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SOURCES OF NEEDS

IAHB has established procedures for identifying and analyzing the continuing education needs and interests of prospective activity participants. IAHB incorporates a systematic approach to collecting and analyzing information about the educational needs of individuals and/or organizations. This needs assessment was prepared using the following sources.

- Clinical expert opinion
- New/innovative clinical findings
- Data from external sources
- Journal articles or publications
- Society clinical guidelines

NEEDS ASSESSMENT SUMMARY

Interventional medical practitioners are specialists who perform minimally invasive procedures. Most often, these procedures utilize various imaging and catheterization techniques in order to diagnose and treat coronary artery and other atherosclerotic vascular disease. Interventional specialists including interventional radiologists, interventional cardiologists, and endovascular surgeons, are currently perfecting the use of stents and other procedures to keep diseased vessels open, while also evaluating the application these procedures. The rapid new development of imaging technologies, mechanical devices, and types of treatment, while certainly beneficial to the patient, can also lead to ambiguity regarding specific specialty claims on certain

techniques and devices. While these practitioners can be in competition with each other, cooperation and communication are the most advantageous methods to deliver the best medical care to patients, now and in the future. Furthermore, the aging population will greatly increase the number of patients needing care for vascular diseases, making multidisciplinary education on interventional techniques essential.

Peripheral Vascular Disease

Peripheral vascular disease (PVD) includes any disorder of the arteries and veins that comprise the circulatory system excluding the brain and heart. Arterial diseases (also known as peripheral arterial disease or PAD) include those disorders that cause either fixed obstruction or abnormal vascular reactivity of the arteries that supply a given tissue; the obstruction impairs blood delivery and can produce ischemia. Conditions associated with PVD that affect the veins include deep vein thrombosis (DVT), varicose veins, and chronic venous insufficiency. The primary cause of PVD is atherosclerosis, which is a complex process involving endothelial dysfunction, lipid disturbances, platelet activation, thrombosis, oxidative stress, vascular remodeling, inflammatory processes, and genetic factors.[1]

The pathophysiology of PVD follows a progression from formation of lesions in arteries and veins, formation of the fatty streak, fibroproliferative development of atheroma, and development of advanced lesions. These advanced lesions intrude on the lumen, which promotes development of stenoses and chronic ischemic syndromes that prevent circulation of oxygenated blood and can cause formation of blood clots.[1,2] Current estimates suggest that PAD affects almost 10 million people in the United States, with the majority of cases diagnosed in those aged 50 and older. Venous disease is also common—it is estimated that 15-20% of the total population suffers from varicose veins and 0.1-0.2% suffer from chronic venous insufficiency or venous ulcer. In addition, 200,000 new cases of DVT are reported annually in the U.S.

The primary risk factors for PVD include older age, cigarette smoking, comorbid diabetes mellitus (DM), hyperlipidemia, and hypertension.[3] PVD is associated with increased risk of cardiovascular (CV) morbidity and mortality including myocardial infarction and stroke as well as significant functional impairment and decline with disease progression.[4] Early, accurate diagnosis and treatment can prevent or delay some of the CV and functional impairments. Intermittent claudication is the primary symptom of PVD and the ankle-brachial index (ABI) is considered the most sensitive diagnostic test for PVD, which provides a ratio of Doppler-recorded systolic blood pressures in the upper and lower extremities. The ABI ratio declines with increasing arterial obstruction and an ABI less than 0.90 is considered the threshold for diagnosis of PVD.[4] Management of PVD includes modification of risk factors including smoking cessation, antiplatelet therapy, lipid-lowering therapy, hypertension control, and glycemic control for patients with DM.[5]

Despite the availability of interventions to prevent or delay progression of PVD, multiple studies have demonstrated that physicians underutilize many of the pharmacologic regimens and fail to promote lifestyle modifications in patients at risk of PVD or with early stage PVD. Consequently, a significant number of patients require peripheral vascular interventions.[6] The number of peripheral vascular interventions is estimated to have increased 979% since 1995 and it is conservatively estimated that endovascular techniques may replace at least 50% of traditional vascular surgeries in the next few years.[7,8] Peripheral vascular interventions offer significant patient benefits including elimination of risks associated with general or epidural anesthesia and conventional surgery, reduced patient discomfort, faster time for patient recovery, and lower costs.[8] As the population ages, the prevalence of PVD will increase and the need for trained physicians with the requisite knowledge and skills to perform peripheral vascular interventions will increase significantly. However, the Clinical Competence Standards for Peripheral Vascular Interventions note that "Guidelines are currently in effect within subspecialty societies that require training programs to include endovascular procedures within their curricula. However, these guidelines are non-uniform regarding the exposure required, they do not distinguish between different vascular territories, and they lack a standardized mechanism for evaluation of competence."[9]

