SATURDAY, NOVEMBER 12

American Heart Association. life is why

SCIENTIFIC SESSIONS 2016

DailyNews

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AHA publishes scientific statement on the use of digital strategies to improve ECC

A recent AHA scientific statement explores the opportunities and challenges of using digital strategies to strengthen the chain of survival for emergency cardiovascular and cerebrovascular care.

Raina Merchant, MD, MSHP

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

"Studies have shown that you can use phones to alert people who are trained in CPR and get them to a cardiac arrest victim to begin lifesaving compressions minutes before emergency responders can get to the scene," said Raina Merchant, MD, MSHP, assistant professor of emergency medicine and director of the Penn Medicine Social Media and Health Innovation Lab at the University of Pennsylvania, Philadelphia.

The AHA has identified digital strategies such as social media, crowdsourcing and mobile devices as important tools to help meet the 2020 goals of improved cardiovascular health. The Institute of Medicine also has called for increased research into the use of mobile and social media strategies to improve cardiac arrest survival.

Merchant, who was vice chair of the task force that drafted the AHA's scientific statement, "Use of Mobile Devices, Social Media, and Crowdsourcing as Digital Strategies to Improve Emergency Cardiovascular Care," cited two elements that contribute to improved emergency cardiovascular care outcomes — medical intervention and pre-medical intervention by bystanders or patients. In the scientific statement, which was published online in June and in the August issue of *Circulation*, several successful projects using bystanders are highlighted.

"There have been successful programs from my group, from the Netherlands, Japan, Korea and elsewhere to help alert trained bystanders to a nearby cardiac arrest, to help bystanders find the nearest

DIGITAL STRATEGIES continued on page 4

Scientific Sessions program covers full spectrum of cardiac science

From interactive sessions on cutting-edge therapies and procedures to the latest findings from important cardiac trials, this year's Scientific Sessions will give attendees an invaluable opportunity to learn and network with colleagues from around the globe, according to Frank W. Sellke, MD, FAHA, Chairman of the Committee on Scientific Sessions Program.

The American Heart Association's Scientific Sessions 2016 kicks off a diverse educational program today in the eclectic city of New Orleans.

"On behalf of the Committee on Scientific Sessions Program, AHA staff and leadership, I want to welcome everyone to this great city and this great meeting. We have a tremendous program in store," Sellke said. "This year's program features 26 educational tracks covering a broad spectrum of basic, clinical, population and translational science presented in oral and poster presentations by some of the world's preeminent clinicians and researchers."

Among the approximately 5,000 sessions, attendees will find several new offerings, including 18 thought-provoking Main Event sessions that will examine cutting-edge topics in the treatment of cardiovascular disease. These sessions, which begin Sunday afternoon, will cover the latest cardiac regeneration science, the changing landscape of acute coronary syndrome care and new approaches to repairing the damaged cardiovascular system.

"We also have a Main Event session on Monday dedicated to precision medicine that will include talks on new genomic technology for diagnosing disease, personalizing cardiovascular surgery using 3-D printing and simulations, and a special presentation on precision therapeutics from FDA Commissioner Robert M. Califf, MD," Sellke said.

"Another one you won't want to miss on Tuesday will feature a series of TED-style talks focusing on new and future treatments for arrhythmias delivered by some of the leading experts in the field."

SCIENTIFIC SESSIONS continued on page 6

New cardiovascular accreditation service from AHA, ACC

THE NEW YEAR WILL BRING NEW options in cardiovascular accreditation services for hospitals and other facilities across the United States, thanks to a collaboration between the American Heart Association and the American College of Cardiology. The first program offerings will be available in January 2017.

Hospitals, health systems and other facilities can look forward to a single gold standard for high-quality cardiovascular care that patients can easily recognize when choosing their hospital, according to the October announcement. The collaboration will launch a streamlined suite of co-branded cardiovascular accreditation products. Initial focus areas include chest pain, cardiac catheterization, atrial fibrillation and heart failure.

AHA CEO Nancy Brown

ACC CEO Shal Jacobovitz

"The AHA and the ACC have long shared the commitment of ensuring the highest standards of patient care through our joint development and implementation of clinical guidelines that can improve outcomes," said AHA Chief Executive Officer Nancy Brown. "Bringing together the collective resources and expertise of our two organizations in this new collaboration offers a unique opportunity to further transform healthcare in ways that neither of us can do alone."

In addition to offering disease-specific accreditations, a multifaceted cardiac accreditation program will allow

CARDIOVASCULAR ACCREDITATION continued on page 14

TODAY AT SESSIONS

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

8:15-9:15 a.m
Future of Trauma and Resuscitation Trial Design
Great Hall A

9 a.m.-Noon
Early Career Opening General Session
Rivergate

9:30-10:15 a.m.
2016 Awards for Lifetime Achievement in Cardiac Resuscitation Science, Trauma Resuscitation Science, and Ian G. Jacobs Award for International Group Collaboration to Advance Resuscitation Science
Great Hall A

10:30-11:45 a.m.
ReSS Best of the Best Oral Abstract Presentations and Presentation of the Best Abstract Awards for Cardiac and Trauma Resuscitation Science
Great Hall A

1:15-2:45 p.m.
ReSS Poster Session
Great Hall C-D

2-3:15 p.m.
Samuel A. Levine Young Clinical Investigator Award Finalists
Room 245

3:45-5 p.m.
Laennec Young Clinician Award Finalists
Rooms 225-227

4:30-5:45 p.m.
Late-Breaking Resuscitation Science Session
Great Hall A

5:45-6:45 p.m.
Update on the IOM Cardiac Arrest Report and Future Directions
Great Hall A

HEARTY HUMOR by Jonny Hawkins

HIGHLIGHTS FROM THE PROGRAM CHAIR

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

Welcome to the 2016 American

Heart Association Scientific Sessions — the premier cardiovascular science meeting in the world. This year's program looks to be one of the best ever, covering every aspect of basic, clinical and population science.

The Committee on Scientific Sessions Program, along with Vice Chair Eric D. Peterson, MD, MPH, and the AHA staff have arranged exceptional content within basic, clinical and population science. We've added educational and simulation programs alongside the usual quality scientific, clinical and translational lectures and poster presentations. And we have outstanding Main Event sessions and Late-Breaking Clinical Trials that will change the way we treat cardiovascular disease patients.

Saturday's highlights include the Early Career Day program from 9 a.m.-5 p.m., with specialty science and career development breakout sessions in nearly all areas of interest to early career members (see below for details). The program concludes with a reception at 5 p.m. in the Early Career Lounge, Hall F. Whatever the field of interest, young investigators can attend several outstanding programs, learn new techniques and cutting-edge science, and network with young and established colleagues.

Frank W. Sellke, MD, FAHA

The Resuscitation Science Symposium begins today and continues through Monday. We'll start with introductions at 8 a.m. in Great Hall A, followed by the Plenary Session, "Future of Trauma and Resuscitation Trial Design." From 9:30-10:15 a.m., we'll have the 2016 awards presentations, including the Lifetime Achievement in Cardiac Resuscitation Science and Trauma Resuscitation Science awards and the Ian G. Jacobs Award for International Group Collaboration to Advance Resuscitation Science. Next, we highlight the Best of the Best: Oral Abstract Presentations and present the Best Abstract Awards for Cardiac and Trauma Resuscitation Science (10:30-11:45 a.m.).

At 12:15 p.m., a Women in Resuscitation Networking Meeting (brown bag session) will be in rooms 201-202. The ReSS Plenary Session II, "Long-Term Outcomes: What Matters to Patients," will be held at 2:45-4 p.m. in Great Hall A. The day's resuscitation science programming will conclude with "Late-Breaking Resuscitation Science" at 4:30 p.m.

Check out the improved Mobile Meeting Guide app and the Help Desk in the registration area to make the most of your time. By popular demand, we have also brought back the paper Scientific Sessions Program Book.

