



12 News From SVS

SVS will debut a new "DC Update" electronic newsletter this month.

VOL. 15 • NO. 9 • SEPTEMBER 2019

Vascular Specialist

SVS | Society for Vascular Surgery | Official Publication

Vascular Societies Respond to FDA Paclitaxel Warning

BY THE PRESIDENTS OF SVS, SCVS,
VESS, AND THEIR COLLEAGUES

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public's health by ensuring the safety and efficacy of America's drugs and medical devices. This includes the initial evaluation and market approval of new products developed to address human disease and, on occasion, the reevaluation of previously approved products about which new concerns have arisen. Such are the circumstances that led to the recent FDA reappraisal

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AHA Highlights Limitations of Perfusion Testing for Critical Limb Ischemia

BY MARK S. LESNEY
MDEdge NEWS
FROM CIRCULATION

A new assessment statement from the American Heart Association reviewed the strengths and limitations of current imaging techniques for critical limb ischemia (CLI), the severest form of peripheral arterial disease (PAD).

The main techniques discussed were the ankle-brachial index (ABI), toe-brachial index (TBI), toe systolic

pressure, transcutaneous oximetry (TcPO₂), and skin perfusion pressure (SPP). The literature review also identified what the authors saw as opportunities for technology improvement.

"No single vascular test has been identified as the most important predictor of wound healing or major amputation for the threatened limb," wrote Sanjay Misra, MD, of the Mayo Clinic in Rochester, Minn., and colleagues, on behalf of the American Heart Association Council on Peripheral Vascular Disease, the Council on

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FROM THE EDITOR

I Am America's Top Doctor

BY MALACHI G. SHEAHAN III, MD
MEDICAL EDITOR, VASCULAR SPECIALIST

Recently I received an email from a woman I will not name. She was happy to announce that I had been selected as a Top Cardiologist representing Durham, North Carolina. Since I am not a cardiologist, nor have I ever been to Durham, this was a bit puzzling. What was genuinely surprising about the email, however, was not this woman's mercurial relationship with facts. Instead, it was the reality that I wanted to believe it. For a split second, wild rationalizations came quickly. "Did I give medical assistance on a layover in Charlotte? Am I Duke basketball coach Mike Krzyzewski's personal doctor? Of course I don't deserve this award. But maybe?"

Compliment a physician's appearance, and he or she will probably be suspicious of your intentions. But compliment their clinical ability? The one thing they have spent their entire lives honing? Doctors will take this at face value. That is our weakness, and it is a weakness that drives a very lucrative industry.

My experience is not unique. A few years ago, a New York-based firm informed Marshall Allen that he had been named a "Top Doctor." The problem was that Mr. Allen was not a doctor; he was an investigative journalist. Mr. Allen's subsequent research uncovered a number of these organizations awarding such dubious honors as "Super Doctor," "Best Doctor," and "Top Doctor." Mr. Allen did receive his plaque (at a discounted rate of \$99) and noted: "Obviously, the Top Doctor Awards company has questionable standards."¹

Sorting out the various organizations that purport to select the best doctors can be an arduous



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process. At least a dozen currently exist. In 2012, ABC News investigated the Consumers' Research Council of America, the issuer of the "Top Doctor" awards.² The ABC probe revealed that many of the currently listed honorees had significant, even criminal issues. Dr. Conrad Murray, convicted of manslaughter in the death of Michael Jackson, was still listed as a "Top Cardiologist" years later. Dr. Earl Bradley remained on the "Top Pediatrician" list even while serving 14 life sentences for molesting 103 children.

If you live in a metropolitan area, your regional magazine almost certainly publishes an annual "Best Doctors" issue. Many of these lists are compiled by Castle Connolly, a research company founded in 1992. In full disclosure, I am listed in the Castle Connolly database (at least until we publish this article!). John Connolly, the president and CEO of Castle Connolly, reports that they employ a full-time research team and update their lists annually. Their selection method is unique in that it relies heavily on peer nomination. Critics call the process a popularity contest, which favors doctors from bigger groups and ones who have been in practice for many years. Since the awards

can bring in patients and money, many hospital systems buy in. Advertising campaigns are formed around the best doctor lists. There are even reports of hospital CEOs offering cash incentives to Castle Connolly doctors who nominate peers from within their hospital. While I don't recall ever receiving an invitation for nominations from Castle Connolly, I have gotten requests from institutions where I previously worked to nominate physicians from within their systems.

For many of these best doctor businesses, the money flows directly from the awarded physician to the company. Of course, the cash is usually laundered through plaques or advertisements. For Castle Connolly, it is a bit more complicated. Doctors can't pay directly for listing, but their full profile isn't available online unless their institutions have paid at least \$11,000 to join the "Partnership for Excellence Hospital" program. Castle Connolly also offers to place physicians in a New York Times ad for \$3,350. They claim this ad will allow physicians to not only attract new patients but also "reinforce your status with current patients!"² How exactly would that work? Yes, Mrs. Jones, shame about your above-knee amputation, but have you seen my glossy spread in the Times?

Castle Connolly also partners with American Registry to offer plaques commemorating these awards. Some include a mock-up of the cover of the "Best Doctors" issue of your local magazine, reminiscent of the fake Wheaties box covers I coveted as a child. Of course, I would never buy something so frivolous, but if YOU wanted to get me one, the Museum Quality Prestige Series Mahogany With Gold Trim looks nice.

What is a "Top Doctor" anyway? What claims

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Vascular Specialist

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The Society for Vascular Surgery headquarters is located at 9400 W. Higgins Road, Suite 315, Rosemont, IL 60018.

Vascular Specialist (ISSN 1558-0148) is published monthly for the Society for Vascular Surgery by Frontline Medical Communications Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Phone 973-206-3434, fax 973-206-9378

Subscription price is \$230.00 per year.

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do these sites make? Michael Doherty, president and CEO of TopDocs.com, told ABC News that the name of his website is “not inferring in any way that the doctors in the site are top doctors.” Hmm, maybe the “Top” stands for Top Dressed? Super Doctors offers this disclaimer: “Super Doctors” is the name of a publication. It is not a title or moniker conferred upon individuals. No representation is made that the quality of the medical services provided by the physicians listed in this Web site will be greater than that of other licensed physicians.”¹

So not only can I not call myself a “Super” doctor, I’m not even better than anyone else? Maybe the “Super” is supposed to be sarcastic? Even the Castle Connolly list only claims that these doctors are “among the best.” Among the best? That sounds like Loser Town to me. Where do the BEST DOCTORS go to broadcast their preeminence? Let’s check the commercial airline magazines.

Where did this begin? I’m not sure who thinks Southwest Airlines is a reliable source for medical

referrals. What is the thought process here?

Well, I’ve read the Taylor Swift puff piece, learned Five Ways To Do Pasadena, and stared at the North Atlantic route map for 20 minutes. I guess it’s time to find a hair transplant surgeon!

Still, flip through the pages of an airline magazine and there they are, between the lists of Top American Steakhouses and ads for shady online universities. Behold the Top Neurosurgeons of New York, complete with the image of a happy looking gentleman helpfully holding a disincorporated spine. I miss Sky Mall.

Of course, these lists proliferate because there is no perfect system for picking the best doctors. Peer nominations are nice but in no way comprehensive. Let’s face it, on most days I wouldn’t even be voted best doctor in my own house (although my polling numbers do improve dramatically on the nights I bring home pizza).

Online physician rating sites are also deeply flawed. While I would like to rest on the laurels of my 5-star grade on [vitals.com](#), the five patient sample size seems insufficient. So the public is left to sift through meaningless awards, google rankings, and terrible advice. Even doctors have trouble explaining how to find the best among them. Writing for *Slate Magazine*, Dr. Kent Sepkowitz, a

New York City physician, offered this awful guidance: “... it’s OK to hate your surgeon. You simply need him to cut and sew very intelligently. So always select the surgeon who has already done the most iterations of whatever procedure you need.”³ Sexism aside, there is much to hate here. We all know the best surgeons are distinguished by their knowledge of when to operate as much as how to operate. If you go to the doctor who performs the most laser veins you are probably gonna come out with some veins lasered.