In addition to a lack of standardized training guidelines, including a minimum number of procedures required for the demonstration of competence, physicians are continually challenged by the need to acquire skills to perform newer, less-invasive interventions for treatment of PVD. These include, but are not limited to new or refined techniques such as transcatheter lytic therapy, percutaneous transluminal balloon angioplasty, percutaneous renal revascularization, stents and stent-grafts, bypass grafting including infrainguinal and femoral-popliteal or femoral-tibial-pedal bypass grafts, endoluminal treatment of abdominal aortic aneurysms, endovascular removal of thrombus, and transcatheter embolotherapy. These interventions are enhanced when integrated with multimodality noninvasive imaging procedures including duplex sonography, magnetic resonance imaging, computed tomography imaging, and contrast angiography.[2,8,10,11] Training and standards for performance of these new procedures and techniques are an ongoing need for physicians performing state-of-the science peripheral vascular interventions.

The minimal skills required in competence in the vascular interventionist for peripheral interventions include the following.[9]

- Ability to safely gain vascular access from multiple sites including femoral, popliteal, and upper extremity arteries, as well as femoral, upper extremity, and neck veins
- Ability to obtain hemostasis including application of compression and vascular closure devices
- Ability to manipulate guidewires and catheters
- Ability to place and deploy angioplasty equipment including balloons, atherectomy devices, stents, and distal protection devices
- Ability to recognize and treat procedure-related complications (eg, dissection, pseudoaneurysms, embolism, vessel perforation, or occlusion, stent thrombosis, and adverse hemodynamic events)
- Ability to perform catheter-directed thrombolysis/thrombectomy
- Ability to perform vascular interventions in each of the following: aorta and lower extremity arteries, brachiocephalic and upper extremity arteries, mesenteric and renal arteries, central and peripheral veins, and pulmonary arteries

In addition to these technical skills, clinicians require knowledge of normal vascular anatomy and its variations; the etiology and pathophysiology of PVD; vascular biology; normal mechanisms of blood vessel function and hemostasis regulation; procedures; and interpretation of test results for the diagnosis of vascular disease, especially occlusive diseases, aneurysmal disease, arterial dissection, and arterial and venous thromboembolism, which comprise the majority of disorders treated by peripheral interventions.[9]

Carotid Artery Disease

Carotid stenosis is one of the major preventable causes of ischemic strokes,[12] and the prompt evaluation and treatment of patients with symptomatic carotid stenosis is essential to reduce the risk of recurrent cerebrovascular events such as ipsilateral stroke following a transient ischemic attack (TIA).[13] The recently developed and validated ABCD scoring system (based on age, blood pressure, clinical features, duration of TIA, and presence of diabetes) has been demonstrated to successfully estimate the short-term risk of a stroke after a TIA, and high ABCD scores appear to identify patients with moderate-to-severe carotid stenosis.[13]

In 2006 the American Heart Association (AHA) and American Stroke Association (ASA) released guidelines for the prevention of stroke that addressed both carotid endarterectomy (CEA) and carotid angioplasty and stenting (CAS) for the treatment of extracranial carotid disease.[14] The AHA/ASA guidelines recommend

- CEA with a perioperative morbidity and mortality <6% for patients with recent TIA or ischemic stroke within the previous 6 months and ipsilateral severe carotid stenosis (70%-99%)
- CEA, depending on patient-specific factors (eg, age, gender, and comorbidities), for patients with recent TIA or ischemic stroke and ipsilateral moderate carotid stenosis (50%-69%)
- There is no indication for CEA with carotid stenosis <50%

- CAS is not inferior to CEA and may be considered in patients with symptomatic severe stenosis (>70%) and
    - The stenosis is difficult to access via CEA
    - Medical conditions are present that would greatly increase surgical risk
    - Special circumstances exist, such as radiation-induced stenosis or previous CEA with recurrent stenosis
- CAS is reasonable when performed by physicians with established periprocedural morbidity and mortality rates of 4%-6%

Similarly, in 2008 the Society for Vascular Surgery (SVS) released clinical practice guidelines for the management of atherosclerotic carotid artery disease that detail recommendations and suggestions for treatment strategies in various patient populations.[15] According to the guidelines, the SVS

- Recommends optimal medical therapy rather than revascularization in symptomatic and asymptomatic patients with low-grade carotid stenosis (<50% in symptomatic patients and <60% in asymptomatic patients)
- Recommends CEA plus optimal medical therapy in symptomatic patients with moderate-to-severe carotid stenosis ($\geq$50%)
- Suggests CAS as a potential alternative to CEA in symptomatic patients with moderate-to-severe carotid stenosis ($\geq$50%) and high perioperative risk
- Recommends CEA plus medical management in asymptomatic patients with moderate-to-severe carotid stenosis ($\geq$60%) as long as perioperative risk is low
- Recommends against CAS for asymptomatic patients with carotid artery stenosis

