.2
Chest pain	3.1	3.5

<sup>1</sup> Includes: dyspnea, dyspnea exertional, dyspnea at rest, nocturnal dyspnea, dyspnea paroxysmal nocturnal

**Bradycardia** In clinical studies BRILINTA has been shown to increase the occurrence of Holter-detected bradyarrhythmias (including ventricular pauses). PLATO excluded patients at increased risk of bradycardic events (e.g., patients who have sick sinus syndrome, 2nd or 3rd degree AV block, or bradycardic-related syncope and not protected with a pacemaker). In PLATO, syncope, pre-syncope and loss of consciousness were reported by 1.7% and 1.5% of BRILINTA and clopidogrel patients, respectively. In a Holter substudy of about 3000 patients in PLATO, more patients had ventricular pauses with BRILINTA (6.0%) than with clopidogrel (3.5%) in the acute phase; rates were 2.2% and 1.6% respectively after 1 month.

**Gynecomastia** In PLATO, gynecomastia was reported by 0.23% of men on BRILINTA and 0.05% on clopidogrel. Other sex-hormonal adverse reactions, including sex organ malignancies, did not differ between the two treatment groups in PLATO.

**Lab abnormalities** Serum Uric Acid: Serum uric acid levels increased approximately 0.6 mg/dL from baseline on BRILINTA and approximately 0.2 mg/dL on clopidogrel in PLATO. The difference disappeared within 30 days of discontinuing treatment. Reports of gout did not differ between treatment groups in PLATO (0.6% in each group). Serum Creatinine: In PLATO, a >50% increase in serum creatinine levels was observed in 7.4% of patients receiving BRILINTA compared to 5.9% of patients receiving clopidogrel. The increases typically did not progress with ongoing treatment and often decreased with continued therapy. Evidence of reversibility upon discontinuation was observed even in those with the greatest on treatment increases. Treatment groups in PLATO did not differ for renal-related serious adverse events such as acute renal failure, chronic renal failure, toxic nephropathy, or oliguria.

#### Postmarketing Experience

The following adverse reactions have been identified during post-approval use of BRILINTA. Because these reactions are reported voluntarily from a population of an unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Immune system disorders** - Hypersensitivity reactions including angioedema [see *Contraindications* (4.4) in full Prescribing Information].

#### DRUG INTERACTIONS

**Effects of other drugs** Ticagrelor is predominantly metabolized by CYP3A4 and to a lesser extent by CYP3A5.

**CYP3A inhibitors** [see *Warnings and Precautions* and *Clinical Pharmacology* (12.3) in full Prescribing Information].

**CYP3A inducers** [see *Warnings and Precautions* and *Clinical Pharmacology* (12.3) in full Prescribing Information].

**Aspirin** Use of BRILINTA with aspirin maintenance doses above 100 mg reduced the effectiveness of BRILINTA [see *Warnings and Precautions* and *Clinical Studies* (14) in full Prescribing Information].

**Effect of BRILINTA on other drugs** Ticagrelor is an inhibitor of CYP3A4/5 and the P-glycoprotein transporter.

**Simvastatin, lovastatin** BRILINTA will result in higher serum concentrations of simvastatin and lovastatin because these drugs are metabolized by CYP3A4. Avoid simvastatin and lovastatin doses greater than 40 mg [see *Clinical Pharmacology* (12.3) in full Prescribing Information].

**Digoxin** Digoxin: Because of inhibition of the P-glycoprotein transporter, monitor digoxin levels with initiation of or any change in BRILINTA therapy [see *Clinical Pharmacology* (12.3) in full Prescribing Information].

**Other Concomitant Therapy** BRILINTA can be administered with unfractionated or low-molecular-weight heparin, GPIIb/IIIa inhibitors, proton pump inhibitors, beta-blockers, angiotensin converting enzyme inhibitors, and angiotensin receptor blockers.

#### USE IN SPECIFIC POPULATIONS

**Pregnancy** Pregnancy Category C: There are no adequate and well-controlled studies of BRILINTA use in pregnant women. In animal studies, ticagrelor caused structural abnormalities at maternal doses about 5 to 7 times the maximum recommended human dose (MRHD) based on body surface area. BRILINTA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In reproductive toxicology studies, pregnant rats received ticagrelor during organogenesis at doses from 20 to 300 mg/kg/day. The lowest dose was approximately the same as the MRHD of 90 mg twice daily for a 60 kg human on a mg/m<sup>2</sup> basis. Adverse outcomes in offspring occurred at doses of 300 mg/kg/day (16.5 times the MRHD on a mg/m<sup>2</sup> basis) and included supernumerary liver lobe and ribs, incomplete ossification of sternbrae, displaced articulation of pelvis, and misshapen/misaligned sternbrae. When pregnant rabbits received ticagrelor during organogenesis at doses from 21 to 63 mg/kg/day, fetuses exposed to the highest maternal dose of 63 mg/kg/day (6.8 times the MRHD on a mg/m<sup>2</sup> basis) had delayed gall bladder development and incomplete ossification of the hyoid, pubis and sternbrae occurred. In a prenatal/postnatal study, pregnant rats received ticagrelor at doses of 10 to 180 mg/kg/day during late gestation and lactation. Pup death and effects on pup growth were observed at 180 mg/kg/day (approximately 10 times the MRHD on a mg/m<sup>2</sup> basis). Relatively minor effects such as delays in pinna unfolding and eye opening occurred at doses of 10 and 60 mg/kg (approximately one-half and 3.2 times the MRHD on a mg/m<sup>2</sup> basis).

**Nursing Mothers** It is not known whether ticagrelor or its active metabolites are excreted in human milk. Ticagrelor is excreted in rat milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from BRILINTA, a decision should be made whether to discontinue nursing or to discontinue drug, taking into account the importance of the drug to the mother.

**Pediatric Use** The safety and effectiveness of BRILINTA in pediatric patients have not been established.

**Geriatric Use** In PLATO, 43% of patients were ≥65 years of age and 15% were ≥75 years of age. The relative risk of bleeding was similar in both treatment and age groups. No overall differences in safety or effectiveness were observed between these patients and younger patients. While this clinical experience has not identified differences in responses between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

**Hepatic Impairment** BRILINTA has not been studied in the patients with moderate or severe hepatic impairment. Ticagrelor is metabolized by the liver and impaired hepatic function can increase risks for bleeding and other adverse events. Hence, BRILINTA is contraindicated for use in patients with severe hepatic impairment and its use should be considered carefully in patients with moderate hepatic impairment. No dosage adjustment is needed in patients with mild hepatic impairment [see *Contraindications, Warnings and Precautions*, and *Clinical Pharmacology* (12.3) in full Prescribing Information].

**Renal Impairment** No dosage adjustment is needed in patients with renal impairment. Patients receiving dialysis have not been studied [see *Clinical Pharmacology* (12.3) in full Prescribing Information].

#### OVERDOSAGE

There is currently no known treatment to reverse the effects of BRILINTA, and ticagrelor is not expected to be dialyzable. Treatment of overdose should follow local standard medical practice. Bleeding is the expected pharmacologic effect of overdosing. If bleeding occurs, appropriate supportive measures should be taken. Other effects of overdose may include gastrointestinal effects (nausea, vomiting, diarrhea) or ventricular pauses. Monitor the ECG.

#### NONCLINICAL TOXICOLOGY

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

[see section (13.1) in full Prescribing Information]

##### PATIENT COUNSELING INFORMATION

[see section (17) in full Prescribing Information]

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## Aggressive targets set

In addition to the overall mission to improve the cardiovascular health of all Americans through programs targeting hypertension, healthy diet and physical activity, the AHA's domestic agenda includes ensuring Americans receive preventive and secondary access to care through the Affordable Care Act as well as a new state-level project in partnership with the Robert Wood Johnson Foundation to reduce obesity rates in the U.S.

Globally, the AHA is working with international cardiology groups to replicate or adapt its evidence-based programs to help other countries reach the WHO targets. In Brazil, the association has partnered with the Brazilian Society of Cardiology to adapt the Hands-Only CPR campaign and Go Red For Women initiative.

The AHA also recently finalized an agreement with the European Society of Cardiology to pilot Get With The Guidelines in Europe. Get With The Guidelines is AHA's hospital-based program that has successfully improved care for people with stroke, heart failure, atrial fibrillation and cardiac arrest by promoting consistent adherence to the latest scientific evidence.