In the end, maybe our ventures into physician quality metrics will pay off. I expect there will be many hurdles to jump before systems such as the Vascular Quality Initiative are made public. For now at least, anyone can seemingly declare themselves a Top Doctor. Unfortunately the burden of proof lies with the patients.

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Vascular Response

Paclitaxel from page 1

of paclitaxel delivering devices, including both stents and balloons, following the publication of a meta-analysis performed by Katsanos et al¹ of the original randomized controlled trial (RCT) data which indicated a significantly increased late (3-5 year) mortality hazard ratio (HR) of 1.93 in PAD patients treated with paclitaxel devices. The initial FDA advisory issued on Jan. 17, 2019 stated that “the benefits [of paclitaxel] continue to outweigh the risks.”²

However, following their replication of the Katsanos findings and completion of their own patient-level analysis revealing a significantly increased mortality HR of 1.57, they issued a second communication on March 15, 2019,³ advising that “alternative treatment options should generally be used for most patients.” Also announced at that time was their intention to convene a panel of experts to assist them in clarifying the mortality signal observed with the use of these devices and guide further recommendations.

This panel was held on Jun. 19-20, 2019, at which time the FDA, Dr. Katsanos, industry representatives, and others presented data from their respective analyses. The only new analysis of the combined patient-level RCT data was performed and presented by VIVA and demonstrated a

significantly increased mortality HR of 1.38. Industry presentations of their individual datasets were noted by the panel to be lacking in statistical vigor when compared to the meta analyses, particularly related to the sample size and length of follow up. This was the case despite several device manufacturers having made significant progress in obtaining long term follow up on their RCT patients.

The SVS focused its presentations on how the SVS Vascular Quality Initiative (VQI) and our Patient Safety Organization could be used to address this question. As the only national registry collecting device-specific identification, instituted in 2016, longer follow-up of existing and future VQI patients, as well as methodologies to fortify VQI registry data through harmonization and cross-linking with other PAD and national registries are natural applications for our VQI.

We furthermore proposed two advanced analytical strategies including: (1) using an advanced software application to enhance early detection of a mortality signal in the VQI registry and (2) collaboration with the Medical Device Epidemiology Network using linkages to Medicare claims data allowing retrospective analysis of paclitaxel devices, effectively extending their follow up

period. We highlighted the role that RAPID (Registry Assessment of Peripheral Interventional Devices), an already existing multi-disciplinary public private partnership between the FDA, specialty societies (including SVS, ACC, and SIR) and industry, could play in bringing clarity to this and other critical questions about long term safety and performance.

Following thoughtful consideration of the body of evidence, on Aug. 7, 2019, the FDA issued their third Health Care Provider letter on the late paclitaxel mortality signal,⁴ reiterating its presence while acknowledging that more study will be required to bring true clarity to the situation. They noted that existing analyses are compromised by “a small sample size, pooling of studies of different paclitaxel-coated devices that were not intended to be combined, substantial amounts of missing study data, no clear evidence of a paclitaxel dose effect on mortality, and no identified pathophysiologic mechanism for the late deaths.” They went on to state that “for many patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents provide a more favorable benefit-risk profile based on currently available information.”

The SVS, SCVS, and VESS concur with the FDA decision to keep these devices available while more data is accumulated and analyzed. We also agree that alternative treatment

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strategies, including lifestyle changes, exercise, medical therapies, and other revascularization techniques, may provide equal or better clinical effectiveness for intermittent claudication, the dominant and labeled indication for use of these devices, and should be part of every physician-patient discussion.

We appreciate the delicate balance that the FDA has struck in this challenging situation where they are charged with both ensuring patient safety and providing access to technology which could ameliorate

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disease. The SVS will continue to support its membership in advocating for the full range of treatment options and understands that there are some conditions where continued use of the devices may be deemed optimal. The SVS will continue to pursue next steps and to be engaged in achieving final clarity to the questions that remain.

Suggestions for Future RCTs

We would be remiss in our responsibility to our patients were we not to take this opportunity to also express our concerns about perceived deficiencies in the process of peripheral vascular device approval and marketing which has made this such a difficult call to make, and one that might still be proven to be wrong.

Study Endpoints and Resulting Labeling Should Be Appropriate for the Condition

In response to the consistently demonstrated mortality signal seen in patients treated with paclitaxel devices, the FDA was forced to determine the tipping point between increased mortality and clinical benefit. Intermittent claudication (IC) can be extremely disabling but the long-term limb prognosis is generally benign, particularly when lifestyle modifications and medical therapy are applied. Let's begin by recognizing the precise nature of the endpoint of mortality, the state and timing of which is indisputable and from which there simply are no "re-dos."

Regulatory trials for drug-eluting devices in the superficial femoral artery have typically employed primary patency at one year as the key primary endpoint. In these trials, loss of primary patency is defined by either a clinically-driven target lesion revascularization (CD-TLR) event or Duplex ultrasound (DUS)-defined restenosis at the treatment site. These endpoints are typically analyzed in a time-to-event (Kaplan-Meier) fashion. TLR, in any of its forms, is undoubtedly the weakest of all endpoints used to measure clinical effectiveness of a medical device. We must understand and accept the non-blinded nature of these trials, and the potential for observer bias. The decision to perform a repeat procedure for IC is highly subjective, from the perspective of both the patient and the physician, as is its timing. Many patients with restenosis or even occlusion may be asymptomatic or may not choose another intervention.

The standard definition of "target lesion" is within 5 mm of the original lesion. Not only is the lack of precision surrounding TLR subject to bias and abuse, but this is compounded by an inadequate length of follow-up to fully gauge both the occurrence and clinical impact of restenosis. DUS assessments for patency are typically included in the trial designs, but these are performed at scheduled intervals and the compliance with each DUS timepoint is generally not reported. Loss of patency as defined by DUS criteria should be assigned temporally within a window (e.g. in life table fashion, where events are conventionally assigned to the beginning of each window), rather than on a specific date of occurrence. When the trial data is locked at a specified time (e.g. 365 days), the information from imaging studies that may occur just beyond it is excluded.

With these major compromises understood, one year is woefully inadequate to capture the full incidence and clinical impact of restenosis after angioplasty or stenting in the SFA for IC, as well as any increased mortality.

Devices have to provide meaningful, sustained benefit and safety over the life of the product and the patient to be worthy of use in humans.

Furthermore, given that the patient populations in the RCTs for approval of these devices were 90% claudicants, walking distances and quality of life determinations should be requisite components of the trials. In that regard it would be more appropriate to keep the trials homogeneous to IC, and then allow for labeling that respects the clinical indication and functional benefits of the products. Similarly, when purporting to show benefit in CLTI patients, the endpoints should include amputation and wound healing. How can a meaningful balance between mortality and clinical benefit be determined when the endpoints are so disparate in definition, precision, and potential for bias?

The Comparators Should Be Appropriate for the Condition

To allow market approval to be based on an improvement in revasculariza-

tion rates, whether driven by restenosis or recurrence of symptoms, when the comparator is plain old balloon angioplasty (POBA) grossly overstates the benefit of a new device. POBA is rarely the standard of care in PAD and is an inappropriate comparator under most circumstances. Furthermore, comparators should not be limited to other interventional devices, but rather should include both non-revascularization methods as well as surgical revascularization. How can an appropriate balance between mortality and the use of a new device be achieved when the benefits of the new device, which invariably comes with increased cost and possibly risk, are overstated by comparison to an obsolete revascularization method?

The Natural History of the Condition and Total Product Life Cycle Need to be Considered

While we understand the pressure on the FDA to facilitate the rapid approval of devices for market, one year follow-up is inadequate for many devices and many disease states. SVS guidelines support a minimum of two years of benefit to be considered efficacious in IC. If we learn nothing from the turmoil around paclitaxel, as it appears we have not from silicone breast implants, hip prostheses, pelvic mesh, and aortic endografts, it is that devices have to provide meaningful, sustained benefit and safety over the life of the product and the patient to be worthy of use in humans.