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

EARLY CAREER PROGRAM SATURDAY, NOV. 12

SESSION NUMBER	SESSION TITLE	LOCATION	TIME
EC.PVDFIT.01	PVD FIT – Venous Disease	Main Event 2	9-11 a.m.
EC.AHA.01	Early Career Opening General Session	Rivergate	9 a.m.-Noon
EC.PVDFIT.02	PVD FIT – Cerebrovascular Disease and Stroke	Main Event 2	11:15 a.m.-Noon
EC.AR.01	Part 1: Considering Electrophysiology as a Specialty	Rooms 338-339	1-1:40 p.m.
EC.CLCD.01	Launch Your Cardiology Career: Pearls from the Mentors	Room 245	1-2 p.m.
EC.CVSA.01	Keys to Success for Every Level in Cardiovascular Surgery and Anesthesia – Session 1	Room 224	1-2:30 p.m.
EC.ATVB.01	Early Career Breakouts hosted by BCVS and ATVB – Session 1	Rooms 211-213	1-2:45 p.m.
EC.CVSN.01	Reaching Above and Abroad in Cardiovascular and Stroke Nursing – Session 1	Rooms 272-273	1-2:45 p.m.
EC.CVDY.01	Evolving Fields and Opportunities in Pediatric Cardiology	Room 271	1-3 p.m.
EC.FGTB.01	Next-Generation Sequencing Classroom	Room 210	1-3 p.m.
EC.EQL.01	Cutting Edge Methods in Big Data and Beyond – Session 1	Rooms 346-347	1-5 p.m.
EC.CVRI.01	CVRI Imaging Bootcamp	Rooms 343-344	1-5 p.m.
EC.PVDFIT.03	PVD FIT – Diseases of the Aorta and Major Branches	Main Event 2	1:20-3:40 p.m.
EC.AR.02	Part 2: My Story: A Panel Discussion on the Different Types of EP Career Options	Rooms 338-339	2-3:10 p.m.
EC.CVSA.02	Keys to Success for Every Level in Cardiovascular Surgery and Anesthesia – Session 2	Room 224	2:30-5:30 p.m.
EC.PVDFIT.04	PVD FIT – Lower Extremity Peripheral Artery Disease	Main Event 2	2:40-4 p.m.
EC.3CPR.01	Emerging Science from the 3CPR Early Career Committee	Room 214	3-5 p.m.
EC.CVSN.02	Reaching Above and Abroad in Cardiovascular and Stroke Nursing – Session 2	Rooms 272-273	3-5 p.m.
EC.ATVB.02	Early Career Breakouts Hosted by BCVS and ATVB – Session 2	Rooms 211-213	3-5 p.m.
EC.FGTB.02	From the Oval Office of Functional Genomics	Room 210	3-5 p.m.
EC.AR.03	Part 3: Early Career EP Clinical Session	Rooms 338-339	3:30-5:30 p.m.
EC.PVDFIT.05	PVD FIT – Successful Training and Practice in Vascular Medicine	Main Event 2	4-5 p.m.
	Early Career Reception (Sponsored by AHA/ASA Professional Membership)	Early Career Lounge, Hall F	5-6 p.m.

SCIENTIFIC SESSIONS BY THE NUMBERS

5 days of comprehensive, unparalleled learning

18,000 attendees from more than **100** countries

More Than **5,000** presentations from the world's leaders in cardiovascular science

More than **1,500** invited lecturers

25 basic, clinical and population programming tracks

More than **200** exhibitors showcasing the latest cardiovascular technology and resources

Target: BP improving outcomes, reducing costs

Practices participating in the Target: BP program — a collaboration between the American Heart Association and the American Medical Association to reduce heart attacks and strokes by improving hypertension control — have seen improved health outcomes and declining healthcare costs since the program launched a year ago.

At Doctor's Medical Center, Miami, 70 percent of its hypertension patients are well-controlled compared to 60 percent three years before the program was implemented, according to Claudio Micieli, MPH, chief operating officer of the medical group.

Claudio Micieli, MPH

Michael K. Rakotz, MD, FAHA

He cited reduced emergency room visits, hospital admissions and healthcare costs, and expected reductions in cardiovascular disease complications. He also noted better patient outcomes since the hospital adopted Target: BP. He's especially proud of the improved hypertension control because 80 percent of the practice's patients are black or Hispanic, which are higher-risk populations for hypertension.

"Our success shows that improving blood pressure control is possible — even in low-resource, high-risk areas," Micieli said. "When a group like the AHA enters a partnership with a medical group, a lot can be accomplished."

Michael K. Rakotz, MD, FAHA, vice president of chronic disease prevention at the AMA, said the direct and indirect costs of hypertension in the U.S. were estimated at $48.6 billion in 2012 and are projected to reach $274 billion by 2030, citing an AHA report on heart disease and stroke statistics published earlier this year in *Circulation*.

"The implementation of effective interventions to prevent hypertension and its complications are important steps in addressing rising costs in the U.S. healthcare system," Rakotz said.

An article titled "Cost Effectiveness of Hypertension Therapy According to 2014 Guidelines" published last year in *The New England Journal of Medicine* estimated that there would be 56,000 fewer cardiovascular events and 13,000 fewer deaths from cardiovascular causes annually if providers followed the most recent national guidelines for managing hypertension.

"Treatment algorithms have been shown to be effective in improving blood pressure control," Rakotz said. "That's a cost-effective intervention. And we've had existing guidelines for decades. They're just not as widely adopted as we'd like to see."

Failure to follow guidelines or adhere to protocols can be costly, and so can patients' failure to adhere to treatment.

Rakotz cited data pooled from the European Healthcare Access Panel, which estimated direct costs associated with hypertension at 51 billion euros annually ($55.6 billion U.S.) in the five largest countries in the European Union — Germany, the United Kingdom, France, Italy and Spain. A large percent of that is spent on antihypertensive medications, he noted. In addition, data from the Statistical Office of the European Commission in Luxembourg estimated annual savings of 332 million euros ($364 million U.S.) if patient adherence to antihypertensive therapy increased to 70 percent.

"Treatment nonadherence coupled with nonadherence to treatment guidelines is a global problem," Rakotz said. "In the United States alone, according to AHA statistics, it's estimated that of the 80 million adults who have hypertension, only about half of them have their blood pressure under control. This not only has devastating consequences on the health of the nation, but also a significant economic impact."

Target: BP includes training materials for primary care clinicians to improve early diagnosis and appropriate treatment of hypertension with evidence-based treatment protocols and management guidelines. For more information about resources and tools available for healthcare providers, visit booth 2003 in the Science & Technology Hall. More information about Target: BP can be found at **www.targetbp.org.** ▼

TARGET: BP PANEL DISCUSSION

For a more in-depth look at the Target: BP program, join Claudio Micieli, MPH, chief operating officer of Doctor's Medical Center, Miami, for a panel discussion from 9-10:15 a.m. Monday in room 345. "Target: BP — First Year in Review" will explore best practices and lessons learned from successful Target: BP participants.

CAREER PROGRESSION: SVATI H. SHAH, MD, MS, MHS

AT AN EARLY AGE, SVATI SHAH noticed health disparities between her native India and the United States, which triggered her pursuit of a medical career.

"I had several relatives blinded from cataracts, which is a completely treatable condition (in the United States)," she said. "The background of seeing suffering in India made me always want to be a doctor."

Shah's medical journey began with a master's degree in public health at Johns Hopkins University in Baltimore, Maryland, followed by medical school at the University of Washington in Seattle. She focused on internal medicine because it offered flexibility and resonated with her public health research goals.

As a resident at Brigham and Women's Hospital in Boston, Shah had "amazing cardiology mentors" who combined a passion for patient care and research — paving her path to cardiology. During rounds, half of her conversations were about patient care and the other half about the latest research that could be applied to patient care, she said.

"It was an integrated approach to taking care of patients that inspired me to make cardiology a career," said Shah, vice chief of translational research and associate director of the cardiology fellowship in the Division of Cardiology, Department of Medicine, at Duke University in Durham, North Carolina.