"It is because of some of these AHA programs that we've seen a reduction in cardiovascular disease and stroke mortality in the U.S. over the past decade," Sacco said. The cardiovascular disease mortality rate in the U.S. dropped 31 percent from 2000 to 2010. The mortality rate for stroke dropped 36 percent over that same time. "We hope applying these programs in other countries has similar success."

The AHA is also giving small grants to cardiology societies in Brazil, Mexico, Colombia, Chile and Argentina to support initiatives aimed at supporting their national plans to reach the "25 by 25" goal.

In January, the U.N. granted the AHA special consultative status with the Economic and Social Council, the group that creates policy recommendations for the U.N. and its member states.

"The designation opens the door for AHA to talk to U.N. officials about approaches to cardiovascular disease and stroke," Sacco said.

Researchers and healthcare professionals working in cardiology, neurology and related fields worldwide will be impacted by the Global NCD Action Plan. Learn how you can help to ensure follow-through of the plan in your country by visiting The NCD Alliance at [ncdalliance.org](http://ncdalliance.org).



American Heart Association | American Stroke Association®

## PROFESSIONAL MEMBERSHIP

[my.americanheart.org](http://my.americanheart.org)

# *Welcome, New 2013 American Heart Association Fellows*

As a Fellow of the American Heart Association/  
American Stroke Association, you are a part of  
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of cardiovascular and stroke professionals. The  
American Heart Association recognizes your  
scientific and professional accomplishments  
and volunteer leadership and service.

Fellows, stop by the FAHA Lounge in the Hall B  
to relax, network and recharge.

If you are interested in Fellowship, please stop by  
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**FAHA** continued from page 1

fellows as Fellows of the American Heart Association. The entire science Council-based fellowship program was changed in 2001 to reflect this new designation, allowing the FAHA (pronounced “FAH-ha”) title to be used by all 16 Councils.

There are now 4,574 active FAHAs. The number of new honorees selected each year depends largely on the number of applicants, but in any given year a class of about 100 new FAHAs are chosen in the spring and fall.

All new FAHAs receive an official election letter and certificate and are encouraged to attend their individual Annual Council Dinners during the year. The amount of pomp and circumstance also varies by Council. Some hold official presentation ceremonies and other simply ask recipients to stand up and be recognized during their annual dinner.

**Benefits, criteria**

FAHAs receive many benefits during Scientific Sessions and throughout the year, including early registration access prior to the conference and eligibility to nominate FAHA candidates.

During Sessions, they receive a special ribbon on their name badge which gives them exclusive access to the conference’s FAHA lounge, where members can relax and mingle with other FAHAs.

The criteria for fellowship vary slightly by Council, but a few common rules apply:

- Fellowship is open to physicians, scientists, nurses and other healthcare professionals who have been an AHA member for at least two years with a membership level of Premium Professional or Premium Professional Plus.

**What FAHA Means to Me**

“Receiving the FAHA designation was an honor and privilege. Being a FAHA is a sign of excellence that we earn from our colleagues who recognize our scientific and clinical accomplishments.”

**Hossein Ardehali, MD, PhD, FAHA**  
Northwestern University, Feinberg School of Medicine  
Chicago, IL  
*Council on Basic Cardiovascular Sciences (BCVS)*



“As a young investigator in Canada, being a FAHA has provided a greater sense of belonging within the AHA and opportunities for mentorship and collaboration within the broader cardiovascular community.”

**Kristian B. Filion, PhD, FAHA**  
Assistant Professor of Medicine  
McGill University, Montreal, QC, Canada  
*Council on Epidemiology and Prevention (EPI)*



“FAHA means peer acknowledgement of contributing to a professional group of experts and leaders in cardiovascular and/or cerebrovascular science and medicine by research, clinical practice, teaching and volunteering.”

**Kenneth I. Maynard, PhD, FAHA**  
Head, External Innovation, TSU Aging  
Sanofi US, Inc, Bridgewater, NJ  
*Stroke Council*



“It is an honor to be a FAHA, which to me means I am one small part of the ‘heart’ of the organization — the remarkable network of devoted volunteers who work with the AHA to achieve its goals of improving cardiovascular health for all Americans.”

**Dariush Mozaffarian, MD, DrPH, FAHA**  
Co-Director, Program in Cardiovascular Epidemiology  
Associate Professor of Medicine and Epidemiology  
Harvard School of Public Health, Boston, MA  
*Council on Lifestyle and Cardiometabolic Health*



“Becoming FAHA is an honor, recognition by the AHA of excellence in volunteer service and scientific and clinical contributions, and a statement of my commitment to furthering the mission of the AHA to build healthier lives, free of cardiovascular diseases and stroke.”

**L. Kristin Newby, MD, MHS, FAHA**  
Professor of Medicine  
Duke University Medical Center, Durham, NC  
*Council on Clinical Cardiology (CLCD)*



“Being a FAHA in the Council for High Blood Pressure Research is an honor since it is recognition by my peers of service to the Council and my scholarly activities.”

**Jane F. Reckelhoff, PhD, FAHA**  
Billy S. Guyton Distinguished Professor Director, Women’s Health  
Research Center University of Mississippi Medical Center, Jackson, MS  
*Council for High Blood Pressure Research (CHBPR)*

- Applicants must have a sponsor who is an active FAHA.
- Applicants must be able to demonstrate evidence of scientific, clinical and/or educational contributions that support the AHA/ASA’s mission of building healthier lives free of cardiovascular diseases and stroke.
- Applicants must show evidence of significant volunteer service and/or leadership within the AHA/ASA. While the criteria for international candidates are the same as for domestic members, international members can show volunteer leadership

and/or service in organizations or societies similar to the AHA from their own countries.

- Applications are peer reviewed. Once the FAHA title is earned, recipients must maintain membership at the Premium Professional or Premium Professional Plus level in order to maintain active FAHA status.

Michael H. Criqui, MD, MPH, FAHA, shares Musunuru’s appreciation for the designation.

In the late 1970s, Criqui earned what at the time was an associate fellowship, followed later by full fellowship status.

Criqui is a past chair of the AHA’s Interdisciplinary Committee on Prevention and a chair of the Council on Epidemiology and Prevention from 2000 until 2002. Criqui, who now serves as Distinguished Professor and Chief, Division of Preventive Medicine at the University of California, San Diego School of Medicine, said the name of the honor may have changed over the years but the importance hasn’t.

“In my judgment, the most important professional organization I belong to is the American Heart Association,” he said. “I am proud of being a FAHA.” ▼

**Have Another Serving of Science!****AHA Cardiovascular Evening Symposium**

When the day ends at the convention center, AHA science keeps going. Join us at the evening sessions for compelling education that you can apply to your practice.

**Diabetes and Cardiovascular Disease: Current Controversies**

## PRESENTATIONS

## MODERATORS

Valentin Fuster, New York, NY  
David Schneider, Colchester, VT

**Medical Therapy for Patients with Diabetes in Primary and Secondary Prevention: An Update**

Paul Poirier, Quebec, QC, Canada

**Challenges to Treatment: Adherence and Compliance**

Christi Deaton, Manchester, UK

**There is Still a Role for Drug-Eluting Stents in Selected Patients with Diabetes Who Have Multivessel CAD**

David Holmes, Rochester, MN

**CABG is the Right Option for Almost All Patients with Diabetes and Multivessel CAD**

Marc Ruel, Ottawa, ON, Canada

**Diabetes and Stable CAD: Medical Therapy is The Proven Option**

William Weintraub, Newark, DE

**Saturday, Nov. 16, 7 – 9 p.m.**  
**Omni Dallas Hotel | Dallas Ballroom BC**



Complimentary registration will begin at 6 p.m. and will be followed by a modest dinner. Seating is limited, so please arrive early to get your seat!

Supported by an educational grant from Merck

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**DALLAS**  
BIG THINGS HAPPEN HERE

# Teaching Gardens planting seeds for healthy change in grade schools

**A**merican Heart Association Teaching Gardens planted at elementary schools in 31 states are educating kids firsthand about the importance of healthy diets.

The AHA teamed with child-nutrition activist and philanthropist Kelly Meyer to create these real-life learning laboratories, where children are taught how to plant seeds, nurture growing plants, harvest produce and ultimately understand the value of good eating habits. More than 200 gardens are reaching more than 93,000 students and countless parents and siblings.

In Dallas, Moss Haven Elementary School has created a “farm” with multiple herb, vegetable and fruit beds, a compost area, row crops, native plants, indoor hydroponics and chicken coops.