Factors that contribute to high risk in CEA and promote the use of CAS for treating carotid stenosis include both anatomic risk factors and medical risk factors.[15-17] High risk is associated with previous CEA with recurrent stenosis; prior radiation therapy to the neck with permanent skin changes; previous ablative neck surgery; common carotid artery stenosis below the clavicle or lesions high in the cervical internal carotid artery; contralateral vocal cord paralysis; presence of tracheostomy stoma; severe tandem lesions; dialysis-dependent renal failure; low left ventricular ejection fraction; oxygen- or steroid-dependent chronic lung disease; age >80 years; open heart surgery needed within 6 weeks or myocardial infarction (MI) within the preceding 4 weeks; congestive heart failure; and unstable angina.[15-17] However, a recent retrospective chart review revealed no significant difference in long-term survival or stroke rate between medical high-risk patients undergoing CAS or CEA.[18]

The SVS clinical practice guidelines note that patients who want to avoid surgical scarring or perioperative morbidity and mortality risks may opt for CAS; this choice may be further strengthened by the lack of consensus about the optimal surgical techniques for CEA.[15] Often, though, a decision between CEA and CAS in clinical practice is primarily based upon the extent of stenosis.[12] It has been suggested that, with the range of available surgical, endovascular, and medical therapies, selecting the optimal treatment for each individual patient should depend upon the method through which the lowest morbidity rates and most favorable outcomes are likely to be achieved.[17] Additionally, it is evident that the AHA/ASA guidelines address a somewhat different clinical focus than that of the SVS guidelines; therefore, physicians may need to take into account both sets of guidelines when determining a treatment strategy for carotid stenosis.

Preliminary results have been recently released from both the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) and the International Carotid Stenting Study (ICSS) and, like previous clinical trials, their results have demonstrated little agreement. Data from CREST, which included more than 2500 symptomatic and asymptomatic patients across the U.S. and Canada, were reported at the 2010 ASA International Stroke Conference. The data revealed no significant difference in the primary end point of any stroke, MI, or death during the periprocedural period, or in ipsilateral stroke during follow-up between CAS

(7.2%) and CEA (6.8%).[19] Similarly, no significant difference was observed in rates of ipsilateral stroke during a mean follow-up of 2.5 years between CAS (2.0%) and CEA (2.4%).[19] Differences between groups were observed at 30 days for individual components of the primary end point; the rate of stroke was significantly higher with CAS (4.1%) than with CEA (2.3%), whereas the rate of MI was significantly greater with CEA (2.3%) than with CAS (1.1%).[19]

Data from ICSS, which enrolled 1713 recently symptomatic carotid stenosis patients across several European countries, include 120-day interim safety results and a magnetic resonance imaging (ICSS-MRI) substudy investigating ischemic brain lesions following treatment.[20,21] Although final results are anticipated in 2012, ICSS appears to show conflicting data as compared with CREST. Stroke, death, or procedural MI were significantly greater in CAS patients than CEA patients (8.5% versus 5.2%, respectively). Similarly, CAS patients were found to have a greater risk of any stroke than CEA patients (7.7% versus 4.1%, respectively), and CAS patients were found to have a greater risk for all-cause death than CEA patients (2.3% versus 0.8%, respectively).[20]

Despite the importance of treating carotid stenosis, the various screening techniques (ie, ABCD score[13] and imaging methods[12,13]) that can be used to detect the lesions, and clinical guidelines from the AHA/ASA and the SVS, the optimal therapeutic regimen for carotid stenosis remains uncertain.[15,22] Adding to this uncertainty is the conflicting data reported from several studies and meta-analyses in regard to whether CEA is a superior treatment option compared with CAS.[19,20,23-28] It is likely that differences in methodology and patient populations contribute to these conflicting data. Based on these considerations, physicians require education on the recommended therapeutic options in various patient populations; recent data from meta-analyses and randomized controlled trials comparing CAS with CEA; and an analysis of the methodological and patient selection differences among clinical trials and meta-analyses.

Vascular Access

Femoral artery access during diagnostic and interventional procedures, such as percutaneous coronary intervention (PCI), is associated with a 2.4%-9.5% risk of bleeding and thrombotic complications, leading to approximately a 12-fold increased risk of death and 4-fold increased risk of myocardial infarction.[29-32] These post-procedure vascular complications have been shown to increase hospital costs by $4830 and length of stay by 2.1 days.[33] As such, femoral access management represents one of the best opportunities to increase efficiency and lower costs associated with these procedures.