One of Shah's mentors at Brigham and Women's Hospital recommended the field of genetic epidemiology. She soon began working on a genetics project and later earned a master's in genomics at Duke, where she was awarded a five-year American Heart Association Career Development Award as a fellow. The award supported one year of fellowship and her early faculty years.

"There is no way I could have joined the faculty with a 75 percent research agenda without that AHA grant," said Shah, who has attended Scientific Sessions since 2002 and is presenting this year.

At Duke, where she has worked for more than 15 years, Shah started the Center for Human Genetics, which has allowed her to combine the clinical research she does at the Duke Clinical Research Institute with evolving molecular technologies and molecular investigations in genetic epidemiology.

Shah is also co-director of translational research at the Duke Molecular Physiology Institute, where she is investigating the molecular epidemiology of cardiovascular disease using metabolomics, genomics and bioinformatics. The lab takes a quantitative statistical and a mechanistic approach to identify biomarkers and mechanisms of cardiometabolic disease pathogenesis.

Shah also sees patients with inherited cardiovascular disorders at the cardiovascular genetics clinic at Duke.

"The diversity and the mix (of my work) keep me really excited and really challenged," she said. "I feel lucky that I get to live at the interface of evolving molecular technologies and discovery science. We're looking at human populations and human disease. Whatever we find, we understand how it might influence how we take care of patients. The work we're doing is really setting a foundation for precision medicine in real time."

Shah highlighted the role of the AHA in her career development, which goes beyond the research support that she receives. The AHA also helped foster her leadership skills, demonstrated by her work with the Functional Genomics and Translational Biology (FGTB) Council that she now chairs.

"We've been able to create innovative programs around clinical genetics and genetics education through the FGTB Council," she said. "I'm appreciative of the AHA for giving us that flexibility." ▼

The AHA uses the tagline "Life Is Why" to answer the question: Why do we do the lifesaving work we do? We asked Svati H. Shah, MD, MS, MHS, the same thing:

American Heart Association®
life is why™

"Research is why. Heart disease profoundly affects a patient and family's physical and emotional well-being. Working on heart disease gives me immense personal satisfaction, in that I may be able to do something impactful in my lifetime to help patients and their families prevent it."

MEMBER SPOTLIGHT

John Spertus, MD, MPH
Clinical Director of Outcomes Research, Saint Luke's Mid America Heart Institute; Missouri/Lauer Endowed Chair, University of Missouri-Kansas City
Kansas City, Missouri

How long have you been an AHA/ASA Professional Member?
I've been a member for 20 years.

Why did you join?
Not only is the AHA a leading agent for change in improving the care for patients with heart disease, it is also founded in patients. I am very patient-centered in my research and have greatly enjoyed the AHA's commitment to improve the public's engagement in the fight against heart disease. Through its support of research, education and public policy, it is an honor to be associated with the AHA.

Are you involved in AHA councils?
I helped found and lead the AHA Council on Cardiovascular Quality and Outcomes (QCOR). I have greatly enjoyed volunteering for the AHA on many of its efforts to measure and improve the quality of cardiovascular care and have benefited from its generous support of the Outcomes Research Center grant. Currently, I am involved in efforts to create a patient-powered research network as a centerpiece of the AHA Institute for Precision Cardiovascular Medicine, a truly transformative vision in the fight against cardiovascular disease.

What do you enjoy most about these roles?
I love the feeling that I am contributing to medical knowledge and healthcare quality. I have also greatly enjoyed and benefited from networking with other scientists and advocates throughout the country. Collectively, these activities have been some of the most rewarding of my career.

How else are you involved with the AHA?
I have been a huge supporter of our local Heart Ball and have contributed as much as I can to its success. This has also been a very rewarding part of my career and lets me engage with my local community as I emphasize the importance of the AHA to our country's struggle with heart disease.

Why is membership valuable to you?
It is a privilege to support such an important and impactful organization. Other great advantages of membership have been the opportunity to access the AHA scientific journals and to participate in national conferences, including Scientific Sessions and the QCOR Scientific Forum on Outcomes Research and Quality of Care.

What message would you convey to your colleagues about being an AHA member?
There is nothing more satisfying than contributing to the advancement of scientific knowledge and the promotion of healthcare quality. It enables one to have a major impact on patients and is among the most rewarding aspects of my career. The AHA boldly advances these goals, and it is a privilege to work with this organization on such an important mission. ▼

Journals embrace smart technology to deliver interactive print experience

Trend Watch, a new magazine published for the AHA/ASA journals by Wolters Kluwer, lets you know which articles your peers are reading, citing and sharing online — and discover what's having the most impact in your field.

"Our clinical and research community is on the go and more tech-savvy than ever before," said Robert M. Carey, MD, MACP, FAHA, FRCPI, chair of the AHA's Scientific Publishing Committee. "By using cutting-edge technology, you can access full-text articles for free, directly from the pages of *Trend Watch*, with a simple tap on your smartphone screen."

Trend Watch, which is published biannually, compiles articles from the 12 AHA/ASA journals that are generating the most online buzz and lets readers access them through smart devices. In the latest issue, there are more than 180 articles of digital content covering 19 topical areas — from heart failure and coronary artery disease to nutrition science, quality of care, stroke, behavioral medicine and more.

Readers can use a downloadable app called Blippar to access "Blippable" articles, including:

ACUTE CORONARY SYNDROMES
Genetic Risk Scores Predict Recurrence of ACS
Circulation: Cardiovascular Genetics

QUALITY OF CARE
Impact of Vitamin K Antagonists on Quality of Life
Circulation: Cardiovascular Quality and Outcomes

BEHAVIORAL MEDICINE
Circadian Misalignment and Cardiovascular Risk
Hypertension

The latest *Trend Watch* is available at AHA HeartQuarters (Booth 1052), Wolters Kluwer (Booth 1853) and Wiley (Booth 1943). Download the Blippar app in the iOS App store or Google Play store, and BLIPP (scan) the cover image (pictured above) for a demonstration. Learn more at **www.ahajournals.org/site/trendwatch.**

More from the AHA/ASA Journals and Blippar

Blippar brings the journal cover to life with video, direct article access and more. Scan the "*Circulation* Doodle" in the bottom, left corner of the journal cover to launch a new experience each month. Learn more about the *Circulation* Doodle at http://circ.ahajournals.org/content/circulation-cover-doodle.

Also, look for print ads in the journals and at conferences that carry an "interactive" Blippar badge for instant access to unique journal features, such as *Hypertension*'s Clinical-Pathological Conference videos, *Stroke* webinars and more. ▼

DIGITAL STRATEGIES

continued from page 1

AED, and to help people learn more about the signs and symptoms of MI and stroke," Merchant said. "We know these digital strategies can work, but we also know that there are significant research gaps."

There are more than 285 million mobile subscribers in the United States, the AHA statement notes, and more than 50 million of these devices are smartphones. In addition, there are growing numbers of other consumer devices designed to monitor health.

According to the statement, mobile devices, social media such as Facebook and Twitter, and crowdsourcing can provide the public with information that is personalized; specific to language, geography and skill set; context specific; and provided at just the right time for use. Digital strategies allow information to be updated and transmitted in real time to facilitate a dialogue or visual exchange between individuals in the field and emergency medical personnel and healthcare providers.

The AHA task force emphasized that digital strategies must be evaluated with the same rigor as any other medical intervention, including formal assessments of evidence to inform clinical practice guideline recommendations. The report calls for research projects to study the roles that digital strategies might play in cardiac arrest, acute MI and stroke. ▼

Joseph A. Hill, MD, PhD, named editor-in-chief of *Circulation*

On July 1, Joseph A. Hill, MD, PhD, became editor-in-chief of *Circulation,* the American Heart Association's principal scientific journal.

"There's never been a more exciting time in cardiovascular medicine: The arsenal of tools we now have and the path-breaking developments in science and clinical care are unprecedented," he said. "But at the same time, the challenges are similarly unprecedented and daunting. Heart disease is already the No. 1 killer in the West, and there's going to be an explosion of heart disease in the developing world. It's going to be an epidemic."