“This has made an impact on our whole community, and the kids are leading the way for change,” said Kim Aman, a Moss Haven teacher and Teaching Garden champion. “When we started our farm we wanted kids to get outside more and learn about science in the field. As we got going, we noticed that we were impacting our students’ health as well. We compost in our cafeteria and bring it to the farm for soil amendment.”

While the country struggles to address childhood obesity, Teaching Gardens are beginning to change the culture of healthy eating at schools. Research shows:

- Students are more interested in vegetables.
- Teachers believe kids are eating more vegetables at school – from sack lunches to the serving line.
- The cafeteria has fewer fried vegetables and more fresh vegetables.

- Schools are including parents in their garden activities.
- About two-thirds of schools incorporate the gardens into specific grade-level curriculum.

Aman’s motto? If children grow it, they will eat it.

“We have kids who never ate veggies, but they’ll try our Swiss chard, banana peppers, kale and eggplant,” she said. “We have taste tests in the hall on the way to recess where kids try samples of things growing in the garden. They weigh in their opinions on butcher paper and there are always overwhelmingly positive comments on the things they try.”

Some areas of the country have even adopted Vertical Teaching Gardens, which can be grown inside classrooms in climates where growing can’t be done outdoors during the school year.

Aman thinks everyone should take a look at their habits and what they’re serving their kids.

“Being unhealthy crosses all walks of life. The more we can get Teaching Gardens in our schools, the better off the health of our nation will become,” Aman said. “Getting involved at the district decision-making level is important as well. They have funding and resources that can support this movement.”

For more information, visit [heart.org](http://heart.org) and [teachinggardens.wordpress.com](http://teachinggardens.wordpress.com). ▼



Kim Aman

PAID ADVERTISEMENT

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- Complete the evaluation.
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# ATRIAL FIBRILLATION

continued from page 1

focusing on therapies that are known to be the most effective.

AFib accounts for one-third of hospitalizations for irregular heartbeats. The number of AFib patients is expected to rise to 12 million by 2050 as the U.S. population ages.

Over the past two decades, hospital admissions of AFib patients grew by 66 percent, with treatment costs reaching an estimated \$26 billion annually.

“We believe that if you can control the complications of atrial fibrillation, then you can reduce hospital readmissions,” said William Lewis, MD, chief of cardiology at MetroHealth Medical Center, Director of Heart and Vascular Center at MetroHealth Medical Center, professor of medicine at Case Western Reserve and Chair of the Get With The Guidelines-AFIB Clinical Work Group.

The program includes data elements and measures associated with the use of blood

thinners or anticoagulants for treating AFib patients. While studies have shown that such therapy, along with patient monitoring, could reduce the risk of stroke in AFib patients by 68 percent, many healthcare providers didn't prescribe it out of concern for complications.

Get With The Guidelines-AFIB helps minimize risks by helping physicians identify patients who can benefit from and are appropriate for blood thinner therapy. The program also provides hospitals and physicians with patient education materials to better equip patients to comply with the recommendations for managing their condition and associated risk after discharge from the hospital.

A retrospective analysis of AFib patients who already had experienced a stroke showed that use of a complementary Get With The Guidelines program focused on stroke patients could significantly improve the use of blood thinners, increasing the number of eligible

patients who could receive the drug therapy to 95 percent.

“We were able to move the bar higher in our goal of saving lives,” Lewis said.

The appropriate use of blood thinners isn't the only treatment promoted in Get With The Guidelines-AFIB. The program also helps health providers monitor the use of antiarrhythmic drugs and heart rate control therapies.

Get With The Guidelines-AFIB includes an online data tool that helps healthcare providers identify AFib patients at risk of stroke and provides clinical decision and technical support, including quality improvement consultation from a dedicated field team. The program features access to clinical tools and resources, including webinars and education,



William Lewis, MD

and enables a hospital to collect data that can be benchmarked against other U.S. hospitals.

Get With The Guidelines-AFIB was developed by an advisory group composed of electrophysiologists, clinical cardiologists, an advanced practice nurse; and experts in heart failure management, neurology, hematology, pharmacology and anticoagulation management.

Enrollment for Get With The Guidelines-AFIB began in June. Overall, more than 42 percent of U.S. hospitals participate in the AHA's Get With The Guidelines program, comprising a database of nearly 5.5 million patient records. The 12-year-old program also offers modules for the treatment of stroke, heart failure, resuscitation and ACTION Registry. ▼

PAID

## Adempas (riociguat) tablets, for oral use Initial U.S. Approval: 2013

### BRIEF SUMMARY of prescribing information CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

#### WARNING: EMBRYO-FETAL TOXICITY

**Do not administer Adempas to a pregnant female because it may cause fetal harm [see Contraindications (4) and Use in Specific Populations (8.1)].**

**Females of reproductive potential: Exclude pregnancy before the start of treatment, monthly during treatment, and 1 month after stopping treatment. Prevent pregnancy during treatment and for one month after stopping treatment by using acceptable methods of contraception [see use in Special Populations (8.6)].**

**For all female patients, Adempas is available only through a restricted program called the Adempas Risk Evaluation and Mitigation Strategy (REMS) Program [see Warnings and Precautions (5.2)].**

#### 1 INDICATIONS AND USAGE

##### 1.1 Chronic-Thromboembolic Pulmonary Hypertension

Adempas is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class [see Clinical Studies (14.1)].

##### 1.2 Pulmonary Arterial Hypertension

Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH), (WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening. Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominately patients with WHO functional class II-III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%) [see Clinical Studies (14.2)].

#### 4 CONTRAINDICATIONS

##### 4.1 Pregnancy

Adempas may cause fetal harm when administered to a pregnant woman. Adempas is contraindicated in females who are pregnant. Adempas was consistently shown to have teratogenic effects when administered to animals. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus [see Use in Specific Populations (8.1)].

##### 4.2 Nitrates and Nitric Oxide Donors

Co-administration of Adempas with nitrates or nitric oxide donors (such as amyl nitrite) in any form is contraindicated [see Drug Interactions (7.1), Clinical Pharmacology (12.2)].

##### 4.3 Phosphodiesterase Inhibitors

Concomitant administration of Adempas with phosphodiesterase (PDE) inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or nonspecific PDE inhibitors (such as dipyridamole or theophylline) is contraindicated [see Drug Interactions (7.1), Clinical Pharmacology (12.2)].

#### 5 WARNINGS AND PRECAUTIONS

##### 5.1 Embryo-Fetal Toxicity

Adempas may cause fetal harm when administered during pregnancy and is contraindicated for use in women who are pregnant. In females of reproductive potential, exclude pregnancy prior to initiation of therapy, advise use of acceptable contraception and obtain monthly pregnancy tests. For females, Adempas is only available through a restricted program under the Adempas REMS Program [see Dosage and Administration (2.3), Warnings and Precautions (5.2) and Use in Specific Populations (8.1, 8.6)].

##### 5.2 Adempas REMS Program

Females can only receive Adempas through the Adempas REMS Program, a restricted distribution program [see Warnings and Precautions (5.1)].

Important requirements of the Adempas REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- All females, regardless of reproductive potential, must enroll in the Adempas REMS Program prior to initiating Adempas. Male patients are not enrolled in the Adempas REMS Program.
- Female patients of reproductive potential must comply with the pregnancy testing and contraception requirements [see Use in Specific Populations (8.6)].
- Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive Adempas.

Further information, including a list of certified pharmacies, is available at [www.AdempasREMS.com](http://www.AdempasREMS.com) or 1-855-4 ADEMPAS.

##### 5.3 Hypotension

Adempas reduces blood pressure. Consider the potential for symptomatic hypotension or ischemia in patients with hypovolemia, severe left ventricular outflow obstruction, resting hypotension, autonomic dysfunction, or concomitant treatment with antihypertensives or strong CYP and P-gp/BCRP

inhibitors [see Drug Interactions (7.2), Clinical Pharmacology (12.3)]. Consider a dose reduction if patient develops signs or symptoms of hypotension.

##### 5.4 Bleeding

In the placebo-controlled clinical trials program, serious bleeding occurred in 2.4% of patients taking Adempas compared to 0% of placebo patients. Serious hemoptysis occurred in 5 (1%) patients taking Adempas compared to 0 placebo patients, including one event with fatal outcome. Serious hemorrhagic events also included 2 patients with vaginal hemorrhage, 2 with catheter site hemorrhage, and 1 each with subdural hematoma, hematemesis, and intra-abdominal hemorrhage.