New Device Trials Need To Be Designed and Conducted To Assess for Late Events Such as Mortality

The woefully inadequate long-term follow-up rates in many of the paclitaxel RCT trials is inconsistent with the ethical contract between physicians and patients who accept the risks associated with an investigational device. Greater effort needs to be made to ensure continued patient follow-up and ascertainment of patients' complications and mortality, including the cause thereof. At the present time the FDA recommends "diligent monitoring" of patients who have been treated with paclitaxel-eluting devices, but does not define how providers and manufacturers should achieve this, nor do they mandate the reporting of such monitoring.

Putting the Burden on the Patient Is Not the Answer

It is in vogue these days to suggest that patient preference should

drive decisions around the type of revascularization undertaken, including whether or not to perform one in the first place. While it is not unreasonable to expect that a patient considering equally efficacious treatment options would elect to proceed with the minimally invasive option, it is also clear that some providers may be incentivized to recommend that option. Furthermore, is it reasonable and realistic to expect patients to be able to evaluate the body of evidence around paclitaxel and make an informed decision when even the FDA panel members were unable to conclusively determine the risks of paclitaxel devices? Let's not forget that informed consent documents in clinical trials are written at the eighth-grade level precisely because many patients lack the necessary education to comprehend the language, much less synthesize such complicated data. The FDA is working with manufacturers to change the labeling of these devices, which may provide standard language for these challenging conversations but is unlikely to provide true informed consent for this complex scenario. Ultimately, while patient preference should be a significant factor in the choice of therapy delivered, the physician is the most knowledgeable and influential source of information for the patient and, therefore, the physician must take significant ownership of any decision made.

Summary

In summary, we believe that the mortality signal around the use of paclitaxel devices in PAD patients is real based on the data presented to date. While the exact mechanism remains elusive at this time and will require further study, just because we do not understand it does not mean we can ignore it.

While we await more rigorous analyses of significantly enhanced datasets, something that will take time, we believe that interim reports of analyses of statistically inadequate datasets, including those of the individual original RCTs, which were neither designed nor powered to assess mortality, serve only to confuse rather than clarify the situation. Given the finality of death and the availability of other alternatives to provide clinical benefit in the PAD population, we believe that these devices should be used sparingly in most patients at this time unless there is compelling clinical rationale to do otherwise.

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FDA Update: Higher Late Mortality With Paclitaxel-Coated Devices

BY CHRISTOPHER PALMER
MDEDGE NEWS

Paclitaxel-coated devices, which are used to treat peripheral artery disease (PAD), appear to have a nearly 60% higher mortality risk than uncoated devices, according to a letter to health care providers from the Food and Drug Administration.

This letter updates details about long-term follow-up data and panel conclusions reviewed by the Food and Drug Administration, as well as recommendations from the agency regarding these devices. On Jan. 17, 2019, the FDA notified providers regarding an apparent increased late mortality risk seen with paclitaxel-eluting stents and paclitaxel-coated balloons placed in the femoropopliteal artery

in patients with PAD. The agency issued an update March 15.

In a public meeting June 19-20, the Circulatory System Devices Panel of the Medical Devices Advisory Committee discussed long-term follow-up data that demonstrated a 57% relative increase in mortality among PAD patients treated with paclitaxel-coated devices when compared with those receiving uncoated devices. The panel concluded that the late mortality signal was real and warranted further study and action, a conclusion with which the FDA has concurred.

Among other recommendations issued by the FDA, health care professionals should continue to closely monitor patients who've already received

the devices and fully discuss the risks and benefits of these devices with patients. The FDA has decided that, given the demonstrated short-term benefits of these devices, clinical studies may continue and should collect long-term safety and effectiveness data.

The magnitude of this late mortality signal should be interpreted with caution, the FDA noted in the update, because of the wide confidence intervals (although the relative risk was 1.57, the 95% confidence interval was 1.16-2.13, which translates to 16%-113% higher relative risk), pooling studies of different devices that weren't meant to be combined, missing data, and other reasons.

The full letter, including more detailed data and the full list of recommendations, is available on the FDA's website.

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Lastly, we hope that this situation promotes reflection on how devices are trialed and approved in the future to ensure that their clinical benefit is authentic and their risks fully evaluated.

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White and Black Patients Have Similar Rates of Giant Cell Arteritis

BY STEVE CIMINO
MDEDGE NEWS
FROM JAMA OPHTHALMOLOGY

Although giant cell arteritis (GCA) had been established in previous studies as more common in white populations, a new study in JAMA Ophthalmology with a larger sample of black patients found similar incidence rates between black and white individuals.

To determine the incidence of biopsy-proven GCA (BP-GCA) in a racially diverse cohort, Anna M. Gruener of Nottingham (England) University Hospitals NHS Trust and coauthors analyzed the medical records of more than 10 years of patients who underwent temporal artery biopsy at Johns Hopkins Wilmer Eye Institute in Baltimore. Of the 586 patients in the study, 167 (28.5%) were black, 382 (65.2%) were white, and 37 (6.3%) were other or unknown. The mean age was 70.5 years.

Of the 573 patients who were aged 50 years and older, 92 (16.1%) had a positive biopsy for BP-GCA; 14 were black (8.4% of all black patients), 75 were white (19.6% of all white patients), and 3 were other or unknown. The population-adjusted, age- and sex-stan-

dardized incidence rates per 100,000 were 3.1 (95% confidence interval, 1.0-5.2) for black patients and 3.6 (95% CI, 2.5-4.7) for white patients.

Overall, BP-GCA occurred more frequently in women than in men (incidence rate ratio, 1.9; 95% CI, 1.1-3.4; $P = .03$) but at similar levels in white and black patients (IRR, 1.2; 95% CI, 0.6-2.4; $P = .66$).

In an accompanying editorial, Michael K. Yoon, MD, and Joseph F. Rizzo III, MD, of Harvard Medical School, Boston, praised the researchers for conducting their study in a population with a large percentage of black patients, a noted weakness of earlier studies in this area (JAMA Ophthalmol. 2019 Aug 8. doi: 10.1001/jamaophthalmol.2019.2933).

That said, the two doctors also recognized the limitations of the work done by Gruener et al., including relying on U.S. Census data to calculate adjusted incidence rates instead of local racial distribution and also the potentially problematic choice to count patients with healed arteritis as having BP-GCA.

Still, Dr. Yoon and Dr. Rizzo commended Gruener et al. for questioning previous findings on