Hill finds himself in a unique position to help confront those challenges. Launched in 1950 and published weekly, the peer-reviewed *Circulation* is a leading authority on all matters of the heart, read by thousands of cardiovascular scientists, healthcare providers and others interested in cardiovascular medicine.

"It's long been the flagship journal on an international scale, operating with the very highest of standards. In the practice and science of cardiovascular biology, it's the go-to journal," said Hill, who took over the helm of *Circulation* after a 12-year run by Joseph Loscalzo, MD, PhD, FAHA.

At 58, Hill has been paying close attention to *Circulation* throughout his long, distinguished career as a general cardiologist.

He earned his medical and doctoral (pharmacology) degrees at Duke University and completed fellowships at the Institut Pasteur in Paris and the Brigham and Women's Hospital, Harvard Medical School, Boston. He joined the UT Southwestern Medical Center faculty in 2002 and now lives in Dallas. Today, he is chief of the center's division of cardiology and director of the Harry S. Moss Heart Center.

As professor of internal medicine and molecular biology, Hill is a three-time winner of a UT Southwestern Outstanding Teacher Award. As a researcher, he focuses on molecular biology and heart tissue regeneration.

In addition to being responsible for the overall content and design of *Circulation*, Hill is also in charge of the elaborate peer-review process that begins with sorting through a mountain of research articles and ends with picking the roughly 6 percent of those articles that make it into print.

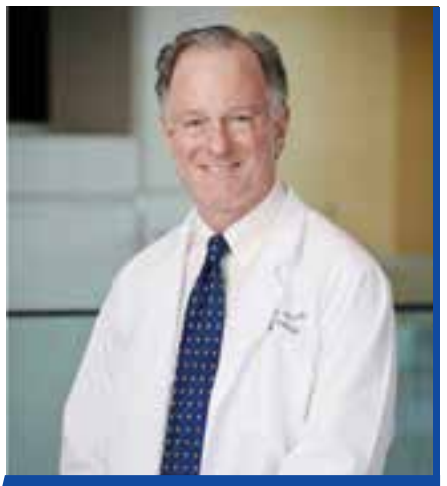
"We're especially interested in work that changes the way you think … the way you think about patients and the way you think about science," Hill said.

"We want content that changes the direction cardiovascular research is headed," he continued. "A big part of the job is to solicit content, from review articles on timely topics to shorter pieces to opinion pieces, in which we're reaching out to thought leaders to get their considered perspectives."

In addition to taking the reins of *Circulation*, Hill also will help with its six subspecialty journals: *Circulation: Arrhythmia and Electrophysiology, Circulation: Cardiovascular Genetics, Circulation: Cardiovascular Imaging, Circulation: Cardiovascular Interventions, Circulation: Cardiovascular Quality & Outcomes,* and *Circulation: Heart Failure.*

While the role of editor-in-chief of *Circulation* comes with a mile-long list of responsibilities, Hill will have plenty of help from a small army of dedicated editors.

"We've recruited an extraordinary team," he said. "We've formulated a global editorial model, one where we have a third of our editors in Dallas, a third in the U.S. outside of Dallas, and a third outside of the U.S. Cardiovascular disease is a global problem, so we've positioned *Circulation* as a global journal. We're attacking the problem on a global scale."



Joseph A. Hill, MD, PhD

Hill will hold the position of *Circulation*'s editor-in-chief for five years, and at the end of the term he will be eligible for a second five-year term. He's optimistic the journal will be publishing major scientific breakthroughs throughout his tenure and for years to come.

"One area of particular promise is regenerative medicine and rebuilding heart [muscle]. Right now, if you lose a heart cell in a heart attack, it's gone forever. But in the next 20 years, I think we'll be able to reverse that," Hill said.

"This is an incredibly exciting time," he added. "It's a tremendous opportunity, privilege and honor to help shape and sculpt the future of cardiovascular medicine." ▼

Air pollution down in New Orleans after smoking ban

New Orleans' indoor air pollution levels dropped 96 percent after 100 days of an indoor smoking ban, according to a study released in August.

The air pollution monitors confirmed that the smoking ban that passed in April 2015 is preserving the health of patrons, entertainers, hospitality workers and residents in New Orleans. The ordinance prohibits smoking in most indoor public places, including bars, restaurants and casinos.

"I applaud the New Orleans City Council for standing up for the health of its residents," said American Heart Association CEO Nancy Brown after the measure passed. "This is one of the strongest smoke-free laws in the nation."

New Orleans has long been considered a meeting and tourist destination, and the city's convention center is the sixth-largest in the nation. The AHA requires its convention host cities to have strong smoke-free workplace laws.

A team from the Roswell Park Cancer Institute in Buffalo, New York, tested the air pollution levels in one casino and more than a dozen bars that had previously allowed smoking. The casino's air pollution levels dropped 99 percent, nearly eliminating the air particle pollution.

Some New Orleans restaurant and bar owners argued that a smoke-free law could cut into their business, but a 2013 report from the Centers for Disease Control and Prevention shows bans do not hurt revenue. Many other studies show smoke-free laws do not.

Smoke-free laws are a growing trend, as nearly 65 percent of the U.S. population lives in a community or state with a smoke-free law that, at a minimum, requires restaurants and bars to be smoke free, according to the American Nonsmokers' Rights Foundation.

An estimated 38,000 Americans die every year from heart disease caused by secondhand smoke, and even 30 minutes of exposure can trigger a heart attack. Studies also show that the risk of developing heart disease is about 25 to 30 percent higher among people exposed to environmental tobacco smoke at home or work. ▼

SCIENTIFIC SESSIONS

continued from page 1

The Late-Breaking Clinical Trials and Clinical Science: Special Report sessions are among the most anticipated every year at Scientific Sessions. The four Late-Breaking Clinical Trials sessions will be held Sunday, Monday, Tuesday and Wednesday. There are two Clinical Science: Special Report sessions Monday and two more Tuesday.

"Featuring the latest breakthroughs in patient care, these sessions are always a high point of the meeting, and this year is certainly no exception," said Sellke, chief of cardiothoracic surgery at Brown Medical School and the Lifespan Hospitals in Providence, Rhode Island. "This week we will hear findings of some really high-profile trials covering areas such as heart failure, cardiac surgery, the use of one or two internal mammary arteries and interventional cardiology."

Sellke also recommends this year's Frontiers in Science program, which includes four daylong summits offering in-depth coverage of the latest research in arrhythmias, stem cell therapy, thrombosis and peripheral vascular disease. Three of the Frontiers in Science summits will be held Monday; the stem cells summit will be held Tuesday.

In addition to traditional didactic programming, Scientific Sessions includes a number of enhanced interactive learning opportunities, such as the Simulation Zone and Abstract Rapid Fire Oral sessions in the Science and Technology Hall.

"The Science and Technology Hall, which includes the exhibit hall, is always a great place to interact and get hands-on experience with the latest devices and information on all the products and services related to cardiovascular care," Sellke said. "You'll find the poster area conveniently adjacent to the exhibits, offering even more opportunities to network with colleagues and interact with poster presenters."

With so much going on and so many sessions to choose from, Sellke encourages attendees to download the Scientific Sessions Mobile Meeting Guide for the most up-to-date meeting news, session schedules, city information and more. The mobile app is available at **scientificsessions.org/mobile**. Also check out page 2 in each issue of the *Daily News*, where Sellke will provide an overview of some of the top sessions and activities. ▼

New resuscitation guidelines update CPR chest compressions

Updated resuscitation guidelines from the American Heart Association refine how fast and how deep chest compressions should be delivered during CPR.

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

The changes are based on a large study that showed as compressions surpassed 120 per minute, rescuers didn't push as hard on the chest, decreasing blood circulation. At 100 to 119 per minute, only 35 percent of compressions didn't go deep enough.

The study, "Chest Compression Rates and Survival Following Out-of-Hospital Cardiac Arrest," was published in the April 2015 issue of the journal *Critical Care Medicine*.

"Compressing more than 120 times per minute is pretty difficult and most people will naturally compress 100 to 110 times per minute," said Clifton Callaway, MD, PhD, chair of the AHA's Emergency Cardiovascular Care Committee and professor and executive vice-chair of emergency medicine and Ronald D. Stewart Endowed Chair of Emergency Medicine Research at the University of Pittsburgh School of Medicine.