##### 5.5 Pulmonary Veno-Occlusive Disease

Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD). Therefore, administration of Adempas to such patients is not recommended. Should signs of pulmonary edema occur, the possibility of associated PVOD should be considered and, if confirmed, discontinue treatment with Adempas.

#### 6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Embryo-Fetal Toxicity [see Warnings and Precautions (5.1)]
- Hypotension [see Warnings and Precautions (5.3)]
- Bleeding [see Warnings and Precautions (5.4)]

##### 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.

The safety data described below reflect exposure to Adempas in two, randomized, double blind, placebo-controlled trials in patients with inoperable or recurrent/persistent CTEPH (CHEST-1) and treatment naive or pre-treated PAH patients (PATENT-1). The population (Adempas: n = 490; Placebo: n = 214) was between the age of 18 and 80 years [see Clinical Studies (14.1, 14.2)].

The safety profile of Adempas in patients with inoperable or recurrent/persistent CTEPH (CHEST 1) and treatment naive or pre-treated PAH (PATENT 1) were similar. Therefore, adverse drug reactions (ADRs) identified from the 12 and 16 week placebo-controlled trials for PAH and CTEPH respectively were pooled, and those occurring more frequently on Adempas than placebo ( $\geq 3\%$ ) are displayed in Table 1 below. Most adverse events in Table 1 can be ascribed to the vasodilatory mechanism of action of Adempas.

The overall rates of discontinuation due to an adverse event in the pivotal placebo-controlled trials were 2.9% for Adempas and 5.1% for placebo (pooled data).

**Table 1: Adverse Reactions Occurring More Frequently ( $\geq 3\%$ ) on Adempas than Placebo (Pooled from CHEST 1 and PATENT 1)**

Adverse Reactions	Adempas % (n=490)	Placebo % (n=214)
Headache	27	18
Dyspepsia and Gastritis	21	8
Dizziness	20	13
Nausea	14	11
Diarrhea	12	8
Hypotension	10	4
Vomiting	10	7
Anemia (including laboratory parameters)	7	2
Gastroesophageal reflux disease	5	2
Constipation	5	1

Other events that were seen more frequently in riociguat compared to placebo and potentially related to treatment were: palpitations, nasal congestion, epistaxis, dysphagia, abdominal distension and peripheral edema. With longer observation in uncontrolled long-term extension studies the safety profile was similar to that observed in the placebo controlled phase 3 trials.

#### 7 DRUG INTERACTIONS

##### 7.1 Pharmacodynamic Interactions with Adempas

**Nitrates:** Co-administration of Adempas with nitrates or nitric oxide donors (such as amyl nitrite) in any form is contraindicated because of hypotension [see Contraindications (4.1), Clinical Pharmacology (12.2)].

**PDE Inhibitors:** Co-administration of Adempas with phosphodiesterase (PDE) inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) and nonspecific PDE inhibitors (such as dipyridamole or theophylline), is contraindicated because of hypotension [see Contraindications (4.3), Clinical Pharmacology (12.2)].

##### 7.2 Pharmacokinetic Interactions with Adempas

**Smoking:** Plasma concentrations in smokers are reduced by 50-60% compared to nonsmokers. Based on pharmacokinetic modeling, for patients

# Hands-Only CPR kiosk helps teach travelers lifesaving skill on the fly

Some people play games on their phones, read a book or nap while waiting for a flight. But travelers at Dallas/Fort Worth International Airport can use their idle time to learn how to save lives at a Hands-Only™ CPR kiosk.

The kiosk, which was placed in Terminal C, Gate 7 in July, allows hands-on practice with a CPR manikin and an automated practice-while-watching CPR program. It's part of the American Heart Association's

goal of increasing the number of people trained to save lives.

"A lot of people at the airport are sitting around, and they have some down time, and they can put that down time to good use and learn how to do CPR," said Ahamed Idris, MD, a professor of Surgery and Internal Medicine at the University of Texas Southwestern Medical Center in Dallas.

Idris, who also serves as a volunteer for AHA's Emergency Cardiovascular Care



The Hands-Only CPR kiosk at Dallas/Fort Worth International Airport.

(ECC) programs, said a critical shift in thinking occurred within the last decade after a shortened training course resulted

in improved CPR performance. Trainees who took a 20-minute course showed better performance than those taking a three- to four-hour class. Those results also held over time, Idris said.

"This was a real paradigm shift in our understanding of how people learn CPR," said Idris, who, along with other ECC volunteers, help create and revise the *AHA Guidelines for CPR and ECC* every five years.



Ahamed Idris, MD

## Hands-Only CPR fast, simple

Even without formal training, anyone can be a lifesaver by remembering the two steps to Hands-Only CPR: First call 9-1-1, then push hard and fast in the center of the chest, preferably to the beat of the classic disco song, "Stayin' Alive," until help arrives. With Hands-Only CPR, you don't use rescue breaths.

The DFW kiosk's video program shows the steps of Hands-Only CPR, followed by a practice session and a 30-second CPR test. Through the aid of a touch screen, the kiosk provides feedback about the proper hand placement and the depth and rate of chest compressions.

Results are electronically sent to the AHA, which has teamed with American Airlines and DFW Airport on the six-month pilot program. The results are being analyzed to help determine the overall effectiveness of the kiosk as a training methodology and to determine any revisions to the machine that could enhance the user's experience.

In the first few days it was in place, some 700 people used the kiosk, exceeding expectations, Idris said. By mid-November, roughly 4,500 passengers had used it.

"We hope the Hands-Only CPR kiosk at DFW Airport really takes off," he said. "We'd love to see other high-traffic places do the same so more people can learn this lifesaving skill."

Jeral Ahtone, MD, area medical director with American Airlines Occupational Health Services, said travelers can take comfort in this innovative sort of training.

"The more lifesavers we have at the airport, the better off we all are," he said. "It takes just a couple of minutes, and you never know when or where you might need to save a life."

For more information about Hands-Only CPR, visit [www.heart.org/handsonlycpr](http://www.heart.org/handsonlycpr). ▼

## ADVERTISEMENT

who are smokers, doses higher than 2.5 mg three times a day may be considered in order to match exposure seen in nonsmoking patients. Safety and effectiveness of Adempas doses higher than 2.5 mg three times a day have not been established. A dose reduction should be considered in patients who stop smoking [see *Dosage and Administration (2.4) and Clinical Pharmacology (12.3)*].

**Strong CYP and P-gp/BCRP inhibitors:** Concomitant use of riociguat with strong cytochrome CYP inhibitors and P-gp/BCRP inhibitors such as azole antimycotics (for example, ketoconazole, itraconazole) or HIV protease inhibitors (such as ritonavir) increase riociguat exposure and may result in hypotension. Consider a starting dose of 0.5 mg 3 times a day when initiating Adempas in patients receiving strong CYP and P-gp/BCRP inhibitors. Monitor for signs and symptoms of hypotension on initiation and on treatment with strong CYP and P-gp/BCRP inhibitors. A dose reduction should be considered in patients who may not tolerate the hypotensive effect of riociguat [see *Dosage and Administration (2.5), Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)*].

**Strong CYP3A inducers:** Strong inducers of CYP3A (for example, rifampin, phenytoin, carbamazepine, phenobarbital or St. John's Wort) may significantly reduce riociguat exposure. Data are not available to guide dosing of riociguat when strong CYP3A inducers are co-administered [see *Clinical Pharmacology (12.3)*].

**Antacids:** Antacids such as aluminum hydroxide/magnesium hydroxide decrease riociguat absorption and should not be taken within 1 hour of taking Adempas [see *Clinical Pharmacology (12.3)*].

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Pregnancy Category X  
Risk Summary

Adempas may cause fetal harm when administered to a pregnant woman and is contraindicated during pregnancy. Adempas was teratogenic and embryotoxic in rats at doses with exposures approximately 3 times the human exposure. In rabbits, riociguat led to abortions at 5 times the human exposure and fetal toxicity at doses with exposures approximately 15 times the human exposure. If Adempas is used in pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus [see *Contraindications (4.1)*].

### Animal Data

In rats administered riociguat orally (1, 5, 25 mg/kg/day) throughout organogenesis, an increased rate of cardiac ventricular-septal defect was observed at the highest dose tested. The highest dose produced evidence of maternal toxicity (reduced body weight). Post-implantation loss was statistically significantly increased from the mid-dose of 5 mg/kg/day. Plasma exposure at the lowest dose is approximately 0.15 times that in humans at the maximally recommended human dose (MRHD) of 2.5 mg three times a day based on area under the time-concentration curve (AUC). Plasma exposure at the highest dose is approximately 3 times that in humans at the MRHD while exposure at the mid-dose is approximately 0.5 times that in humans at the MRHD. In rabbits given doses of 0.5, 1.5 and 5 mg/kg/day, an increase in spontaneous abortions was observed starting at the middle dose of 1.5 mg/kg, and an increase in resorptions was observed at 5 mg/kg/day. Plasma exposures at these doses were 5 times and 15 times the human dose at MRHD respectively.