The reference standard for hemostasis of the femoral vascular access site is manual or mechanical compression, which involves the application of heavy pressure for 15 to 30 minutes followed by prolonged bed rest. Manual compression is indicated for use in several subsets of patients including those whose arteriotomy site is below the femoral bifurcation, where the common femoral artery is <5 mm in diameter, and in cases where there is extensive plaque, calcification, or scar tissue.[30] Additionally, manual compression is used in cases where a closure device fails, which occurs in up to 8% of cases.[30] Although this technique is easy to learn, associated with minimal cost, and usable for all patients, manual compression may be painful and can cause deep vein thrombosis due to femoral vein compression and stasis.[29,30]

A variety of vascular closure devices (VCDs) have been introduced in an effort to improve patient outcomes, patient comfort, and catheterization laboratory efficiency.[34,35] These devices are typically indicated for use in patients in whom the femoral puncture entry point in the common femoral artery is 1 or 2 cm above the femoral bifurcation or for patients who have undergone many procedures and who may have fibrosis around the artery.[30] Femoral angiography is now routinely used to evaluate the presence or extent of PVD, extensive calcifications, or plaque, and aid in proper sheath placement. Together with assessment of anticoagulant use, this information can be used to select the optimal femoral access management technique.

As a group, VCDs generally result in improved patient satisfaction and comfort related to avoidance of prolonged sheath insertion and manual compression.[36] Because time to hemostasis is reliably shortened

compared with manual compression, patients are generally able to ambulate much sooner.[35,37-40] Although early ambulation may not translate into reduced length of stay for patients undergoing PCI, studies have shown that femoral access management with one of these devices can shorten hospital stays following diagnostic procedures.[34,39,41]

Although VCD technology is an important part of diagnostic and interventional procedures in many institutions, concerns remain regarding the potential for device-associated complications, device cost, and, for some devices, lack of superiority over manual compression.[29] Potential complications include infection, femoral artery compromise, arterial laceration, uncontrolled bleeding, pseudoaneurysm, atrioventricular fistula, device embolism, and limb ischemia.[29] When these complications occur after PCI, they can be more severe when compared with manual compression, but there is no evidence to suggest that patient outcomes are worse.[41,42] The overall complication rate of vascular access and closure decreased from 3.4% in 2002 to 2% in 2006, although it is unclear whether this result is due to better access techniques, better adjunctive sheath and pharmacological management, or better VCD and deployment techniques.[29,43]

Currently, the data suggest that the primary devices in use for femoral access management are generally similar to one another in efficacy and incidence of complications.[29] Consequently, device selection is made in large part based on surgeon preference and aptitude with the technique. Dauerman and colleagues (2007) maintain that for VCD utilization to achieve its maximum potential to improve clinical outcomes, educational and practice opportunities are critical, particularly with regard to access technique.[29] As the field progresses, vascular surgeons and hospitals will continue to devise best practice strategies that include the use of routine femoral angiography to identify patients with major risk factors; selecting anticoagulation and antiplatelet strategies to minimize bleeding risk; defining protocols and measures within a hospital or clinic; and improving communication regarding the importance of adhering to established treatment protocols.

Anticoagulant Therapies

Venous thromboembolism (VTE) is a serious condition that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE).[44] Although the National Quality Forum (NQF) endorsed consensus standards in 2006 for the prevention and treatment of VTE,[45] the US Surgeon General's Call to Action in 2008 indicated that these guidelines are not routinely followed and indicate significant gaps in the application of evidence-based interventions.[46] The lack of adherence to the guidelines includes both prevention and treatment of VTE, and it was suggested that clinicians may not be aware of, or inadvertently overlook, these guidelines.[46]

The NQF consensus standards include a policy statement, 17 characteristics of preferred practices, and 2 performance measures. The policy statement, encompassing all healthcare facilities, urges the implementation of an evidence-based written policy for improving risk assessment, prevention, diagnosis, and treatment of VTE.[45] The 17 preferred practices further define the goal of the policy statement. Current guidelines recommend the short-term or long-term use of anticoagulant therapy for the prevention of VTE or PE in patients undergoing general surgery or major orthopedic surgery, and for treatment and secondary prevention of acute DVT and PE.[47] Treatment of VTE typically includes rapid initial anticoagulation with parenteral anticoagulants to minimize risk of thrombus extension and subsequent PE, and extended therapy with oral anticoagulants is administered to prevent recurrent VTE.[48]