The upper limit for depth came from a small study that suggested that injuries were possible with chest compressions beyond 2.4 inches. That study was published in the June 2013 issue of *Resuscitation*, the journal of the European Resuscitation Council.

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

The AHA recommends that anyone who sees an adult suddenly collapse should call 911 and push hard and fast on the center of the chest, a technique known as Hands-Only CPR.

The AHA guidelines are used to train millions of potential rescuers and are integrated into state and local emergency medical services protocols. They have been updated every five years through a process involving more than 250 international experts from the AHA and six other resuscitation councils that form the International Liaison Committee on Resuscitation.

The newest set of guidelines also re-emphasize the value of breaths during CPR by people willing and able to deliver them.

Callaway expects conventional CPR with breaths as compared to Hands-Only CPR will be a topic of discussion among experts as new research emerges. But for those untrained or unable to give the breaths, "it's better to give compressions than not do anything at all," he said.

More than 350,000 Americans have a cardiac arrest outside of a hospital each year, and only 12 percent survive, often because bystanders don't know how to start CPR or are afraid they'll do something wrong.

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

"To be in cardiac arrest is the most critically ill human condition," said Robert Neumar, MD, PhD, immediate past chair of the AHA's Emergency Cardiovascular Care Committee. He is also professor and chair of the University of Michigan Health System's Department of Emergency Medicine. "Every able-bodied person should be able to respond to cardiac arrest by at least recognizing it, calling 911 and doing chest compressions." ▼

Childhood obesity: Do birth mode, mother's BMI matter?

Using data from the Boston Birth Cohort, researchers analyzed the association of birth mode (Cesarean vs. vaginal delivery) and the mother's pre-pregnancy body mass index (BMI) to the development of childhood overweight and obesity (OWOB).

The research will be presented at 3:45 p.m. Sunday during an oral abstract session in rooms 354-355.

American Heart Association | American Stroke Association®

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2016 Unofficial Satellite Events

SATURDAY, NOV. 12

1:30-3 p.m.
Nonprofit Symposium
The Year in Cardiology – A Transatlantic View of the *European Heart Journal*
Supported by Oxford University Press
Hilton Garden Inn, New Orleans Convention Center, Gardenia Room

7-8:45 p.m.
Nonprofit Symposium
What a Cardiologist Needs to Know about Managing Sudden Cardiac Arrest (SCA) Risk
Sponsored by Barnes Jewish Hospital
Supported by Med Ed Consulting, Inc.
Hilton New Orleans Riverside
Registration: http://BarnesJewish.org/neworleans2016

7-9 p.m.
Industry-supported Symposium
Repatha (evolocumab): Product Overview
Sponsored by Amgen
Supported by Amgen

SUNDAY, NOV. 13

7-8:30 p.m.
Industry-supported Symposium
Multidisciplinary Management of Acute and Chronic Heart Failure: A Clinical Workshop
Sponsored by Novartis
Supported by Novartis
Hilton New Orleans Riverside, Grand Salon A & B, First Floor

7-9 p.m.
Industry-supported Symposium
A Clinician's Guide to Using NOACs Safely and Effectively
Sponsored by Postgraduate Institute for Medicine
Supported by Medtelligence
New Orleans Downtown Marriott at the Convention Center, River Bend Ballroom
Registration: 6:30 p.m.; http://events.medtelligence.net/ha16.html

7-9 p.m.
University/Nonprofit Symposium
The Heart Brain Clinic: A Collaborative Approach to Optimize Patient Care
Sponsored by Mayo Clinic
Supported by Mayo Clinic
New Orleans Downtown Marriott at the Convention Center, Blaine Kern A-D, First Floor

7-9 p.m.
Industry-supported Symposium
Using Best Evidence to Achieve Glycemic Target and Reduce Cardiovascular Risk in Type 2 Diabetes
Sponsored by Forefront Collaborative
Supported by Boehringer Ingelheim Pharmaceuticals, Inc.
JW Marriott New Orleans
Registration: forefrontcollab.com/CV_Diabetes

7-9:15 p.m.
Industry-supported Symposium
Navigating the Complex Maze of LDL-Lowering Therapies: A Real World Roadmap for the Cardiovascular Specialist
Sponsored by CMEducation Resources
Supported by Sanofi and Regeneron Pharmaceuticals
Hilton New Orleans Riverside, Grand Ballroom C-D
Registration: www.Reg-LDL.com

7-10 p.m.
Industry-supported Symposium
Controversies in Anticoagulation Optimizing Outcome for Atrial Fibrillation
Sponsored by EMCREG-International
Supported by Janssen Scientific Affairs
The Westin New Orleans Canal Place, Grand Ballroom
Registration: www.emcreg.org

MONDAY, NOV. 14

7-9 p.m.
Industry-supported Symposium
Achieving LDL-C Goal for all Patients in the Era of PCSK9 Inhibitors
Sponsored by AcademicCME
Supported by Amgen, Inc.
New Orleans Downtown Marriott at the Convention Center, Blaine Kern Ballroom, First Floor
Registration: 6:30 p.m.; http://academiccme.com/LDL-C

7-9 p.m.
Industry-supported Symposium
The Foundational Role of IV Iron Repletion in Heart Failure and Associated Co-Morbid Conditions
Sponsored by CMEducation Resources
Supported by American Regent
Hilton New Orleans Riverside, Grand Ballroom C-D
Registration: www.Reg-IDA.com

7-9:15 p.m.
Industry-supported Symposium
Seeing Diabetes Through Heart Shaped Glasses: Multidisciplinary Perspectives on the Management of Comorbid Type 2 Diabetes and Cardiovascular Disease
Sponsored by Institute for Medical and Nursing Education, Inc
Supported by Boehringer Ingelheim Pharmaceuticals/Lilly USA
Hilton New Orleans Riverside, Salon A & B
Registration: www.caringfordiabetes.com/heart

7-9:30 p.m.
Industry-supported Symposium
Applying Guideline Recommended and Recent Evidence-based Therapies in the Treatment of Chronic Heart Failure
Sponsored by Paradigm Medical Communications
Supported by Novartis Pharmaceuticals Corporation
Hilton New Orleans Riverside, Napoleon Ballroom
Registration: www.paradigmmc.com/519

TUESDAY, NOV. 15

7-8:45 p.m.
Industry-supported Symposium
Evolving Perspectives on Intensive LDL-C Lowering and Plaque Regression: Potential Impact on Treatment Strategies
Sponsored by Amgen
Supported by PSL Group Services SARL
The Westin New Orleans Canal Place, Magnolia Ballroom (Third Floor)

7-9 p.m.
Industry-supported Symposium
Delving Deeper into the Complexities and Perplexities of Oral Anticoagulation
Sponsored by Paradigm Medical Communications, LLC
Supported by Paradigm Medical Communications, LLC
New Orleans Downtown Marriott at the Convention Center, Blaine Kern Ballroom (A-D)
Registration: 6:30 p.m.; www.paradigmmc.com/518

Investigators announced for new heart failure research network

The scientific teams that will lead a new American Heart Association-funded research network charged with unlocking the mysteries behind heart failure have been selected.

The AHA's Heart Failure Research Network will fund four centers:

- **Duke University Medical Center, Durham, North Carolina:** Researchers will address knowledge gaps related to heart failure and diabetes by studying the biology of the conditions and how to treat them.
- **Massachusetts General Hospital, Boston:** Researchers will study hypertrophy and why not all patients with hypertrophy develop heart failure.
- **University of Colorado, Denver:** Effective drug treatments for heart failure are limited, so the aim is to develop personalized, affordable medications that will benefit a large group of patients.
- **University of Utah, Salt Lake City:** Researchers want to know why a patient and a heart get better with an intervention — a shift from the standard approach of trying to understand why someone gets worse. The goal is to offer new treatment approaches.