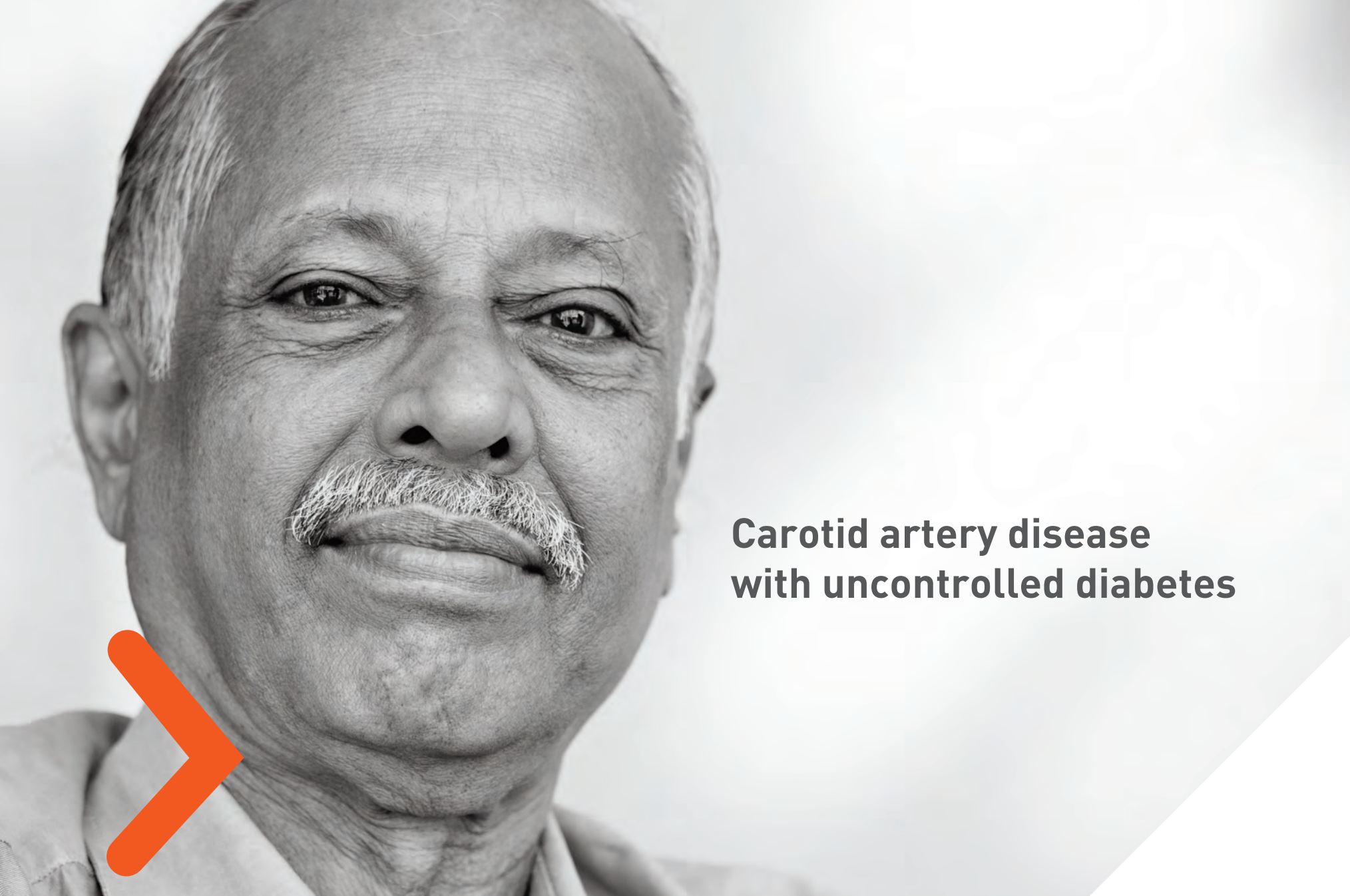
GCA rates. "Although the authors' methods are imperfect," they wrote, "the studies that had previously established a low incidence of GCA in black patients were also flawed in design."

The study had no outside funding source, and no conflicts of interest were reported.

SOURCE: Gruener AM et al. JAMA Ophthalmol. 2019 Aug 8. doi: 10.1001/jamaophthalmol.2019.2919.

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*Reimbursement eligible criteria for the TCAR Procedure per the Medicare National Coverage Determination (20.7) on PTA including CAS

Please visit SilkRoadMed.com for instructions for use and to learn more about TCAR

Trainees, Apply for Advocacy Scholarship and Learn How Government Impacts Practices

SVS trainees can “specialize” in more than just vascular surgery. Those interested in health policy can apply to spend a day in Washington to learn about issues that impact vascular surgery. The recipient will spend time on Capitol Hill and share with policymakers and their staffs issues of concern for vascular surgeons and patients across the country. Applications for the SVS Vascular Surgery Train-

ee Advocacy Travel Scholarship are due by Oct. 31. The recipient will receive \$1,500 to defray travel costs to participate in Hill visits and learn more about SVS’ health policy and advocacy activities. The scholarship is sponsored by the SVS Resident and Student Outreach Committee. Applicants must be SVS Candidate Members currently enrolled or accepted in a vascular surgery

training program and have an earnest interest in advocacy and policy issues related to vascular surgery. Visit vsweb.org/Awards.

“This experience was a strong, foundational step towards my professional intention of continuing a relationship with congressional leaders.”
Anahita Dua, MD, MS, MBA, 2017 recipient

Washington Update: Advocacy, Policy News

‘DC Update’ Newsletter Debuts: The Society for Vascular Surgery has a new electronic newsletter, “DC Update” to keep SVS members informed of the events in Washington, D.C., that impact their lives. Initially, the newsletter (sent Sept. 16) will appear every other month.

“We want – and need – our members to be aware of how what happens at the Centers for Medicare & Medicaid Services, at the Food and Drug Administration and elsewhere on Capitol Hill affects them,” said Sean Roddy, MD, chair of the SVS Policy and Advocacy Council, which is overseeing the newsletter. “‘DC Update’ will keep members up to date and also let them know when we need letters writ-

ten to communicate our concerns.”

“DC Update” also will be posted on the SVS website at vsweb.org/Newsletters.

Committee Shines Spotlight on Red Tape Burden: The SVS and other vascular societies have endorsed proposed solutions for the regulatory administrative burden of IT and electronic health records. In submitting the endorsement several months ago, the societies also referenced the 2018 SVS survey on wellness and burnout, identifying EHRs as a significant stressor of clinical practice. Read more on the SVS Government Relations Committee take on the issue at vsweb.org/RedTape.



ALEXKAVA/GETTY IMAGES

VQI Makes Major Changes to Hemodialysis Access Registry

Major enhancements are coming to the SVS Vascular Quality Initiative’s Hemodialysis Access Registry, with completion expected by the end of the year.

The registry captures all arterio-venous fistulas and grafts procedures, including A-V fistulas using transposed veins and A-V grafts using autogenous, prosthetic or biological material. It has been in use since 2011.

The comprehensive improvements focus not only on simplifying the data entry process but also capturing additional information, particularly about post-procedure interventions. These additional interventions will carry forward to every follow-up entered after the first indexed procedure.

The registry also now will capture A-V fistulas created via new endovascular techniques, at least two of which already have Food and Drug Administration approval. Another key change is elimination of the current “early” and “late” follow-up forms in favor of one follow-up at between nine and 21 months.

In another notable change, the reg-

istry also will integrate with the FDA Global Unique Device Identification Database (GUDID) for easier capture of prosthetic graft manufacturer and device details.

Other changes by category include:

History:

- Prior accesses
 - o The number of prior AVF/AVG is captured along with characteristics of the access, such as location and previous vein used
 - o History of tunneled catheter and other central venous devices added

Procedural:

- Access Type
 - o Endovascular AVF added
 - o Integration with GUDID for AV graft added
 - o Ability to capture if graft portion of HeRO was changed for another type of graft
- Inflow artery and outflow vein options expanded
- Concomitant procedures expanded, to include angioplasty, stents, endarterectomy, branch ligation, patch, superficialization, lipectomy and liposuction

- Immediate post-op complications and management expanded, to include bleeding, steal, Ischemic neuropathy and thrombosis

The registry also clarifies pre-operative imaging questions and refines access function variables to better capture access status at follow-up.

The enhancements mean important quality data will be collected, imperative to setting benchmarks, said Karen Woo, MD, chair of the VQI Hemodialysis Workgroup.

She acknowledged that providers will find it challenging to collect all post-procedure interventions, particularly if a procedure took place at another location.

Nonetheless, this information is vital to understanding the long-term outcomes of vascular access. “Post-procedure interventions for vascular access are some of the most poorly understood outcomes of hemodialysis vascular access. Even knowing there was an intervention and the date will be helpful in learning how to improve vascular access outcomes and the dialysis patient experience,” she said.

Hemodialysis vascular access is one area of vascular surgery that has made few strides forward since the Brescia Cimino fistula was first described in 1966, she said. “Collecting high-value, high-quality data will allow the VQI community to collectively identify best practices that advance vascular access care.”

The vascular access workgroup is spearheading the registry improvements. Other members include: Drs. Brigitte Smith, University of Utah; Gary Lemmon, Indiana University; John Lucas, Greenwood Leflore Hospital; Mike McNally, University of Tennessee; Charles Ozaki, Brigham and Women’s Hospital; and Theodore Yuo, University of Pittsburgh.

The Vascular Quality Initiative is a network of regional quality groups, with 12 registries. It improves the quality, safety, effectiveness and cost of vascular health care through collecting, analyzing and sharing data of pre-operative risk factors, intra-procedural variables, post-procedural outcomes and one-year follow-up data. For more information, visit vsweb.org/VQI.

Your SVS: Meet SVS Officers

The Society for Vascular Surgery has new officers for the 2019-20 year, elected at the 2019 Vascular Annual Meeting.

New President Dr. Hodgson Dr. Hodgson holds the David Sumner endowed chair in Vascular and Endovascular Surgery at Southern Illinois University and is medical director of the David S. Sumner Vascular Laboratory at Memorial Medical Center.