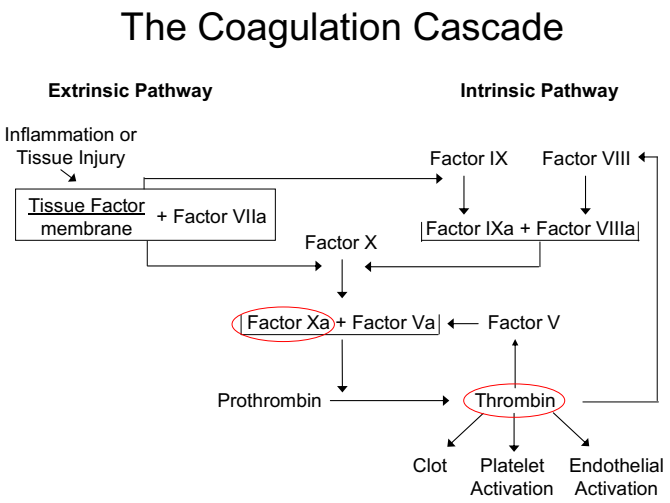
Recently, the American College of Chest Physicians (ACCP) released evidence-based clinical practice guidelines that address the management of vitamin K agonists (VKAs). The guidelines address dosages of VKAs and the monitoring of INR values and, importantly, the optimal management of VKA therapy. The ACCP guidelines recommend that healthcare providers "should manage oral anticoagulation therapy in a systematic and coordinated fashion, incorporating patient education, systematic INR testing, tracking, follow-up, and good patient communication of results and dosing decisions as occurs in an anticoagulation management service."[49] Despite the guidelines and the efficacy of VKAs, oral anticoagulants are underutilized; 2 different reports have indicated that approximately 50% of those patients who should receive oral anticoagulants actually did.[50] Several factors have been suggested to explain the undertreatment of

patients at risk for thromboembolism including physician reluctance, patient preference, and the drugs themselves. Physicians may not appropriately apply risk stratification or the treatment guidelines, and they tend to overestimate the bleeding risks associated with VKAs.[50] Patients have little knowledge of thromboembolism, the complications associated with the conditions, and the need for antithrombotic therapy, and as many as 40% of patients prefer to not receive the drugs.[50] In addition, frailty of older people, cognitive impairment, poor compliance in monitoring and treatment, and associated comorbidities and concomitant medications have all been reported to reduce the initiation of VKA administration.[50]

Rapid initial anticoagulation is accomplished through the use of parenteral anticoagulants such as heparin, low-molecular-weight (LMW) heparin (eg, enoxaparin), or fondaparinux. Although these agents have proven effective for treating and reducing thromboembolism, the need for daily subcutaneous injections makes them inconvenient for long-term use outside of the clinical setting and they require dosing adjustments and monitoring to stay within the therapeutic range.[48] Currently, the only oral anticoagulants available are VKAs, including warfarin. However, like the parenteral anticoagulants, the VKAs have significant limitations.[48] The orally available VKAs have a slow onset of action that necessitates overlap with a parenteral anticoagulant for a minimum of 5 days.[49] The safety and efficacy of VKAs depends on a very narrow therapeutic window, and it has been demonstrated that patients are typically within the therapeutic range only 63%-68% of the time and can be in the therapeutic range as little as 30% of the time.[50] Consequently, frequent monitoring is necessary because subtherapeutic responses are associated with increased risk of thrombosis and excessive anticoagulation increases the risk of hemorrhage.[49,51] However, evidence indicates that most primary care physicians do not have the necessary training in warfarin dosing and management and a study in France revealed that a significant percentage of patients had inadequately monitored INR levels.[52] It has been suggested that standard protocols for warfarin dose adjustments based on the ACCP guidelines should be implemented, including the utilization of computer-based dose management services.[52] However, nearly 30,000 emergency department visits per year are prompted by warfarin-related bleeding complications and standardized treatment algorithms are rarely used, as evidenced by the variability in care provided for patients with INR values outside of the therapeutic range.[52]

Further complicating matters, the therapeutic dose of warfarin varies among patients due to genetic differences in metabolism, dietary intake of vitamin K, and administration of concomitant medications that interfere with warfarin metabolism.[49,51] Due to the link between genetics and efficacy of warfarin, the FDA recently initiated labeling change of warfarin that encourages pharmacogenetic testing for various relevant polymorphisms that interfere with the drug.[53] Thus, current anticoagulation options are difficult to manage and require frequent monitoring, which place a heavy burden on patients and the healthcare system.[51]

Novel oral anticoagulants are under investigation for the prevention and treatment of thromboembolism. It is expected that any enzyme in the coagulation signaling cascade (**Figure 1**) should reduce fibrin polymer formation from fibrinogen, resulting in a reduction in clot formation.[54] Thus, any enzyme in the cascade is a potential target for a novel anticoagulant; however, thrombin and factor Xa (FXa) are involved in both the intrinsic and extrinsic activation pathways. Therefore, direct inhibitors of these enzymes are expected to provide more effective anticoagulation than other enzymes in the signaling pathway.[54] These drugs include apixaban, dabigatran, and rivaroxaban.