### 8.3 Nursing Mothers

It is not known if Adempas is present in human milk. Riociguat or its metabolites were present in the milk of rats. Because many drugs are present in human milk and because of the potential for serious adverse reactions in nursing infants from riociguat, discontinue nursing or Adempas.

### 8.4 Pediatric Use

Safety and effectiveness of Adempas in pediatric patients have not been established.

### 8.5 Geriatric Use

Of the total number of subjects in clinical studies of Adempas, 23% were 65 and over, and 6% were 75 and over [see *Clinical Studies (14)*]. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Elderly patients showed a higher exposure to Adempas [see *Clinical Pharmacology (12.3)*].

### 8.6 Females and Males of Reproductive Potential

**Pregnancy Testing:** Female patients of reproductive potential must have a negative pregnancy test prior to starting treatment with Adempas, monthly during treatment, and one month after discontinuation of treatment with Adempas. Advise patients to contact their health care provider if they become pregnant or suspect they may be pregnant. Counsel patients on the risk to the fetus [see *Boxed Warning and Dosage and Administration (2.2)*].

**Contraception:** Female patients of reproductive potential must use acceptable methods of contraception during treatment with Adempas and for 1 month after treatment with Adempas. Patients may choose one highly effective form

of contraception (intrauterine devices [IUD], contraceptive implants or tubal sterilization) or a combination of methods (hormone method with a barrier method or two barrier methods). If a partner's vasectomy is the chosen method of contraception, a hormone or barrier method must be used along with this method. Counsel patients on pregnancy planning and prevention, including emergency contraception, or designate counseling by another healthcare provider trained in contraceptive counseling [See *Boxed Warning*].

### 8.7 Renal Impairment

Safety and efficacy have not been demonstrated in patients with creatinine clearance <15 mL/min or on dialysis [see *Clinical Pharmacology (12.3)*].

### 8.8 Hepatic Impairment

Safety and efficacy have not been demonstrated in patients with severe hepatic impairment (Child Pugh C) [see *Clinical Pharmacology (12.3)*].

## 10 OVERDOSAGE

In cases of overdose, blood pressure should be closely monitored and supported as appropriate. Based on extensive plasma protein binding, riociguat is not expected to be dialyzable.

## 17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (*Medication Guide*).

### Embryo-Fetal Toxicity

Instruct patients on the risk of fetal harm when Adempas is used during pregnancy [see *Warnings and Precautions (5.1) and Use in Specific Populations (8.1)*]. Instruct females of reproductive potential to use effective contraception and to contact her physician immediately if they suspect they may be pregnant. Female patients must enroll in the Adempas REMS Program.

### Adempas REMS Program

For female patients, Adempas is available only through a restricted program called the Adempas REMS Program [see *Warnings and Precautions (5.2)*]. Male patients are not enrolled in the Adempas REMS Program.

Inform female patients (and their guardians, if applicable) of the following important requirements:

- All female patients must sign an enrollment form.
- Advise female patients of reproductive potential that she must comply with the pregnancy testing and contraception requirements [see *Use in Specific Populations (8.6)*].
- Educate and counsel females of reproductive potential on the use of emergency contraception in the event of unprotected sex or contraceptive failure.
- Advise pre-pubertal females to report any changes in their reproductive status immediately to her prescriber.

Review the Medication Guide and REMS educational materials with female patients.

### Other Risks Associated with Adempas

- Inform patients of the contraindication of Adempas with nitrates or nitric oxide donors or PDE-5 inhibitors.
- Advise patients about the potential risks/signs of hemoptysis and to report any potential signs of hemoptysis to their physicians.
- Instruct patients on the dosing, titration, and maintenance of Adempas.
- Advise patients regarding activities that may impact the pharmacology of Adempas (strong multi pathway CYP inhibitors and P-gp/BCRP inhibitors and smoking). Patients should report all current medications and new medications to their physician.
- Advise patients that antacids should not be taken within 1 hour of taking Adempas.
- Inform patients that Adempas can cause dizziness, which can affect the ability to drive and use machines [see *Adverse Reactions (6.1)*]. They should be aware of how they react to Adempas, before driving or operating machinery and if needed, consult their physician.

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## SCIENTIFIC SESSIONS continued from page 1

in 2009 and 2010. “There is so much to hear, so many people with whom to interact and so much new information that may directly impact your day-to-day job no matter your specialty or interests. It is thrilling and relevant.”

With everything spread across 26 programming tracks, there is clearly plenty for everyone. Yet a handful of activities merit special recognition.

### Clinical Practice Guidelines

In 2008, the National Heart, Lung, and Blood Institute initiated a series of cardiovascular prevention guidelines by sponsoring rigorous, comprehensive, systematic evidence reviews on assessment of cardiovascular risk, lifestyle modifications that reduce risk, and management of elevated blood cholesterol and body weight in adults. In 2013, the AHA and the American College of Cardiology were assigned the task

of finalizing these cardiovascular prevention guidelines, along with other stakeholder and professional organizations.

Pending publication of the Clinical Practice Guidelines for Cardiovascular Prevention, on Wednesday, these guidelines will be the subject of in-depth examination by the presidents of both AHA and ACC, as well as panelists representing the writing groups for each guideline. Harrington described the session as a discussion of “how we got here, and where we’re taking it from here.”

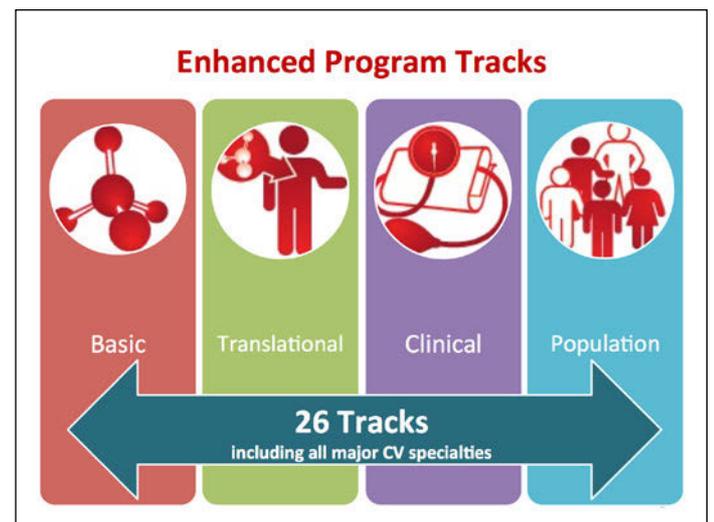
“Maybe the most fun and interesting will be a panel discussion to flesh out some of the questions everybody wants to know and put it all in perspective,” Harrington said.

### Global Congress on Physical Activity

Did you pack any athletic shoes? Be sure to wear them with your “work clothes” Tuesday. “Sneaker Day” is part of an

expanded approach to the five-day series of seminars and how-to sessions befitting the annual “congress” element of Sessions, this year focusing on physical activity and fitness.

“Every discipline from discovery science to hardcore exercise science up to public policy will be covered in the Global Congress,” said Harrington, who will be sporting heart-disease-awareness-red running shoes. “We’re going to have public figures talking about the impact of physical activity from a public



policy standpoint. And we’re going to be doing some really fun, visible things within the convention center to bring more attention to physical activity. I think it’s going to be fantastic.”

One of those fun things is a Walking Path staked by decals on the floor throughout the convention center – along with a Walking Challenge. Attendees are encouraged to register through [my.americanheart.org](http://my.americanheart.org) or at the Walking Challenge booth. The first 2,000 to sign up will receive a bluetooth-enabled tracking device that will count their steps; it pairs with an iPhone/iPad app that will tally a leaderboard shown on monitors throughout the convention center. The top 20 individual walkers will be recognized Wednesday morning, as will the top five Councils. A 1-mile Fun Walk/5k Fun Run is back for the 21st straight year, as well, held Tuesday morning.