Dr. Hodgson was the inaugural editor of the Vascular Education and Self-Assessment (VESAP) and stayed on as co-editor in chief for the subsequent two editions. He has published more than 100 articles in medical journals, as well

as more than 40 book chapters on vascular surgery topics. He also has been the principal investigator of numerous clinical investigational trials and served for six years on the Vascular Surgery Board.

President-elect Dr. Ronald Dalman is the Walter C. and Elsa R. Chidester Professor and chief of vascular surgery at Stanford University. He served three years as program chair for VAM and has served on the SVS Board of Directors, the Patient Safety Organization Governing Council and several councils and committees.

Vice President Dr. Ali AbuRahma is professor of surgery, chief of

vascular and endovascular surgery and director of the vascular surgery fellowship and integrated residency programs at West Virginia University, Charleston, W.Va. He also is medical director of the vascular laboratory and co-director of the Vascular Center of Excellence at Charleston Area Medical Center. He most recently was SVS secretary and has served on several boards and committees.

Immediate Past President Dr. Michel S. Makaroun now becomes chair of the SVS Foundation. He is a professor and chair of vascular surgery and of clinical and translational science at the University of

Pittsburgh and co-director of UPMC Heart and Vascular Institute.

Dr. Amy Reed, a newcomer to the lineup, is division chief of vascular surgery and director of Fairview Vascular Services at the University of Minnesota. She has been president of the Association of Program Directors in Vascular Surgery and co-editor of the current edition of VESAP.

Dr. Samuel Money, MBA, treasurer since 2017, is a professor of surgery with the Mayo Clinic in Phoenix, Ariz. Dr. Money has also served on the SVS physician Wellness Task Force and the SVS Foundation Board of Directors.

Your SVS: Important Information for Members

PAD Resources: September is PAD Awareness Month, and SVS has not only resources but also new information for its members.

PAD has been in the news recently; the Journal of Vascular Surgery, for example, has just published a study on the relationship between PAD and high-risk opioid use (vsweb.org/JVS-OpioidPAD) and another on how statin use following intervention for PAD is associated with improved limb salvage and survival (vsweb.org/JVS-StatinsPAD).

Despite affecting an estimated 10 million Americans, PAD is poorly understood and frequently undiagnosed.

Help educate your patients with PAD materi-

als from SVS. You can find PAD fliers in English and Spanish; a Practice Guidelines Pocket card; reporting standards; and a multidisciplinary consensus document at vsweb.org/PAD.

Final Membership Application Date:

Prospective members have one final chance in 2019 – Dec. 1 – to apply for membership. The extensive member benefits include discounts on educational meetings and products; free subscriptions to the Journal of Vascular Surgery for Active, Associate, and International members; networking; and the SVSConnect online community.

Members also receive evidence-based clinical practice guidelines as well as other practice

management resources; leadership and mentoring opportunities; scholarships; research grants for every career stage; an advocacy voice in Washington, D.C.; a job board; and much more. Apply today. Visit vsweb.org/Join.

Dues Due by Year's End: Invoices for 2020 dues will be emailed to all SVS members in early October. Payment is due by Dec. 31 to maintain SVS membership.

Councils, Committees Listing: Want to know who chairs or is a member of a particular SVS council or committee? Updated listings are available at vsweb.org/Committees1920.

From JVS

The Journal of Vascular Surgery's October issue (available approximately Sept. 23) includes four articles that will be available free through Nov 30. The articles address:

- Thirty-day readmissions for diabetic foot ulcers and their cost burden; vsweb.org/JVS-DiabeticFootCost
- The relationship between PAD and high-risk opioid use; vsweb.org/JVS-OpioidPAD
- End-stage renal disease patients and their survival after major lower extremity amputation; vsweb.org/JVS-EndStageRenalSurvival
- Spot stenting versus full coverage stenting following endovascular therapy for femoropopliteal artery lesions; [www.jvascsurg.org/article/S0741-5214\(19\)30179-X/fulltext](http://www.jvascsurg.org/article/S0741-5214(19)30179-X/fulltext)

'Surgery Is Only Part of Our Story' – Branding Initiative Takes Shape

After nearly a year of research, consultation and consideration, after hearing feedback from approximately 300 members on tone, approach and messaging, the Society for Vascular Surgery is about to begin implementing a branding campaign.

The SVS Executive Board approved referral communication planning and production in July. The Springboard consulting firm will test communications with referral sources and tweak as necessary. The campaign is expected to roll out in the spring, ahead of the 2020 Vascular Annual Meeting.

The first phase will target refer-

ral sources. Springboard, the SVS consulting firm on branding, will position vascular surgeons as central partners – the “go-to” specialists – for primary care physicians and other health care providers.

Members who completed the branding survey in June stressed strongly that they prefer that “surgeon” and “surgery” be front and center in any campaign. “Other providers also do vascular interventions, so we will make sure that our communications support a claim that only surgeons can make,” said Joseph Mills, MD. He chairs the SVS Public and Professional Outreach Committee, which

is developing the branding initiative.

Survey respondents particularly liked messaging that points out the comprehensive care a vascular surgeon provides. “Members see ‘comprehensive’ as a distinguishing characteristic and a good branding point,” said Dr. Mills. They also strongly preferred the theme that “surgery is only part of our story.” “Those points were overwhelmingly the favorites.”

A number of implementation steps are under consideration. These may include:

- A robust referral source pres-

Branding continued on page 14

MAKE AN IMPACT...

APPLY FOR

SVS & SVS FOUNDATION AWARDS

The Society for Vascular Surgery and the SVS Foundation's awards, grants and scholarships help our members **change the future**, and also honor those who already have. We support members' research, continuing education and community projects with **awards for every career stage**, and also honor members for career **excellence and innovation**.

Deadlines for many SVS and SVS Foundation Awards are below. Apply now!

SVS | Society for Vascular Surgery

FALL 2019

- SVS Vascular Surgery Trainee Advocacy Travel Scholarship

JANUARY 2020

- General Surgery Resident/ Medical Student VAM Travel Scholarship
- Diversity Medical Student VAM Travel Scholarship

FEBRUARY 1, 2020

- Excellence in Community Service Award

MARCH 1, 2020

- Lifetime Achievement Award
- Medal for Innovation in Vascular Surgery
- Women's Leadership Training Grant

SVS | Foundation

NIH/AHRQ MULTIPLE DEADLINES

- Mentored Research Career Development Awards (K Awards)

JANUARY 2020

- Resident Research Award
- Vascular Research Initiatives Conference Trainee Award

FEBRUARY 1, 2020

- Student Research Fellowship

MARCH 1, 2020

- Clinical Research Seed Grant
- Community Awareness and Prevention Project Grant
- E.J. Wylie Traveling Fellowship

For a complete list of SVS and SVS Foundation awards, visit vsweb.org/Awards



KILROY79/GETTY IMAGES PLUS

NEWS FROM SVS

Surgeons, How's Your Fiscal Health? Are You Under-Insured For Disability Insurance?

Vascular surgeons know they need excellent medical malpractice insurance. But how about disability insurance? SVS members just might be significantly under-insured, potentially impacting their lifestyles after a disability.

SVS' Affinity Program of expanded benefits can connect members with individual disability plans with three companies – Principal Life Insurance Company, Securian, and Lloyd's of London. These plans provide tax-free benefits, protecting hundreds of thousands of dollars – maybe even millions – in future tax-free benefits income.

This is unlike group plans in which the employer or group pays the premium. "You may need 100 percent of the pretax benefit to live on," explained Mark Blocker, broker for the

SVS Affinity Program. "This is the biggest issue members face, in deciding on a disability insurance plan."

Federal and state taxes could reduce a \$300,000 annual benefit through a group or employer-paid plan by \$144,000 (40 percent federal rate and 8 percent state tax rate). "Now the surgeon is down to just \$156,000, or \$13,050 a month," Blocker said.

He also stressed the importance of a policy clearly defining and covering a vascular surgeon as such a surgeon. "Your income is then protected as a 'vascular surgeon,' with no other income offsets to reduce the benefit. You are paid if you cannot perform surgery."