Turpie AG. *Arterioscler Thromb Vasc Biol. 2007;27:1238-1247.*

Figure 1. The Coagulation Cascade. Inhibition of any enzyme in the cascade should reduce clot formation. Ovals indicate targets whose inhibition would provide the most effective anticoagulation.[54]

Several phase II and phase III studies of apixaban have been completed or are currently underway. A phase II dose-ranging study examined the safety and efficacy of apixaban compared with enoxaparin or warfarin in patients undergoing total knee arthroplasty.[55] The primary efficacy outcome was a composite of total VTE and all-cause mortality and was reduced with all doses of apixaban compared with enoxaparin or warfarin. Increasing doses of apixaban were associated with an increased risk of bleeding and another study identified a 2.5 mg bid dose as the optimal regimen; thus, apixaban 2.5 mg bid has been utilized in later trials.[55,56] Phase II trials for treatment of VTE, for secondary prevention in acute coronary syndrome patients, and for thromboprophylaxis in cancer patients are underway with apixaban.[48] Phase III trials of apixaban include those for VTE prevention (the ADVANCE series and ADOPT), VTE treatment (AMPLIFY), and stroke prevention in atrial fibrillation (AF; ARISTOTLE and AVERROES trials).[53,56] At this time, data from ADVANCE I and ADVANCE II indicate that apixaban is associated with decreased VTE and all-cause mortality as well as a decreased incidence of bleeding compared with enoxaparin in patients undergoing total knee replacement.[57,58] Results of both ARISTOTLE and AVERROS are expected in 2010.[59]

Dabigatran etexilate has been investigated in phase III trials for patients undergoing orthopedic surgery and for stroke prevention in AF patients with at least 1 risk factor for stroke. In the RE-MODEL and RE-NOVATE trials dabigatran etexilate was not found to significantly differ with enoxaparin in the primary efficacy endpoints or in bleeding events; however, dabigatran etexilate was found to be inferior to enoxaparin in the primary endpoint in the RE-MOBILIZE trial.[47] In the RE-LY trial of patients with AF, low-dose dabigatran etexilate (110 mg) was associated with rates of stroke and systemic embolism similar to warfarin, as well as lower major bleeding event rates; high-dose dabigatran etexilate (150 mg) was associated with rates of stroke and systemic embolism lower than those with warfarin but with similar major bleeding event rates.[60]

Three phase III clinical trials with rivaroxaban (the RECORD series) for the prevention of VTE have been completed. RECORD I compared the use of rivaroxaban with enoxaparin for extended thromboprophylaxis after hip arthroplasty.[61] Rivaroxaban was significantly more effective for extended thromboprophylaxis than enoxaparin, and the 2 drugs had similar safety profiles.[61] The RECORD 2 study concluded that extended thromboprophylaxis with rivaroxaban (31-39 days) was significantly more effective than short-term treatment (10-14 days) with enoxaparin for the prevention of VTE in patients undergoing hip arthroplasty.[62] Phase III studies are ongoing to evaluate the use of rivaroxaban for the treatment of VTE and stroke prevention in AF.[48] The ROCKET-AF study is currently comparing rivaroxaban with warfarin in more than 14,000 AF patients who have a history of stroke or at least 2 additional independent risk factors for future stroke.[63]

Interventional Technology: Advances in Stenting

The long-term effectiveness of percutaneous interventions was initially limited by very high rates of restenosis that reached 40% in some series of patients.[64] This problem has been addressed with the use of stents.[64,65] However, early bare metal stents (BMS) did not solve the problem of restenosis, which still occurred in as many as 25% of treated arteries. It was rapidly recognized that the stents themselves may contribute to local vascular injury; smooth muscle cell migration; vascular scarring; and recurrent artery blockage.[64] The limitations of BMS prompted development of drug-eluting stents (DES) that delivered medications to the artery wall which were aimed at limiting the growth of scar tissue inside the blood vessel and thus decreasing the likelihood of stent restenosis.[64,66] Sirolimus (also known as rapamycin, a drug that suppresses activation of the immune system) was the first agent employed effectively in DES.[66] Comparison of sirolimus-eluting stents with BMS in large-scale controlled clinical trials indicated that they significantly decreased the risk for reocclusion of the treated vessel by up to 60%.[67,68] Currently, 5 DES are available in the United States, the CYPHER sirolimus-eluting stent, the TAXUS Express and Liberté paclitaxel-eluting stents, the ENDEAVOR zotarolimus-eluting stent, and the XIENCE V everolimus-eluting stent.[66,69-74] Currently available DES have been repeatedly shown to be significantly superior to BMS in decreasing the risk for restenosis, recurrent coronary events, and requirement for revascularization. However, results from several studies resulted in safety concerns about these devices. Studies published in 2006 and 2007 suggested that placement of DES might be associated with increased risk for thrombosis and both cardiac and noncardiac mortality at long intervals after treatment.[75,76] An FDA panel concluded in 2006 that DES are a safe and appropriate therapy for many patients such as those with uncomplicated medical histories who undergo elective stenting of simple blockages.