"These newly funded research networks targeting heart failure have the opportunity to redefine the disease," said Clyde Yancy, MD, past president of the AHA and chief of the cardiology division at Northwestern University Feinberg School of Medicine, Chicago, Illinois

"This work is vitally important, as heart failure will strike one in five of us over 40," he continued. "This condition is not about 'them,' it's about all of us. We must be tireless in our pursuit of more answers, more therapies and more best practices."

Heart failure affects nearly 6 million Americans and treatment costs are projected to double from about $31 billion in 2012 to almost $70 billion in 2030. By 2030, every U.S. adult could be paying $244 each year for heart failure expenses, according to a 2013 policy statement from the AHA.

"The work that will take place at these centers is crucial because heart failure is a growing epidemic as our nation ages — and because we know scientific research is our most powerful tool when it comes to preventing, treating and better understanding all cardiovascular diseases," said AHA CEO Nancy Brown.

The heart failure network is one of several Strategically Focused Research Networks funded by the AHA. Others are studying prevention, high blood pressure, disparities, and women and heart disease. The AHA will launch obesity and children networks in 2017. ▼

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New guidelines offer how-to manual for stroke's aftermath

A diverse team is essential in stroke rehabilitation, according to the American Heart Association/American Stroke Association's guidelines for stroke rehabilitation and recovery, which were published May 4, 2016, in *Stroke*. That team, including the patient and family members, needs to put forth a "sustained and coordinated effort" to optimize recovery, according to the guidelines. And that effort should begin as soon as the patient is able.

The guidelines are the first issued by the AHA and the ASA to address stroke rehabilitation, and the eighth in a series that collectively describes evidence-based practices spanning the continuum of care for stroke patients and their families, from prevention to rehabilitation.

Each year almost 800,000 Americans suffer a stroke. For the more than 80 percent who survive, rehabilitation professionals should aim to ensure patients' abilities are aptly assessed, suitability for discharge to different settings is evaluated, and that patients continue to get comprehensive therapy, said Carolee Winstein, PhD, PT, chair of the guidelines' writing group and director of the Motor Behavior and Neurorehabilitation Laboratory at the University of Southern California, Los Angeles.

To help healthcare providers, patients and their families navigate stroke rehabilitation, the guidelines spotlight the types of care that are most likely to be effective, according to research. Depending on each patient's circumstances, various factors could improve health and future quality of life. These include:

- medicine to prevent dangerous clots
- fall prevention education and balance training
- drugs for depression
- evaluation of osteoporosis risk
- screening and treatment for swallowing problems
- coaching in strategies to aid memory
- speech therapy to improve communication
- mobility training
- regimens to strengthen use of arms and hands
- exercises for problems with eye movement
- enriched surroundings to enhance brain activity
- fitness guidance after rehab to improve cardiovascular health

The newest guidelines "provide a comprehensive and current guide not only to best practices in stroke rehabilitation interventions and medical management, but also to the complex American system of post-acute care for stroke," noted Randie M. Black-Schaffer, MD, medical director of the Stroke Program and director of the Stroke Research and Recovery Institute at Spaulding Rehabilitation Hospital, Boston.

As the new guidelines make clear, the U.S. has a multilevel model of inpatient care for patients after stroke, said Black-Schaffer, who was not part of the group that developed the guidelines.

"Patients often progress from level to level before being well enough to return to the community," she said. "Many of us would like to see a shift to a single level of inpatient post-acute care, where the intensity of rehabilitation and medical care could be varied depending on the patient's needs at different phases of their recovery."

After initial hospitalization, patients might be directed to an inpatient rehabilitation facility for the most intensive level of therapy — or to a skilled nursing facility, nursing home, long-term acute care hospital, or outpatient or in-home care, depending on medical circumstances. Patients, caregivers and healthcare providers should use the new guidelines to ease transitions into these community-based settings, Winstein said.

The guidelines say inpatient rehabilitation centers are preferable for stroke survivors who are medically eligible and able to do rigorous therapy. Those facilities are well-designed to provide complex care, offering patients a broad, integrated team of experts who coordinate treatment, Winstein said.

Outside such a setting, "it's like building a house without a contractor — you have to go to each person for their individual skill," she said. "We need a contractor who's going to put together a group who's going to follow this person after discharge."

The new guidelines also represent a wider focus in the realm of post-stroke care, Black-Schaffer said — beyond just acute care and rehabilitation in the immediate aftermath of a stroke.

"We are beginning to focus on the fact that many stroke patients will survive for decades after their stroke, with ongoing impairment and functional limitation," Black-Schaffer said. "It is incumbent on the rehabilitation community to develop standards of care for the long-term management of these issues so that survivors can live as well as possible. They don't just ride off into the sunset after stroke." ▼

D.C. requires CPR training for high school graduates

Nearly 3,000 students graduating each year from Washington, D.C., public and charter schools will now be trained in Hands-Only CPR, according to a law enacted in October.

"It's important to train high schoolers in CPR and AED use for the same reason it's important to have anyone trained in these efforts: because it saves lives," said D.C. council member Kenyan McDuffie, who supported the legislation. "We looked around at the communities in the country that had the highest rates of survival for cardiac arrest and how they got there — and a big part of it is training folks in the community on CPR and proper AED use."

Washington, D.C., joins 34 states that have passed laws or adopted curriculum changes to require CPR training to graduate high school.

Sarah Roque, the supervisory public health analyst for Washington, D.C. Fire and EMS, said training students means more responders will be ready to help people who suffer cardiac arrests.

"We want to train at least 50 percent of the D.C. population so you have a 50 percent chance of having someone around you who knows CPR," said Roque, who will be working with schools to implement the CPR program.

Starting this school year, students in grades 9-12 must complete CPR training in at least one health class before graduation. Training will include practicing chest compressions and the use of an automated external defibrillator.

"High schoolers in D.C. have community service requirements and they are very much in the community," Roque said. "They're in that really important space where they're able to influence younger folks and older individuals. They can pass it on."

The new law also calls for at least one AED to be placed in each public, charter and private D.C. school. Athletic staff, school nurses and others designated by the schools will be trained to use CPR and AEDs.

The school CPR and AED program will be managed by the Washington, D.C. Fire and EMS department. Its Hands On Heart CPR program has trained more than 11,000 community members in CPR and AEDs since launching a year ago, according to Roque.

About 40 people each hour have a cardiac arrest while not in a hospital, and about nine of 10 do not survive, according to American Heart Association statistics.

According to an AHA policy paper published in the September issue of *School Nurse*, comprehensive cardiac emergency response plans can help schools save more lives and should be required by state law. Receiving immediate bystander CPR can double or even triple a victim's chances of survival, and a shock from a defibrillator within three to five minutes may increase survival as much as 50 percent to 70 percent, the policy said. ▼

Kiosks offer Hands-Only CPR training at airports across the country

Travelers can learn Hands-Only CPR in just a few minutes at five airport kiosks around the United States that provide quick lessons and practice using a video touchscreen and a CPR manikin. The kiosks are supported by the Anthem Foundation and the American Heart Association.

Kiosks are located at Chicago's O'Hare International Airport, Indianapolis International Airport, Hartsfield-Jackson Atlanta International Airport, Baltimore-Washington International Thurgood Marshall Airport and the Global Center for Health Innovation in Cleveland. Kiosks are also planned for Las Vegas and Washington, D.C.

The Hands-Only CPR training kiosks feature a touchscreen with a video program that gives a brief "how to," followed by a practice session and a CPR test. Those few minutes at the airport truly can translate to lifesaving minutes for cardiac arrest victims later, said Clifton Callaway, MD, PhD, chair of the AHA's Emergency Cardiovascular Care Committee, professor and executive vice-chair of emergency medicine and Ronald D. Stewart Endowed Chair of Emergency Medicine Research at the University of Pittsburgh School of Medicine.

"Even in the best 911 systems, professional help will require several minutes to arrive, and the actions of the average citizen can make the difference between surviving and not surviving," he said.

Ohio college student Matt Lickenbrock learned Hands-Only CPR during a layover, then used his new skill just days later to save a fellow student who had been struck by lightning and went into cardiac arrest.