Contact Mark Blocker at mark@nationalaffinity.net or at 949-554-9936; he is available after-hours and on weekends.

Branding

continued from page 13

ence on the SVS website that references vascular surgeons' comprehensive capabilities, differentiators and the benefits they provide the referring source's own team, and further development of a "find a vascular surgeon" tool, among other possibilities.

- Reaching referral sources in a

variety of ways that could include through their professional societies, via society meetings and presentations, advertising and media outreach.

- Providing SVS members with the tools they need to engage referral sources on the local level.

Subsequent phases will focus on consumers, hospital administrators and medical students, with implementation plans developed for each audience.

Members, Please Sign Up To Be Mentors; Influence a Next-Generation Vascular Surgeon

Wanted: Mentors to help shape a medical student or resident's career.

The Society for Vascular Surgery's online community, SVSConnect, is introducing a new "Mentor Match" feature. It provides a simple way to match general surgery residents and medical students with vascular surgeons who can help guide the younger people in their careers in the specialty.

"In surveying our residents and students, they told us how much they'd like someone to mentor them. We're telling them we heard them," said William Shutze, MD, who is spearheading the initiative with Nam Tran, MD. "They're interested in our specialty – and now we need a big pool of volunteers to help them."

Needed are a very diverse group of mentors, from all practice types and from all over the country/world.

Signing up is easy. Mentors must be SVS members and able to sign in on SVSConnect. Once logged in, they just click the "Mentor Match" tab in the main menu and head to the "Get Started" page to enroll. Mentees will be able to sign up later, and all will be notified when the matching process can begin.

Mentees fill out forms indicating their interests in having a mentor; they may choose from different practice settings, training options, research, even navigating work/life balance. Once they locate a possible mentor, the mentee will reach out via email to get the relationship going.

Drs. Shutze and Tran hope that beyond providing career guidance Mentor Match also will draw more surgeons into vascular surgery. Though SVS has taken several active measures in recent years to grow the vascular surgery workforce, it's anticipated demand will exceed supply in coming years. Mentor Match will be a valuable tool to increase the visibility of the specialty and encourage students and residents to explore it as a career option, said Dr. Tran.

"Unless students and residents are fortunate enough to already know or have been introduced to a vascular surgeon, there is very little opportunity for them to be exposed to vascular surgery and to consider it as a career," Dr. Tran said. "Mentor Match will help fill that need, and more. Dr. Shutze and I hope hundreds of members answer this call."

Sign up at vsweb.org/SVSConnect.



DENPOTISEV/GETTY IMAGES

The Arc of Leadership

BY MISTY HUMPHRIES, MD

ON BEHALF OF THE LEADERSHIP AND DIVERSITY COMMITTEE

Two years ago, I wanted answers to the question, "How does leadership style change as one moves through his or her career?" The question resonated with the Leadership and Diversity Committee, and I was awarded the SVS Women's Leadership Training Grant. I spent time with three female leaders at different levels in their careers to see how they lead. It was an amazing experience and I am forever grateful to Drs. Wei Zhou, Division Chief, University of Arizona-Tucson; Melina Kibbe, Chair-Department of Surgery, University of North Carolina; and Julie Freischlag, CEO and Dean, Wake Forest Baptist Medical Center for their time and openness regarding leadership styles, career priorities, changes they made over time and mistakes they made. Here is what they had to say.

Q. What is the greatest part of being a leader?

A. Dr. Kibbe: By far, being able to develop people. One of the things that gives me the greatest pleasure is helping others reach their dreams and follow their passion. As a leader you have the ability to develop programs and people. When you support others the way they need to be supported you see their passion thrive and become a success.

Q: How did you decide you wanted to take the next step as a leader?

A. Dr. Freischlag: I knew there were changes I wanted to make for the better of the organization and that to do things the way I saw as better, I would need to be in the leadership role. It's especially hard when you are in a place where you see change that needs to be made, but you do not have the power to make those changes.

Leadership continued on page 16



THE MOTE VASCULAR FOUNDATION

"Building a successful vascular practice: what you were not taught in your fellowship"

**11th Annual Symposium
December 6-7, 2019**

Each year, the Mote Vascular Foundation offers a symposium in Sarasota, Florida on how to build a successful practice. This is an extremely informative event.

Your airfare, hotel, and dinner functions will be courtesy of the Foundation (to be reimbursed at the end of the conference).

If you are interested in attending the meeting, please register as soon as possible as space is limited. Additional information can be obtained by contacting:

**Russell H. Samson, MD, FACS, DFSVS, RVT
or
Lauren Fishman**

**600 N. Cattlemen Road, Suite 220 Sarasota, FL 34232
PH: 212-355-5702 FX: 212-308-5980**

lfeventsny@gmail.com

CMS Issues Proposed Rules for QPP, Fee Schedule and HOPPS for 2020

SVS' Policy and Advocacy Council is working with its committees' members to submit comments on proposed government rules that will directly impact vascular surgeons and the care they provide to Medicare patients.

The comments are in response to the Centers for Medicare & Medicaid Services (CMS) CY 2020 Proposed Medicare Physician Fee Schedule (PFS) and Year 4 Quality Payment Program (QPP) and the Hospital Outpatient Perspective Payment System (HOPPS) Rules.

CMS issued the proposed rules in late July. Comments are due Sept. 27.

The Physician Fee Schedule includes several provisions of interest for vascular surgeons, including:

- Substantial changes to evaluation and management coding and their reimbursements effective Jan. 1, 2021
- Abdominal Aortography (CPT Codes 75625 and 75630)
- Angiography (CPT Codes 75726 and 75774)
- Duplex Scan Arterial Inflow-Venous Outflow (CPT Codes 93X00 and 93X01)
- Exploration of Artery (CPT Codes 35701, 35X01, and 35X01)
- Iliac Branched Endograft Place-

ment (CPT Codes 34X00 and 34X01)

- Intravascular Ultrasound (CPT Codes 37252 and 37253)
- Stab Phlebectomy of Varicose Veins (CPT Codes 37765 and 37766)
- Market-Based Supply and Equipment Pricing Update
- Professional Liability Insurance and the malpractice RVUs
- Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

For more information on the coding and reimbursement issues included in the proposed CY2020 MFS, visit vsweb.org/MFS2020.

Year 4 (QPP): QPP includes the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models, launched in 2017. It replaced the sustainable growth rate factor (SGR) and the previous quality incentive programs for physicians. CMS has proposed several increases in the requirements for CY 2020, with a physician's performance on these requirements impacting their payments in CY 2022. A total of 9 percent of a physician's Medicare payments could be at risk if a phy-

sician does not participate in 2020.

CMS proposes to use episode-cost measure in MIPS for 2020. Of particular concern – and member comments will be sought – is a new hemodialysis access episode-based cost measure that could impact SVS members' cost scores under MIPS. More information on this issue will be available in upcoming issues of the Pulse electronic newsletter.

CMS also is considering a new reporting program to replace MIPS in 2021, the MIPS Value Pathways. SVS will be reviewing CMS' proposals and commenting extensively on this new program.

Visit vsweb.org/QPP4 for the CMS summary of the Proposed Year 4 QPP rule.

Hospital Outpatient Perspective Payment System (HOPPS)

The HOPPS proposed rule includes several provisions of interest for vascular surgeons, for which SVS is submitting comments:

- Prior authorization for vein ablation
- Hemodialysis duplex (93X00, 93X01)
- New comprehensive APCs for Level 2 vascular procedures

• Clinic visit services furnished in excepted off-campus provider-based departments (PBDs)

• Device pass-through payment applications (Surefire® Spark™ Infusion System and Eluvia™ Drug-Eluting Vascular Stent System)

CMS has proposed several increases in the requirements for CY 2020, with a physician's performance on these requirements impacting their payments in CY 2022.

- New technology pass-throughs for breakthrough devices
- Making public consumer-friendly standard charges for a set of "shoppable services" transparent

Visit vsweb.org/HOPPS2020 for or more information on the coding and reimbursement issues included in the proposed rule.

Leadership

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Q: How did you establish yourself in your new leadership role?