Vascular Restoration Therapy: Efficacy and Safety of Bioabsorbable Stents

DES have significantly reduced restenosis when compared with BMS and are now considered the standard of care for percutaneous coronary intervention (PCI) in patients with symptomatic coronary artery disease (CAD).[77] However, late stent thrombosis has emerged as a major concern with the use of first-generation DES and pathologic studies have suggested that DES are also associated with delayed healing characterized by poor endothelialization of stent struts and persistence of fibrin as compared with BMS.[77] The long-term complications associated with DES have prompted interest in fully bioabsorbable stents. Potential advantages of having the stent disappear from the treated site include reduced or abolished late stent thrombosis; improved lesion imaging with computed tomography or magnetic resonance; facilitation of repeat treatments (surgical or percutaneous) at the same site; restoration of vasomotion; and freedom from side-branch obstruction by struts and strut fracture-induced restenosis.[78,79] Although the concept of bioabsorbable stents has been of great interest, there are significant challenges in the development of a stent that can deliver a drug and for which degradation does not generate an unacceptable inflammatory response.[80-82]

Among the technologies investigated to date for fully bioabsorbable stents are polymeric- and metallic-based stents. The Igaki-Tamai stent was the first absorbable stent implanted in humans but it was not clinically effective.[83] More recently, the PROGRESS-AMS trial assessed the efficacy and safety of an absorbable magnesium alloy stent in 63 patients. Intravascular ultrasound imaging at 4 months after implantation indicated that the stent was degraded by this time, and there were no early or late adverse findings.[84] It was suggested that slower degradation of this stent was warranted to provide sufficient radial force for improvement of long-term patency rates.[84] The bioabsorbable everolimus-eluting stent (BVS) has a backbone of poly-L-lactic acid that provides support, and a coating of poly-D,L-lactic acid that contains and controls the release of the antiproliferative agent everolimus.[85] At 2 years after implantation the stent was bioabsorbed, vasomotion was restored, and restenosis was prevented. The stent was also clinically safe, suggesting freedom from late thrombosis.[86] Other fully absorbable stents in development include a stent constructed from a tyrosine-derived polycarbonate polymer that metabolizes to amino acids, ethanol, and carbon dioxide. Results presented to date for this stent indicated unfavorable outcomes between 4 and 6 months after implantation with a higher-than-anticipated requirement for target lesion revascularization rate driven mainly by reduced stent diameter.[79] Another bioabsorbable stent has an absorbable backbone and coating polymers constructed from repeating salicylate molecules joined by linker molecules. In the first-in-man Whisper trial, a stent with

strut thickness of 200 μm and a crossing profile of 2.0 mm with a stent-to-artery coverage of 65% was implanted in 8 patients. Because of higher-than-expected intimal hyperplasia, subsequent design iterations will have thinner struts, a higher dose of sirolimus, and reduced wall coverage percentage.[79,87]

Management of Chronic Artery Stenosis

Although percutaneous treatment (stent implantation) has been used for the treatment of chronic total occlusions over the past 2 decades, it has 2 important limitations: 1) high failure rate in crossing the occluded lesion; and 2) high restenosis rate after initially successful treatment.[88-91] Therefore, determining the best approach to manage chronic total occlusion (CTO) is important. Results from a registry analysis of 8004 consecutive patients who presented for diagnostic catheterization at a single institution from 1990 to 2000 indicated that CTOs were present in 52% of patients with ≥70% diameter stenosis. This survey also showed that chronic total occlusion was the strongest predictor against the selection of percutaneous intervention as a treatment strategy.[92] Delineation of optimal percutaneous intervention for patients with chronic total coronary occlusions is also important because successful intervention in patients with these lesions has been shown to provide relief from symptoms; decrease the rate of cardiac events; and reduce mortality.[93]

DES reduce lesion recurrence after percutaneous intervention for chronic total occlusion and are used frequently in patients with chronic total occlusions.[94] However, massive plaque burden or calcified plaque may hinder optimal stenting.[94,95] Despite increasing experience with stents in patients with CTO, the evidence base for this treatment remains relatively small and has been generally limited to comparisons between DES and bare metal stents (BMS). Large, high-quality, prospective trials are needed to provide more information on the validity of a percutaneous approach for the management of CTOs.

New interventions have the potential to improve the efficacy and safety of percutaneous management of CTOs and there have been significant advances in treatment over the last several years including stiffer, taper-tipped, and hydrophilic wires that have improved outcomes in patients.[96] Introduction of a new stainless steel device designed to deliver therapeutic, minimally invasive balloon catheters and stents to vessels blocked with total occlusions also has the potential to improve outcomes for patients with these lesions.[97] This catheter has been shown to contribute to treatment success in 91% of a cohort of 44 patients with prior failure of balloon crossing.[97]

NEEDS FULFILLMENT

The Academy of Continued Healthcare Learning (ACHL) has identified the following education needs in the diagnosis and treatment of peripheral arterial, carotid, and venous diseases.