Harrington noted the work of program chairs Ross Arena, PhD, PT, FAHA, and Jean-Pierre Després, PhD, FAHA, in pulling together the meeting agenda. It will include keynote presentations by former U.S. Olympic swimmer Gary Hall Jr. and Kenneth H. Cooper, MD, the “Father of Aerobics.”

### Early-career emphasis

Traditionally, Saturdays have been devoted to early-career investigators. That is still the case – and then some.

Many Saturday sessions will be moderated both by senior leaders and early-career investigators in hopes of providing a deeper perspective around topics like job searches, writing articles, getting grant funding, mentoring – topics that are important regardless of science specialty. Harrington himself is moderating a session along with a junior faculty member from Stanford.

“Usually, the early-career investigators are sitting in the audience listening to senior members talk,” Harrington said. “Now we’re bringing them in to actually plan the discussions and to help moderate so we can stay on topic to what’s important to their generation. You’ll see a lot of our abstract sessions will have a junior and a senior leading it. The junior person can really learn from a senior colleague about how to moderate, and us seniors can learn from the juniors about what areas interest them the most.”

That focus continues through the Early Career Engagement Lounge and Professor Rounds. The lounge, outside the poster hall, is where early-career investigators can network with peers and senior investigators can reach out for mentoring sessions and other conversations. AHA staff will be on hand to discuss volunteering, grants and leadership opportunities.

As the name implies, Professor Rounds are similar to doctors making rounds at the

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\*Estimated 1.0 life year to gain for a 70-year-old patient with severe MR, left ventricular dysfunction, and renal dysfunction with correction.

1. Markwick A, Lee L, Horsfall M, Sinhal A, Chew D. TCT-784 Prognostic implications of moderate and severe mitral regurgitation in contemporary clinical care. *J Am Coll Cardiol*. 2012;60(17)(suppl B):B228.
2. Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J*. 2007;28(11): 1358-1365.
3. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2008;118(15):e523-e661. <http://circ.ahajournals.org/content/118/15/e523.long>. Accessed August 20, 2013.

## SCIENTIFIC SESSIONS continued from previous page

hospital: Professors will visit each poster, most of which are done by early-career attendees.

"I've jokingly called it 'No Poster Left Behind' because the goal is for every single poster to be visited by a professor who will engage that presenter," Harrington said.

### Also noteworthy

Harrington noted several more sessions that address hot topics, including one on cardio-oncology and another on data sharing and open data.

Whether to share data in a very open-source manner is another growing, fascinating subject.

"We'll hear from different stakeholders: why funders think it's important, and what investigators think are the challenges," he said. "We have an AHA volunteer – a layperson – who is going to talk about the public perception, what it means to patients. Even if I'm not helping with this session, I will absolutely be there as an attendee."

Late-Breaking Clinical Trials are always headliners, and Harrington said there was a record crop of exactly 100 submissions. Among the 20 that will be featured are CORAL, which studied renal stenting for treatment of hypertension, and ENGAGE, which looked at a novel anticoagulant for atrial fibrillation. Other interesting studies include a randomized trial investigating optimal temperature for hypothermia in cardiac arrest patients, and one on the effectiveness of teaching cardiovascular health to preschool children.

"It's just a fantastic group of trials," he said.

There also will be 19 Clinical Science: Special Reports spread over four sessions, with one devoted to regenerative science.

Basic science attendees will want to block time to attend a reception Monday night that will spotlight the Top 30 basic science abstracts as well as 20 late-breaking basic science abstracts.

And back for another year, with an updated format are the "Case Theaters: Learning at the Movies."

Considering the vast options, an attendee could be overwhelmed. So Harrington recommends planning ahead.

The AHA makes it easy to narrow the agenda to your interests through filtering tools available on [scientificsessions.org](http://scientificsessions.org) and the app, which has been updated with an activity feed that helps connect attendees.

"With 26 tracks, we've tried to make the meeting a little more accessible based on what your interest is," said Harrington, who is giving a talk Saturday about how to navigate the meeting. "We have search tools – especially on the app – to help you search a lot of different ways: by topic, track, speakers.

"My advice is to take some time with the program and use the online tools to personalize the meeting based on your interests. You can then download a calendar based on that."

Scientific Sessions began in 1925 – the year after the American Heart Association was founded – and has run continuously ever since, save for a hiatus during World War II. This is the eighth time Sessions has been in Dallas since 1978, but the first since 2005.

The convention center has been remodeled and the new Omni Hotel is connected. The ease of access should make Sessions' return to the American Heart Association's hometown more comfortable.

"We want people to walk around and meet

people," Harrington said. "We're trying to create the spirit of community, where people can not only learn about their type of science but also find colleagues and work with them."

Relationships Harrington built and/or nurtured through Sessions are instrumental in this colossal undertaking being such a success.

This includes the last two years he spent as CSSP Vice Chair under current AHA President-elect Elliott Antman, MD, FAHA, and the efforts of his own Vice Chair, Kenneth D. Bloch, MD, FAHA. Harrington said the support of Jessup

### Special Lectures

**Presidential Address**  
Mariell Jessup  
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Gaetano Thiene  
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**Keynote Presentation**  
Kenneth Cooper  
Dallas, Texas



American Heart Association | American Stroke Association

While much of the information presented will be available online, that is only one element of the Sessions experience. It's also about networking, socializing, hallway conversations, exchanging business cards – all the benefits of being somewhere in person.

"What you can't get off the Web is that interaction where you bump into a colleague and say, 'I just saw this. Can I ask you about it?'" Harrington said. "That's the essence of science, those serendipitous conversations. You've got to interact to have those. You've got to shake hands."

His career wouldn't be the same without it.

"The bulk of my research over the last two decades has been in collaboration with colleagues around the globe, and Sessions has been invaluable for the opportunities to meet regularly with these colleagues – to share ideas, what we're doing and to continue building our friendship and working together." ▼

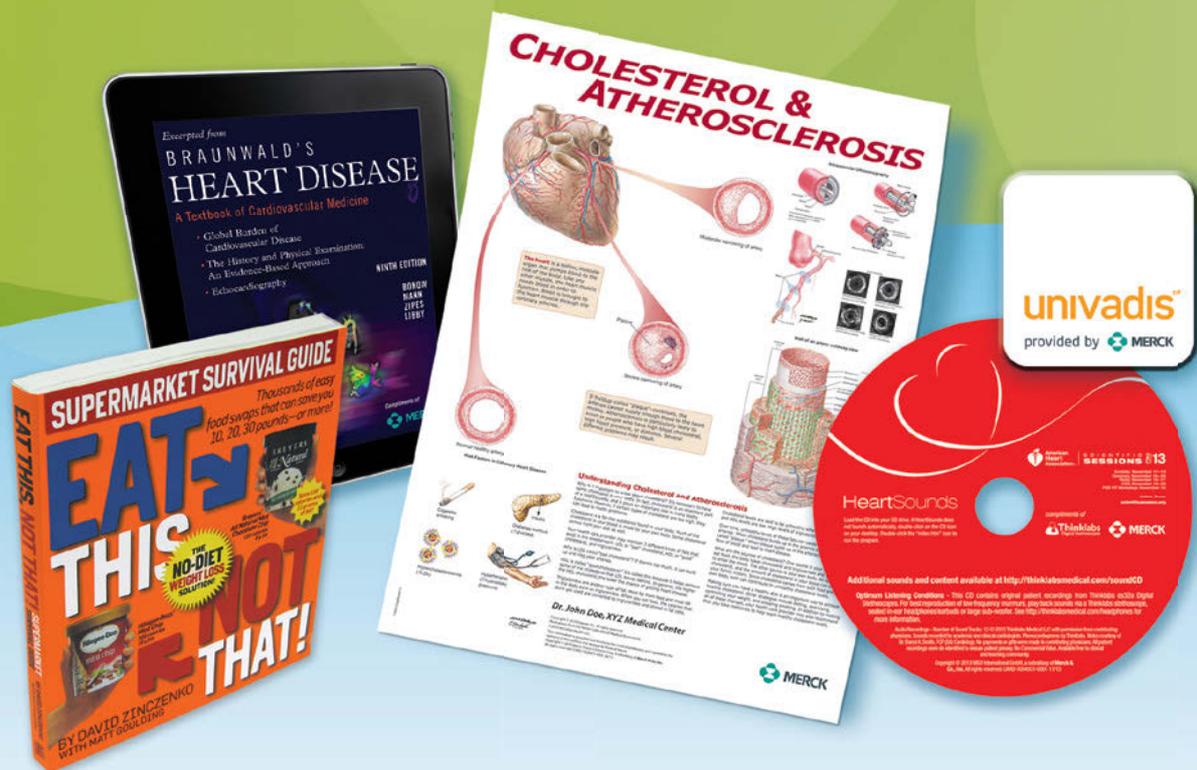
and the entire AHA staff also was invaluable.