"No one ever thinks they'll use CPR. You learn it but hope you don't need to use it," Lickenbrock said.

Out-of-hospital cardiac arrest happens more than 350,000 times a year across the country, often in public places like airports, casinos and sporting facilities. Survival depends on getting CPR right away, and survival rates drop as much as 10 percent for every minute that goes by without intervention.

"Hands-Only CPR requires minimal instruction and can even be coached over the phone by 911 operators," Callaway said. "It can allow a person in cardiac arrest to survive the minutes required until professional help arrives to treat and correct the cardiac arrest — and it can be performed by anyone."

The Anthem Foundation has committed $12.4 million over eight years to help the AHA educate millions of people about Hands-Only CPR. The AHA recently recognized the foundation's support with a Meritorious Achievement award.

"For the past four years, the Anthem Foundation has been working closely with the American Heart Association to help educate people about Hands-Only CPR," said Craig Samitt, MD, Anthem's executive vice-president and chief clinical officer. "To date, we've helped educate and train more than 3 million people in this lifesaving skill, with the goal of preparing them to act in an emergency to save the lives of strangers or those they love most." ▼

CARDIOVASCULAR ACCREDITATION

continued from page 1

hospitals and health systems to achieve the highest standard of cardiac care for all patients. The organizations will identify and recognize high-performing and complex cardiovascular service lines across the nation and provide unbiased, actionable and achievable benchmarks for all hospital and clinical leaders to use to raise their standards of clinical performance.

"The ACC and the AHA are committed to reducing duplication and confusion in the marketplace and providing hospitals with a single source for state-of-the-art accreditation services to enhance quality and optimize patient outcomes and hospital financial performance," said ACC Chief Executive Officer Shal Jacobovitz. "This collaboration will integrate the very latest evidence-based science and ACC/AHA guidelines into a comprehensive suite of accreditation services to support health care institutions' entire cardiovascular care needs."

The AHA will continue to provide stroke certification and accreditation services directly and through collaboration with others, including The Joint Commission. The AHA's Mission: Lifeline Accreditation for STEMI Receiving and Referring Centers will also remain unchanged.

Additional information is available at **www.cardiacaccreditation.org**. ▼

REPATHA® (evolocumab)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information

1. INDICATIONS AND USAGE

1.1 Primary Hyperlipidemia

REPATHA is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).

1.2 Homozygous Familial Hypercholesterolemia

REPATHA is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

1.3 Limitations of Use

The effect of REPATHA on cardiovascular morbidity and mortality has not been determined.

4. CONTRAINDICATIONS

REPATHA is contraindicated in patients with a history of a serious hypersensitivity reaction to REPATHA [*see Warnings and Precautions (5.1)*].

5. WARNINGS AND PRECAUTIONS

5.1 Allergic Reactions

Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with REPATHA, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with REPATHA, treat according to the standard of care, and monitor until signs and symptoms resolve.

6. ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the label:

• Allergic Reactions [*see Warnings and Precautions (5.1)*]

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 clinical practice.

Adverse Reactions in Patients with Primary Hyperlipidemia and in Patients with Heterozygous Familial Hypercholesterolemia

REPATHA is not indicated for use in patients without familial hypercholesterolemia or atherosclerotic CVD [*see Indications and Usage (1.1)*].

The data described below reflect exposure to REPATHA in 8 placebo-controlled trials that included 2651 patients treated with REPATHA, including 557 exposed for 6 months and 515 exposed for 1 year (median treatment duration of 12 weeks). The mean age of the population was 57 years, 49% of the population were women, 85% White, 6% Black, 8% Asians, and 2% other races.

Adverse Reactions in a 52-Week Controlled Trial

In a 52-week, double-blind, randomized, placebo-controlled trial (Study 2), 599 patients received 420 mg of REPATHA subcutaneously once monthly [*see Clinical Studies (14.1)*]. The mean age was 56 years (range: 22 to 75 years), 23% were older than 65 years, 52% women, 80% White, 8% Black, 6% Asian, and 6% Hispanic. Adverse reactions reported in at least 3% of REPATHA-treated patients, and more frequently than in placebo-treated patients in Study 2, are shown in Table 1. Adverse reactions led to discontinuation of treatment in 2.2% of REPATHA-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to REPATHA treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for REPATHA and placebo, respectively).

Table 1. Adverse Reactions Occurring in Greater than or Equal to 3% of REPATHA-treated Patients and More Frequently than with Placebo in Study 2

	Placebo (N=302) %	REPATHA (N=599) %
Nasopharyngitis	9.6	10.5
Upper respiratory tract infection	6.3	9.3
Influenza	6.3	7.5
Back pain	5.6	6.2
Injection site reactions†	5.0	5.7
Cough	3.6	4.5
Urinary tract infection	3.6	4.5
Sinusitis	3.0	4.2
Headache	3.6	4.0
Myalgia	3.0	4.0
Dizziness	2.6	3.7
Musculoskeletal pain	3.0	3.3
Hypertension	2.3	3.2
Diarrhea	2.6	3.0
Gastroenteritis	2.0	3.0

†includes erythema, pain, bruising

Adverse Reactions in Seven Pooled 12-Week Controlled Trials

In seven pooled 12-week, double-blind, randomized, placebo-controlled trials, 993 patients received 140 mg of REPATHA subcutaneously every 2 weeks and 1059 patients received 420 mg of REPATHA subcutaneously monthly. The mean age was 57 years (range: 18 to 80 years), 29% were older than 65 years, 49% women, 85% White, 5% Black, 9% Asian, and 5% Hispanic. Adverse reactions reported in at least 1% of REPATHA-treated patients, and more frequently than in placebo-treated patients, are shown in Table 2.

Table 2. Adverse Reactions Occurring in Greater than 1% of REPATHA-treated Patients and More Frequently than with Placebo in Pooled 12-Week Studies

	Placebo (N=1224) %	REPATHA† (N=2052) %
Nasopharyngitis	3.9	4.0
Back pain	2.2	2.3
Upper respiratory tract infection	2.0	2.1
Arthralgia	1.6	1.8
Nausea	1.2	1.8
Fatigue	1.0	1.6
Muscle spasms	1.2	1.3
Urinary tract infection	1.2	1.3
Cough	0.7	1.2
Influenza	1.1	1.2
Contusion	0.5	1.0

†140 mg every 2 weeks and 420 mg once monthly combined

Adverse Reactions in Eight Pooled Controlled Trials (Seven 12-Week Trials and One 52-Week Trial)

The adverse reactions described below are from a pool of the 52-week trial (Study 2) and seven 12-week trials. The mean and median exposure durations of REPATHA in this pool of eight trials were 20 weeks and 12 weeks, respectively.

Local Injection Site Reactions

Injection site reactions occurred in 3.2% and 3.0% of REPATHA-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in REPATHA-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

Allergic Reactions

Allergic reactions occurred in 5.1% and 4.7% of REPATHA-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for REPATHA and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

Neurocognitive Events

In placebo-controlled trials, neurocognitive events were reported in less than or equal to 0.2% in REPATHA-treated and placebo-treated patients.

Low LDL-C Levels

In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1988 patients treated with REPATHA had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and REPATHA dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by REPATHA are unknown.

Musculoskeletal Events

Musculoskeletal adverse reactions were reported in 14.3% of REPATHA-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for REPATHA and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

Adverse Reactions in Patients with Homozygous Familial Hypercholesterolemia

In a 12-week, double-blind, randomized, placebo-controlled trial of 49 patients with HoFH (Study 4), 33 patients received 420 mg of REPATHA subcutaneously once monthly [*see Clinical Studies (14.3)*]. The mean age was 31 years (range: 13 to 57 years), 49% were women, 90% White, 4% Asian, and 6% other. The adverse reactions that occurred in at least two (6.1%) REPATHA-treated patients, and more frequently than in placebo-treated patients, included:

• Upper respiratory tract infection (9.1% versus 6.3%)
• Influenza (9.1% versus 0%)
• Gastroenteritis (6.1% versus 0%)
• Nasopharyngitis (6.1% versus 0%)

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The immunogenicity of REPATHA has been evaluated using an electrochemiluminescent bridging screening immunoassay for the detection of binding anti-drug antibodies. For patients whose sera tested positive in the screening immunoassay, an in vitro biological assay was performed to detect neutralizing antibodies.