A. Dr. Zhou: Coming into a new hospital as division chief, I first made sure to be clinically present. You need to establish your reputation all over again at a new place. I brought in new procedures and I made sure that we reached out to the community to let them know what was changing. I was also very selective of the first cases I did. You have to have good outcomes. This ensures confidence in others to refer you harder cases and allows you to build a program.

Q: As a female leader, what is the most significant barrier you have faced in your career?

A. Dr. Kibbe: I have been extremely supported. There may have been issues of subconscious or implicit bias that I did not know were present. I did have challenges in my career early on of folks trying to understand how I, as a surgeon scientist in a very clinical department, was contributing to the mission of the institution. I really credit my mentor. He established clear boundaries with my job so that others under-

stood the pressures and expectations that were put on me from the scientific side.

Q: What organizational culture did you change the most when you came into your role?

A. Dr. Freischlag: I think in many of my roles I have been looked at differently because I was a woman. When I went to lead at a very male-dominated institution, I had to work through that. Imagine if a man had to go to work every day and work only around all women, that's what my position was like. As a CEO, many think they can do the job better than I and there's a lot of scrutiny. Ultimately, I bring culture change by being nice and expecting that from those that work with me. I set that as the minimum expectation, and I hold people accountable. I also remind everyone that we work for patients and focus them on the expectation that first and foremost we will provide exceptional patient care.

Q: What is the leadership skill you spend the most time working on?

A. Dr. Zhou: You have to learn to work with people and figure out how to approach each individual. I try to identify each individuals' strengths and weaknesses and address these, so they feel appreciated in the institution.

Q: If you could give your younger self advice, what would it be?

A. Dr. Kibbe: Follow your passion and good things will happen. I sometimes wonder where my optimism comes from, as I am always happy. I think that happiness translated into some of my success.

Dr. Zhou: Spend more time getting to know people. I was so focused academically that I didn't do much networking. I was very focused on my research, and a broader network would've helped me.

Dr. Freischlag: Don't feel as if you have to apologize for anything. I am glad I did all the things I did and had the failures I did. When you fall down, get back up.

Over my year-long leadership quest, I learned I have many of the characteristics of a great leader already, and that we all refine those skills over time. I also learned to give myself grace as I develop my leadership style because we are all a work in progress.



DR. HUMPHRIES

A Call To Address Sexual Harassment and Gender Discrimination in Medicine

BY ERICA L. MITCHELL, MD; LAURA DRUDI, MD; KELLIE R. BROWN, MD; ULKA SACHDEV-OST, MD; AND DAWN COLEMAN, MD

PART II

Outcomes of Sexual Harassment

The negative effects of sexual harassment extend across the lines of industry, occupation, race, and social class. Research has shown that sexual harassment has stronger relationships with women's well-being than other job-related stressors. Sexual harassment and gender discrimination is associated with reductions in professional, psychological, and physical health and the relationship between sexual harassment and these outcomes remains significant even when controlling for (1) personality (negative affectivity, neuroticism, narcissism), (2) demographic factors (age, sex, education level), (3) work-related stressors (workload, rank, specialty), and (4) non-work related stressors.¹

Importantly, subjects of sexual harassment and gender discrimination display classic signs and symptoms of burnout as well as, in some cases, posttraumatic stress disorder. These symptoms include job dissatisfaction, decreased productivity, organizational withdrawal and decline in commitment, and mental health sequelae including anger, depression, anxiety, self-blame, and lowered self-esteem. Other studies show that the negative effects extend to witnesses, workgroups, and entire organizations.^{1,5} The more often women are sexually harassed, the more they think about leaving (and some ultimately do leave). The net result of sexual harassment and gender discrimination is a loss of talent. This loss of talent is costly to institutions and organizations, and to science, engineering, and medicine in general.

Women who experience sexual harassment often incur inevitable tangible and intangible losses, which can be exacerbated after formal reporting. Tangible losses include loss of job or career in medicine, and its associated economic, personal, and social benefits. Of these, loss of income and economic security is often most stressful. Intangible losses include loss of significant relationships or social support, both inside and

outside of the workplace or academic community.¹ Loss of important mentoring or coworker relationships can also add to the psychological stress experienced with loss of the support system. When harassment results in stigmatization and the loss of a highly valued position or career potential, the effects on the target can be devastating, beyond the financial stresses associated with job loss. This is compounded if the woman is labeled as a complainer and someone who "causes trouble" since the academic community is small and well connected. Even if she is able to leave the environment in which the harassment occurred, a "reputation" may prevent future similar job opportunities in academia.

Outcomes of Sexual Harassment for Women in Academic Medicine

Harassment and gender inequity are interdependent processes, and it is no coincidence that the devaluation of women is revealed in disparities in compensation, opportunity, and advancement.^{2,3} Subtle examples of discriminatory treatment are ubiquitous in academic medicine from how competent female students are perceived, the frequency with which women are invited to speak at conferences, the degree to which women and men self-cite, and how supported and inclusive a department feels.¹⁻³

Salary: In 2000, women physicians earned 63 cents for every dollar earned by male physicians.⁶ The gender pay inequity has not improved since 2000 and women physicians ubiquitously receive lower salaries than their male colleagues.⁶⁻⁹ This gender pay gap starts on first hire with newly trained male physicians earning on average \$16,819 more than newly trained female physicians.¹⁰ This gender gap in salary is not explained by specialty choice, practice setting, work hours, or other characteristics.¹⁰ A 2016 study found that on average women earn \$51,315 less than men (\$206,641 vs. 257,957) with sex differences in salary persisting after multivariable adjustment for age, years since residency, specialty, faculty rank, specialty, and measures of research productivity (NIH funding, clinical trials, publication count) and clinical revenue.⁹ This same

study revealed that women professors and associate professors have comparable adjusted salaries to those of male associate and assistant professors, respectively.⁹

The Doximity 2018 Physician Compensation Report revealed a \$105,000 salary difference for women physicians working full-time in all practice settings. These data were adjusted for geographic location, provider specialty and years in practice and revealed no single specialty where women earn more than men. This gender pay gap is a real issue: It defines the value of a women's work and predicts her future worth in retirement dollars. Even a small pay gap can result in women physicians accumulating much less wealth (a difference of \$500,000 or more) over their lifetime than their male counterparts.⁸

Promotion: Despite a constant pipeline of women into medicine in the last 30 years, the rate of ad-

vancement of women into leadership positions in academic medicine has been slower than would be predicted by their growing numbers in medicine.¹¹⁻¹⁴ Women are substantially less likely than men to hold the rank of professor than hold the rank of associate professor, and to advance to even higher academic leadership positions, even after accounting for age, experience, number of hours worked, specialty, and measures of research productivity (number of publications, amount of grant support).¹¹⁻¹⁴

The numbers speak for themselves. Women comprised 9.2% of medical school graduates in 1970-71, 48.6% in 2005-06, 46.3% in 2015-16 and 51% of all entering medical students this academic year.¹¹ Per 2015 AAMC data, female physicians only constitute 37% of full-time medical school faculty, 43% of assistant professors, 33%

Harassment continued on page 18

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2019
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at the GAYLORD NATIONAL RESORT & CONVENTION CENTER
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FDA Approves Gadavist for MRA of Select Arteries

BY LUCAS FRANKI
MDEDGE NEWS

The Food and Drug Administration has approved gadobutrol (Gadavist) injections, for use in conjunction with magnetic resonance angiography (MRA), to evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients. Approval was based on a pair of open-label, phase 3 studies in which the efficacy of gadobutrol was assessed, based on visualization

and performance for distinguishing between normal and abnormal anatomy. MRA with gadobutrol improved visualization by 88%-98%, compared with unenhanced MRA, in which visualization was improved by 24%-82%. Sensitivity and specificity were noninferior to unenhanced MRA.

The safety profile in the two current trials matched data previously gathered, with the most common adverse events including headache, nausea, and dizziness. "Until now, no contrast agents were FDA approved

for use with MRA of the supra-aortic arteries. With FDA's action, radiologists now have an approved MRA contrast agent to help visualize supra-aortic arteries in patients with known or suspected supra-aortic arterial disease, including conditions such as prior stroke or transient ischemic attack," Elias Melhem, MD, chair of the department of diagnostic radiology and nuclear medicine at the University of Maryland, Baltimore, said in the press release.