"It's a huge amount of work, but sort of a labor of love," he said.

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# Training students in CPR saves lives

**T**he American Heart Association is working to train a new generation of lifesavers by encouraging states to require CPR training as a requirement for high school graduation. These advocacy efforts already have yielded laws in 12 states, which will produce more than 822,000 trainees each year.

“Lives are at stake,” said Michael R. Sayre, MD, professor of emergency medicine at the University of Washington and a past chair of the AHA’s Emergency Cardiovascular Care committee.

The AHA has recommended CPR training for students and teachers be part of standard preparation for responding to medical emergencies on school campuses since 2004. Advocacy efforts stepped up in 2012 with the launch of [BeCPRSmart.org](http://BeCPRSmart.org).

Laws or standards that encouraged inclusion of CPR curriculum content in school programming were in place for 36 states as of the 2009-2010 school year. But the AHA wants that training to be more consistent and comprehensive, including hands-on practice.

The 12 states that have passed legislation are Alabama, Arkansas, Iowa, Georgia, Minnesota, North Carolina, Rhode Island, Texas, Tennessee, Virginia, Vermont and Washington.

Cardiac arrest is a leading cause of death in the United States, with emergency medical



Michael R. Sayre, MD

services teams called to nearly 360,000 cases each year outside of a hospital setting.

Studies have shown that the rapid implementation of CPR or use of an automated external defibrillator by bystanders before EMS teams arrive plays a critical role in patient survival.

People who suffer cardiac arrest outside of a hospital have at least twice the chance of surviving

if a bystander starts CPR, Sayre said. The problem is that bystander CPR is performed in less than half of those cases.

This is where training teens can help.

As kids graduate and go their separate ways, there’s a new crop of trainees – potential lifesavers – taking their place each year. Sayre also believes that such education can make it “normal” to know CPR, removing a possible barrier to taking action when needed.

“Think about all the things you learned in high school that you still remember years later,” he said. “That doesn’t mean everyone will know how to do a great job, but at least it can change perceptions that CPR is hard or scary and people will be more likely to do it.”

Sayre said providing training in schools also could help dispel any misconceptions about CPR, such as the fear that you could hurt the victim.

“We want kids to understand that many of those fears are unfounded,” he said. “I always tell people, CPR won’t make things worse.”

The AHA recommends that CPR training in schools introduce and reinforce the importance of how to recognize the signs of cardiac arrest, calling 9-1-1 and providing high quality chest compressions with minimal interruptions. The recommendations call for training that includes hands-on skill practice, and an awareness of the purpose of an AED.

Several studies have shown that trainees, including children, can achieve acceptable levels of CPR proficiency in 30 minutes or less.

Sayre said watching his own kids undergo CPR training in high school underscored the message for him about how empowering it can be.

“They felt like they could really make a difference,” he said.

AHA’s advocacy effort for CPR training targets state legislatures, but Sayre noted that individuals can make a big difference by simply lobbying their local school boards to include the training and volunteer to help get a training program started.

“Even if it’s not a state requirement, you can make a difference,” he said. ▼



American Heart Association

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**Nitrostat® (Nitroglycerin Sublingual Tablets, USP)**  
**Brief Summary of Prescribing Information**

**INDICATIONS AND USAGE**

Nitroglycerin is indicated for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

**CONTRAINDICATIONS**

Allergic reactions to organic nitrates are extremely rare, but they do occur. Nitroglycerin is contraindicated in patients who are allergic to it.

Sublingual nitroglycerin therapy is contraindicated in patients with early myocardial infarction, severe anemia, increased intracranial pressure, and those with a known hypersensitivity to nitroglycerin.

Administration of NITROSTAT is contraindicated in patients who are using a phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil citrate, tadalafil, vardenafil hydrochloride) since these compounds have been shown to potentiate the hypotensive effects of organic nitrates.

**WARNINGS**

The benefits of sublingual nitroglycerin in patients with acute myocardial infarction or congestive heart failure have not been established. If one elects to use nitroglycerin in these conditions, careful clinical or hemodynamic monitoring must be used because of the possibility of hypotension and tachycardia.

**PRECAUTIONS**

**General:** Only the smallest dose required for effective relief of the acute anginal attack should be used. Excessive use may lead to the development of tolerance. NITROSTAT tablets are intended for sublingual or buccal administration and should not be swallowed.

Severe hypotension, particularly with upright posture, may occur with small doses of nitroglycerin. This drug should therefore be used with caution in patients who may be volume-depleted or who, for whatever reason, are already hypotensive. Hypotension induced by nitroglycerin may be accompanied by paradoxical bradycardia and increased angina pectoris.

Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

As tolerance to other forms of nitroglycerin develops, the effects of sublingual nitroglycerin on exercise tolerance, although still observable, is blunted.

In industrial workers who have had long-term exposure to unknown (presumably high) doses of organic nitrates, tolerance rarely occurs. Chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitrates from these workers, demonstrating the existence of true physical dependence.

Several clinical trials of nitroglycerin patches or infusions in patients with angina pectoris have evaluated regimens that incorporated a 10- to 12-hour nitrate free interval. In some of these trials, an increase in the frequency of anginal attacks during the nitrate free interval was observed in a small number of patients. In one trial, patients had decreased exercise tolerance at the end of the nitrate interval. Hemodynamic rebound has been observed only rarely; on the other hand, few studies were so designed that rebound, if it had occurred, would have been detected.

Nitrate tolerance as a result of sublingual nitroglycerin administration is probably possible, but only in patients who maintain high continuous nitrate levels for more than 10 or 12 hours daily. Such use of sublingual nitroglycerin would entail administration of scores of tablets daily and is not recommended.

The drug should be discontinued if blurring of vision or drying of the mouth occurs. Excessive dosage of nitroglycerin may produce severe headaches.

**Information for Patients:** NITROSTAT is a sublingual tablet and should not be chewed, crushed, or swallowed.

If possible, patients should sit down when taking NITROSTAT tablets and should use caution when returning to a standing position. This eliminates the possibility of falling due to lightheadedness or dizziness.

One tablet should be dissolved under the tongue or in the buccal pouch at the first sign of an acute anginal attack. The dose may be repeated approximately every 5 minutes until relief is obtained.

If chest pain persists after a total of 3 tablets in a 15-minute period, or if the pain is different than is typically experienced, prompt medical attention is recommended.

NITROSTAT may be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.

Nitroglycerin may produce a burning or tingling sensation when administered sublingually; however, the ability to produce a burning or tingling sensation should not be considered a reliable method for determining the potency of the tablets.

Headaches can sometimes accompany treatment with nitroglycerin. In patients who get these headaches, the headaches may be a marker of the activity of the drug.

Treatment with nitroglycerin may be associated with lightheadedness upon standing, especially just after rising from a recumbent or seated position. This effect may be more frequent in patients who have also consumed alcohol.

Nitroglycerin should be kept in the original glass container and must be tightly capped after each use to prevent loss of tablet potency.

**Drug Interactions:** Patients receiving antihypertensive drugs, beta-adrenergic blockers, or phenothiazines and nitrates should be observed for possible additive hypotensive effects. Marked orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used concomitantly.

Concomitant use of nitrates and alcohol may cause hypotension.

The vasodilatory and hemodynamic effects of nitroglycerin may be enhanced by concomitant administration of aspirin.

Intravenous administration of nitroglycerin decreases the thrombolytic effect of alteplase. Therefore, caution should be observed in patients receiving sublingual nitroglycerin during alteplase therapy.

Intravenous nitroglycerin reduces the anticoagulant effect of heparin and activated partial thromboplastin times (APTT) should be monitored in patients receiving heparin and intravenous nitroglycerin. It is not known if this effect occurs following single sublingual nitroglycerin doses.

Tricyclic antidepressants (amitriptyline, desipramine, doxepin, others) and anticholinergic drugs may cause dry mouth and diminished salivary secretions. This may make dissolution of sublingual nitroglycerin difficult. Increasing salivation with chewing gum or artificial saliva products may prove useful in aiding dissolution of sublingual nitroglycerin.

Oral administration of nitroglycerin markedly decreases the first-pass metabolism of dihydroergotamine and subsequently increases its oral bioavailability. Ergotamine is known to precipitate angina pectoris. Therefore, patients receiving sublingual nitroglycerin should avoid ergotamine and related drugs or be monitored for symptoms of ergotism if this is not possible.