In a pool of placebo- and active-controlled clinical trials, 0.1% of patients treated with at least one dose of REPATHA tested positive for binding antibody development. Patients whose sera tested positive for binding antibodies were further evaluated for neutralizing antibodies; none of the patients tested positive for neutralizing antibodies.

There was no evidence that the presence of anti-drug binding antibodies impacted the pharmacokinetic profile, clinical response, or safety of REPATHA, but the long-term consequences of continuing REPATHA treatment in the presence of anti-drug binding antibodies are unknown.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to REPATHA with the incidence of antibodies to other products may be misleading.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data available on use of REPATHA in pregnant women to inform a drug-associated risk. In animal reproduction studies, there were no effects on pregnancy or neonatal/infant development when monkeys were subcutaneously administered evolocumab from organogenesis through parturition at dose exposures up to 12 times the exposure at the maximum recommended human dose of 420 mg every month. In a similar study with another drug in the PCSK9 inhibitor antibody class, humoral immune suppression was observed in infant monkeys exposed to that drug in utero at all doses. The exposures where immune suppression occurred in infant monkeys were greater than those expected clinically. No assessment for immune suppression was conducted with evolocumab in infant monkeys. Measurable evolocumab serum concentrations were observed in the infant monkeys at birth at comparable levels to maternal serum, indicating that evolocumab, like other IgG antibodies, crosses the placental barrier. FDA's experience with monoclonal antibodies in humans indicates that they are unlikely to cross the placenta in the first trimester; however, they are likely to cross the placenta in increasing amounts in the second and third trimester. Consider the benefits and risks of REPATHA and possible risks to the fetus before prescribing REPATHA to pregnant women.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In cynomolgus monkeys, no effects on embryo-fetal or postnatal development (up to 6 months of age) were observed when evolocumab was dosed during organogenesis to parturition at 50 mg/kg once every 2 weeks by the subcutaneous route at exposures 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. No test of humoral immunity in infant monkeys was conducted with evolocumab.

8.2 Lactation

Risk Summary

There is no information regarding the presence of evolocumab in human milk, the effects on the breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for REPATHA and any potential adverse effects on the breastfed infant from REPATHA or from the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use

The safety and effectiveness of REPATHA in combination with diet and other LDL-C-lowering therapies in adolescents with HoFH who require additional lowering of LDL-C were established based on data from a 12-week, placebo-controlled trial that included 10 adolescents (ages 13 to 17 years old) with HoFH [*see Clinical Studies (14.3)*]. In this trial, 7 adolescents received REPATHA 420 mg subcutaneously once monthly and 3 adolescents received placebo. The effect of REPATHA on LDL-C was generally similar to that observed among adult patients with HoFH. Including experience from open-label, uncontrolled studies, a total of 14 adolescents with HoFH have been treated with REPATHA, with a median exposure duration of 9 months. The safety profile of REPATHA in these adolescents was similar to that described for adult patients with HoFH.

The safety and effectiveness of REPATHA have not been established in pediatric patients with HoFH who are younger than 13 years old.

The safety and effectiveness of REPATHA have not been established in pediatric patients with primary hyperlipidemia or HeFH.

8.5 Geriatric Use

In controlled studies, 1420 patients treated with REPATHA were ≥ 65 years old and 171 were ≥ 75 years old. No overall differences in safety or effectiveness were observed between these patients and younger patients, 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.

8.6 Renal Impairment

No dose adjustment is needed in patients with mild to moderate renal impairment. No data are available in patients with severe renal impairment [*see Clinical Pharmacology (12.3)*].

8.7 Hepatic Impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment (Child-Pugh A or B). No data are available in patients with severe hepatic impairment [*see Clinical Pharmacology (12.3)*].

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of evolocumab was evaluated in a lifetime study conducted in the hamster at dose levels of 10, 30, and 100 mg/kg administered every 2 weeks. There were no evolocumab-related tumors at the highest dose at systemic exposures up to 38- and 15-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. The mutagenic potential of evolocumab has not been evaluated; however, monoclonal antibodies are not expected to alter DNA or chromosomes.

There were no adverse effects on fertility (including estrous cycling, sperm analysis, mating performance, and embryonic development) at the highest dose in a fertility and early embryonic developmental toxicology study in hamsters when evolocumab was subcutaneously administered at 10, 30, and 100 mg/kg every 2 weeks. The highest dose tested corresponds to systemic exposures up to 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. In addition, there were no adverse evolocumab-related effects on surrogate markers of fertility (reproductive organ histopathology, menstrual cycling, or sperm parameters) in a 6-month chronic toxicology study in sexually mature monkeys subcutaneously administered evolocumab at 3, 30, and 300 mg/kg once weekly. The highest dose tested corresponds to 744- and 300-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

13.2 Animal Toxicology and/or Pharmacology

During a 3-month toxicology study of 10 and 100 mg/kg once every 2 weeks evolocumab in combination with 5 mg/kg once daily rosuvastatin in adult monkeys, there were no effects of evolocumab on the humoral immune response to keyhole limpet hemocyanin (KLH) after 1 to 2 months exposure. The highest dose tested corresponds to exposures 54- and 21-fold higher than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. Similarly, there were no effects of evolocumab on the humoral immune response to KLH (after 3 to 4 months exposure) in a 6-month study in cynomolgus monkeys at dose levels up to 300 mg/kg once weekly evolocumab corresponding to exposures 744- and 300-fold greater than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

This Brief Summary is based on the REPATHA® Prescribing Information v3, 07/16

AMGEN®

REPATHA® (evolocumab)
Manufactured by: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
U.S. License Number 1080
Patent: http://pat.amgen.com/repatha/

For adults with clinical ASCVD on maximally tolerated statin therapy as an adjunct to diet who require additional lowering of LDL-C[1]

REPATHA® THE FIRST AND ONLY PCSK9 INHIBITOR WITH A SINGLE MONTHLY INJECTION[1]

Two dosing options designed with your patients in mind

ONCE A MONTH or EVERY 2 WEEKS

Repatha® *Pushtronex*™ system

single use, on-body infusor with prefilled cartridge

Hidden **29-gauge needle**[2]

Steady delivery of the 420 mg/3.5 mL dose subcutaneously over **9 minutes**[1,2]

Securely adheres to the body so patients can be **hands free** during administration while they perform moderate activities[1,2]

After **one push** of a button, the **on-body** device does the work

Repatha® *SureClick*®

single-use, prefilled autoinjector

Hidden **27-gauge needle**[3]

Delivers the 140 mg/mL dose subcutaneously up to **15 seconds**[1]

Consider for patients who are comfortable self-injecting with a **hand-held** device

Indication

- Repatha® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).
- The effect of Repatha® on cardiovascular morbidity and mortality has not been determined.

Important Safety Information

- Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®.
- Allergic reactions: Hypersensitivity reactions (e.g. rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- Adverse reactions: The most common adverse reactions (> 5% of Repatha®-treated patients and more common than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

  In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).
- Adverse reactions from a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated and placebo-treated patients were 0.1% and 0%, respectively.

  Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

  Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients.

  In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha® are unknown.

  Musculoskeletal adverse reactions were reported in 14.3% of Repatha®-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for Repatha® and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).
- Immunogenicity: Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha®.

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

ASCVD = atherosclerotic cardiovascular disease;
PCSK9 = proprotein convertase subtilisin/kexin type 9.

References: 1. Repatha® (evolocumab) Prescribing Information, Amgen. **2.** Data on file, Amgen[6];2016. **3.** Data on file, Amgen[7]; 2016.

AMGEN® Cardiovascular

USA-145-037687 08-16

Repatha® (evolocumab) injection 140 mg/mL

PRODUCT DEMOS AT **BOOTH 3321**