Find the full release on the Bayer website.

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Harassment

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of associate professors, and 20% of professors.^{11,15} Women who self-identify as Asian, Black or African American, Native American/Hawaiian, Pacific Islander and/or Hispanic make up only 5% of

all professors included in the entire 2015 AAMC faculty roster, emphasizing a particular struggle for women of color to be promoted in medicine. Representation of women in academic surgery is even lower than that seen in other specialties. While women comprise 38% of general surgery residents and 39% of surgical subspecialty

residents, their representation within academic ranks beyond residency is not on par. Women make up 24% of assistant professors, 17% of associate professors, and only 9% of full professors in surgery.¹¹

Leadership: Women comprise 65-80% of the healthcare workforce, 30% of senior leadership positions, 13% of all healthcare CEOs and 0% of CEOs of Fortune 500 healthcare companies. Despite having no difference in self-assessed leadership aspirations or ability to hold leadership positions between the genders, women are significantly less likely than men to have been asked to serve in leadership roles (6% vs. 25%).⁶ For underrepresented minority women, the ability to identify both mentors and sponsors who support their advancement is even more limited.¹⁶ Not surprisingly, women are more likely to feel discriminated against than men (33% vs. 5%).⁶

In academic medicine, gender disparities persist as women seek higher positions of leadership; women account for 19% of all permanent Department Chairs and 19% of permanent Deans.¹¹ Within academic medicine, where research-based faculty tracks alone can lead to top leadership, women are more likely to be clinicians and educators, and to assume the tasks referred to as "institutional housekeeping."⁵ When women do hold leadership positions, these positions typically focus more on image making and education rather than leadership in clinical and/or research roles.^{5,17}

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Dr. Mitchell is a vascular surgeon at Salem (Ore.) Hospital; Dr. Drudi is as vascular surgery resident at McGill University, Montreal; Dr. Brown is a professor of surgery at the Medical College of Wisconsin. Milwaukee; Dr. Sachdev-Ost is an associate professor of surgery at the University of Pittsburgh Medical Center; Dr. Coleman is an associate professor at The University of Michigan, Ann Arbor.

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Pediatric Renovascular Hypertension Symposium To Be Held

A novel and innovative symposium, organized by University of Michigan Medical School faculty, aims to improve outcomes for patients with pediatric renovascular hypertension (PRVH), a rare but potentially life-threatening disorder.

The First International Symposium on Pediatric Renovascular Hypertension will take place Nov. 11-12 in Ann Arbor, Michigan, on the U-M medical campus. Organizers hope to reach care providers that manage and refer infants and children with renovascular hypertension, such as pediatric nephrologists, cardiologists, radiologists and surgeons.

The growing adoption of catheter-based interventions for pediatric renovascular hypertension and the widespread implementation of such techniques by the casual interventionalist has dramatically changed the landscape of care provided to this unique cohort of patients. Moreover, there continues to be inconsistencies in patient selection for revascularization, techniques for such, and surveillance protocols leaving families to navigate complex medical recommendations sometimes independently and with great angst.

“Our multidisciplinary care team at Michigan Medicine has observed a marked increase in the number and complexity of referrals in the last decade. At least one-third of referred patients have failed prior interventions, complicating clinical care outcomes. We have also seen dramatic cases of delayed diagnosis and care, resulting in profound end organ damage. We are committed to advancing the care of these spe-

cial children” says Dawn Coleman, MD.

Pediatric renovascular hypertension secondary to renal artery occlusive lesions and abdominal aortic coarctation risks significant morbidity and mortality. Timely detection and treatment are critical to preventing ischemic nephropathy, chronic kidney disease, cardiopulmonary complications and stroke. However, the pathophysiology remains poorly defined; additionally, the low frequency of this disease limits existing data to institutional series and anecdotal case reports. As such, the optimal management of these children remains elusive.

Moreover, the introduction and expansion of novel open surgical and endovascular techniques for the revascularization of aortic and renal artery lesions for these children has dramatically changed the landscape of patient care in the last decade. As multidisciplinary high volume referral centers of excellence are few, across the globe, patients and families may be challenged to balance vastly differing sets of recommendations.

Distinguished Program; Keynote by Dietz

The First International Symposium on Pediatric Renovascular Hypertension will feature an international array of distinguished physicians and researchers, highlighting the best practices in patient care, recent discovery and ongoing research. The symposium will include a keynote address delivered by Harry Dietz III, MD, of the Johns Hopkins University School of Medicine. Dr. Dietz, as the Victor A. McKusick Professor of Genetics, also

serves as the director of the William S. Smilow Center for Marfan Syndrome Research and will speak to his own personal experience with gene discovery and translational efforts as the world’s leading authority on Marfan Syndrome and related disorders.

The two-day program includes moderated scientific and clinical sessions, devoted to general information about the condition, diagnostic imaging, medical management, revascularization options and current research in addition to expert panels.

Admission is free. The symposium is sponsored by the University of Michigan’s Taubman Institute, which was founded in 2007 by the late entrepreneur and philanthropist A. Alfred Taubman, to support the work of physician researchers with financial grants, the Taubman Prize and other programs. Learn more at TaubmanInstitute.org.

“Helping clinician-scientists launch projects that have the potential lead to better outcomes for patients and their families is a fundamental mission of the Taubman Institute,” said the institute’s director, Charles F. Burant, MD, PhD. “We are delighted to sponsor this inaugural symposium. We expect that the meeting will lead to more timely, personalized treatment for every child with this condition.”

For the full program agenda, registration link and travel information, visit <https://www.umich-pedirvhsymposium.org/>

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CLI Assessment

Perfusion from page 1

Clinical Cardiology, and the Council on Cardiovascular and Stroke Nursing.

Of particular concern were limitations seen in the use of ABI, the most widely used assessment method. “Although ABI was first described to diagnose PAD, it has not been shown to be an accurate predictor of wound healing or major adverse limb events. Clearly, the ABI provides important prognostic information, including the risk of death, myocardial infarction, and stroke ... and should be performed in all patients suspected of having PAD,” but in about 30% of patients with angiographically documented CLI, the ABI is normal or noncompressible, the authors wrote.

And, although recent data indicate that toe pressure may be a better predictor of major adverse limb events and tibial disease in patients with CLI, especially among those with isolated below-knee disease, there was no solid evidence that ABI or TBI have the sensitivity or specificity to be used as perfusion tools to assess wound healing or limb salvage, the authors stated.

However, there may be some technological improvements on the horizon for assessing limb perfusion that might provide eventual benefits, according to the reviewers.

These include the use of indigo carmine angiography to evaluate microcirculation and angiosomal revascularization, the use of CT perfusion or MRI to quantify perfusion and monitor treatment response, the use of contrast-enhanced ultrasound to assess calf muscle perfusion, and hyperspectral imaging.

Among the other issues of concern raised in the AHA statement were the significant demographic disparities that occur in detection and treatment of CLI. The authors noted differences in how CLI is diagnosed, the coexisting conditions that were present, and the disparities in treatment given based on sex and racial differences. For example, women were more likely to experience emergency hospitalization, have differences in blood flow, and have higher disability and death rates.

As for racial disparities, the reviewers found that black and Hispanic patients with CLI were more likely to have diabetes and chronic kidney disease, and were more likely to develop gan-

grene, compared with white patients, who were more likely to have ulcers and pain in their legs while at rest.

In terms of treatment, black patients were 78% more likely to receive lower-extremity amputation for CLI, compared with their white peers, even after adjustment for socioeconomic status, access to facilities with revascularization services, and other factors, according to the report, which was published online in *Circulation*.

“CLI is a complex disease process with great morbidity. This statement highlights the importance of incorporating perfusion assessment into the care of CLI patients. Despite the high prevalence of CLI, strategies for perfusion assessment remain limited. New technologies offer potential opportunities to improve the precision and quality of CLI management,” the researchers concluded.

Dr. Misra and the majority of the authors reported having no relevant disclosures. Several authors reported receiving funding from the pharmaceutical and medical device industries.

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SOURCE: Chandra S. et al. *Circulation*. 2019;140. doi: 10.1161/CIR.0000000000000708.



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