Administration of nitroglycerin is contraindicated in patients who are using PDE-5 inhibitors (e.g., sildenafil citrate, tadalafil, vardenafil hydrochloride). These compounds have been shown to potentiate the hypotensive effects of organic nitrates.

A decrease in therapeutic effect of sublingual nitroglycerin may result from use of long-acting nitrates.

**Drug/Laboratory Test Interactions:** Nitrates may interfere with the Zlatkis-Zak color reaction, causing a false report of decreased serum cholesterol.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Animal carcinogenesis studies with sublingually administered nitroglycerin have not been performed.

Rats receiving up to 434 mg/kg/day of dietary nitroglycerin for 2 years developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes. At high dose, the incidences of hepatocellular carcinomas in males was 48% and in females was 33%, compared to 0% in untreated controls. Incidences of testicular tumors were 52% vs. 8% in controls. Lifetime dietary administration of up to 1058 mg/kg/day of nitroglycerin was not tumorigenic in mice.

Nitroglycerin was weakly mutagenic in Ames tests performed in 2 different laboratories. Nevertheless, there was no evidence of mutagenicity in an *in vivo* dominant lethal assay with male rats treated with doses up to about 363 mg/kg/day, PO, or in *ex vivo* cytogenetic tests in rat and dog tissues.

In a 3-generation reproduction study, rats received dietary nitroglycerin at doses up to about 434 mg/kg/day for 6 months prior to mating of the F<sub>0</sub> generation, with treatment continuing through successive F<sub>1</sub> and F<sub>2</sub> generations. The high dose was associated with decreased feed intake and body weight gain in both sexes at all matings. No specific effect on the fertility of the F<sub>0</sub> generation was seen. Infertility noted in subsequent generations, however, was attributed to increased interstitial cell tissue and aspermatogenesis in the high-dose males. In this 3-generation study, there was no clear evidence of teratogenicity.

**Pregnancy Category C:** Animal reproduction and teratogenicity studies have not been conducted with nitroglycerin sublingual tablets. Teratology studies in rats and rabbits, however, were conducted with topically applied nitroglycerin ointment at doses up to 80 mg/kg/day and 240 mg/kg/day, respectively. No toxic effects on dams or fetuses were seen at any dose tested.

There are no adequate and well-controlled studies in pregnant women. Nitroglycerin should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:** It is not known whether nitroglycerin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nitroglycerin is administered to a nursing woman.

**Pediatric Use:** The safety and effectiveness of nitroglycerin in pediatric patients have not been established.

**Geriatric Use:** Clinical studies of NITROSTAT did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

**ADVERSE REACTIONS**

Headache that may be severe and persistent may occur immediately after use. Vertigo, dizziness, weakness, palpitation, and other manifestations of postural hypotension may develop occasionally, particularly in erect, immobile patients. Marked sensitivity to the hypotensive effects of nitrates (manifested by nausea, vomiting, weakness, diaphoresis, pallor, and collapse) may occur at therapeutic doses. Syncope due to nitrate vasodilatation has been reported. Flushing, drug rash, and exfoliative dermatitis have been reported in patients receiving nitrate therapy.

**OVERDOSAGE**

**Hemodynamic Effects:** The effects of nitroglycerin overdose are generally the results of nitroglycerin's capacity to induce vasodilatation, venous pooling, reduced cardiac output, and hypotension. These hemodynamic changes may have protean manifestations, including increased intracranial pressure, with any or all of persistent throbbing headache, confusion, and moderate fever; vertigo; palpitations; tachycardia; visual disturbances; nausea and vomiting (possibly with colic and even bloody diarrhea); syncope (especially in the upright posture); dyspnea, later followed by reduced ventilatory effort; diaphoresis, with the skin either flushed or cold and clammy; heart block and bradycardia; paralysis; coma; seizures; and death.

No specific antagonist to the vasodilator effects of nitroglycerin is known, and no intervention has been subject to controlled study as a therapy of nitroglycerin overdose. Because the hypotension associated with nitroglycerin overdose is the result of venodilatation and arterial hypovolemia, prudent therapy in this situation should be directed toward increase in central fluid volume. Passive elevation of the patient's legs may be sufficient, but intravenous infusion of normal saline or similar fluid may also be necessary.

The use of epinephrine or other arterial vasoconstrictors in this setting is likely to do more harm than good.

In patients with renal disease or congestive heart failure, therapy resulting in central volume expansion is not without hazard. Treatment of nitroglycerin overdose in these patients may be subtle and difficult, and invasive monitoring may be required.

**Methemoglobinemia:** Methemoglobinemia has been rarely reported in association with organic nitrates. The diagnosis should be suspected in patients who exhibit signs of impaired oxygen delivery despite adequate cardiac output and adequate arterial PO<sub>2</sub>. Classically, methemoglobinemic blood is described as chocolate brown, without color change on exposure to air.

If methemoglobinemia is present, intravenous administration of methylene blue, 1 to 2 mg/kg of body weight, may be required.

# The only currently available FDA-approved sublingual nitroglycerin tablet for the acute relief of angina<sup>1,2\*</sup>



This is not the actual bottle.

## NITROSTAT (Nitroglycerin Sublingual Tablets, USP) is indicated for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease<sup>3</sup>

- Onset of vasodilatory effect occurs approximately 1 to 3 minutes after sublingual administration and reaches a maximum by 5 minutes<sup>3</sup>
- May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack<sup>3</sup>

\*As of September 2013. Based on the FDA-approved Drug Products list from the U.S. Food & Drug Administration Web site.

NITROSTAT tablets are available in doses of 0.3 mg, 0.4 mg, or 0.6 mg.

## Important Safety Information

- Sublingual nitroglycerin therapy is contraindicated in patients with early myocardial infarction, severe anemia, increased intracranial pressure, and those with a known hypersensitivity to organic nitrates including nitroglycerin
- Administration of NITROSTAT is contraindicated in patients who are using a phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil citrate, tadalafil, vardenafil hydrochloride) because these compounds can increase nitroglycerin's hypotensive effects
- The benefits of sublingual nitroglycerin in patients with acute myocardial infarction or congestive heart failure have not been established. If used for these conditions, careful clinical or hemodynamic monitoring must be practiced because of the possibility of hypotension and tachycardia
- Only the smallest dose required for effective relief of the acute anginal attack should be used. Excessive use may lead to the development of tolerance. NITROSTAT tablets are intended for sublingual or buccal administration and should not be swallowed
- Severe hypotension, particularly with upright posture, may occur with small doses of nitroglycerin. This drug should therefore be used with caution in patients who may be volume-depleted or who, for whatever reason, are already hypotensive
- Hypotension induced by nitroglycerin may be accompanied by paradoxical bradycardia and increased angina pectoris
- Nitrate therapy may also aggravate the angina caused by hypertrophic cardiomyopathy
- The drug should be discontinued if blurring of vision or drying of the mouth occurs
- Concomitant use with antihypertensive drugs, beta-adrenergic blockers, phenothiazines, calcium channel blockers and alcohol may cause or aggravate hypotension
- If chest pain persists after a total of 3 tablets in a 15-minute period, or if the pain is different than is typically experienced, prompt medical attention is recommended
- Headache that may be severe and persistent may occur immediately after use. Vertigo, dizziness, weakness, palpitation, and other manifestations of postural hypotension may develop occasionally, particularly in erect, immobile patients. Marked sensitivity to the hypotensive effects of nitrates (manifested by nausea, vomiting, weakness, diaphoresis, pallor, and collapse) may occur at therapeutic doses. Syncope due to nitrate vasodilatation has been reported. Flushing, drug rash, and exfoliative dermatitis have been reported in patients receiving nitrate therapy

**Please see brief summary of full Prescribing Information for NITROSTAT on previous page.**

**References:** 1. US Food and Drug Administration (FDA) Web site. Drugs@FDA: FDA Approved Drug Products: Nitroglycerin. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed October 9, 2013. 2. US Food and Drug Administration (FDA) Web site. Drugs@FDA: FDA Approved Drug Products: Nitrostat. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=NITROSTAT>. Accessed October 9, 2013. 3. Nitrostat [package insert]. New York, NY: Pfizer Inc; 2011.

**NITROSTAT**  
(NITROGLYCERIN SUBLINGUAL TABLETS, USP)  
A TRADITION OF ANGINA RELIEF