- **Guidelines and patient-specific treatment selection for the management of carotid artery disease:** AHA/ASA and SVS clinical guidelines, analysis of how differences between the guidelines may affect treatment selection, and appropriate use of CAS or CEA across patient populations[17] (knowledge and competence)

- **Recent clinical trials and meta-analyses comparing CAS with CEA:** Clinical trial data and meta-analysis results with an emphasis on differing methodologies and patient populations, and application of data to clinical practice[19,20,23-28] (knowledge and competence)

- **Vascular access management:** Data regarding vascular closure devices including access techniques, complications and cost-effectiveness, safety of re-access, and use in high-risk subgroups such as patients with PVD and those receiving anticoagulation therapy[29] (knowledge, competence, and performance)

- **Methods of identifying and managing high-risk patients to reduce bleeding complications:** Evidence-based information regarding the utilization of femoral angiography, clinical bleeding risk algorithms, and anticoagulation/antiplatelet therapy optimization[29] (knowledge, competence, and performance)

- **Utilization of appropriate, evidence-based treatments:** Evidence for improved outcomes in patients who receive evidence-based treatments and all appropriate indicated therapies[98] (knowledge, competence, and performance)

- **Risk assessment in patients with PVD:** Evidence for the need of early diagnosis and management of the disease including the role of the ABI, the clinical stage of peripheral artery disease, and polyvascular disease in the prediction of risk of future cardiovascular events in peripheral artery disease patients[99] (knowledge and competence)

- **Application of clinical guidelines and risk stratification methods in the prevention of stroke associated with VTE and DVT:** Guidelines are not routinely followed and there are significant gaps in the application of evidence-based interventions, suggesting that clinicians may not be aware of, or inadvertently overlook, these guidelines[46] (knowledge and competence)

- **Appropriate treatment and monitoring with oral anticoagulants to improve outcomes in patients at risk for thromboembolism:** Undertreatment of patients with VTE may be associated with factors including physician reluctance, patient preference, and the drugs themselves, and standardized treatment algorithms are rarely used[50] (knowledge, competence, and performance)

- **Screening and treatment selection to improve outcomes in patients with aortic aneurysm:** Earlier and more wide-spread screening for abdominal aortic aneurysm should be undertaken and several factors including risks for individual patients, the timing of surgical intervention, the type of intervention, potential long-term complications, and costs should be more carefully considered prior to a decision on treatment[100,101] (knowledge, competence, and performance)

- **Utilization of appropriate stents for percutaneous interventions:** Despite the FDA assurance that DES are safe and results from recent analyses providing additional support for this conclusion,[102-105] there are still important knowledge and treatment gaps with respect to the use of these devices. A survey of the characteristics, procedural details, and immediate outcomes for 9380 patients with acute coronary syndromes or undergoing elective procedures indicated a substantial fraction of these patients were still treated with BMS. Results from this study also demonstrated that overall in-hospital mortality was higher (2.1%) for patients treated with BMS versus those who received DES (1.2%).[106] (knowledge, competence, and performance)

- **Limitations of existing stents:** Although DES reduce restenosis, particularly in uncomplicated lesions, and have been universally adopted, they may be associated with stent thrombosis.[107,108] This

late complication of DES implantation is receiving increased attention as more long-term information with DES is being accumulated. Thus, there is a significantly unmet need that may be addressed by fully bioabsorbable stents. (knowledge and competence)

- **Patient characteristics that may influence outcomes:** Recently reported results and ongoing studies for fully bioabsorbable stents (eg, 3-year results from the ABSORB trial and the recently initiated ABSORB EXTEND study) are providing longer term results from a wider range of patients being treated with fully bioabsorbable stents.[86,109,110] These results will provide information to guide patient selection for specific types of stent implantation in clinical practice. Cardiologists need to be aware of this information to guide their treatment decisions. (knowledge and competence)
- **Risks, benefits, and techniques in treatment of CTO:** Operator experience and specific instruction in novel dedicated technical devices are needed to increase procedural success in the majority of situations.[96,111] The introduction within the last few years of enhanced guidewires combined with increasing operator experience and creative procedural techniques, such as the retrograde approach and the re-entry subintimal tracking technique, have significantly increased the number of chronic total occlusions that can be successfully managed via a percutaneous approach.[96,112,113] Use of percutaneous approaches for the treatment of CTOs must be undertaken with a full understanding of the potential risks for complications. Risks for serious and life-threatening complications are more frequent compared with percutaneous interventions in vessels with partial occlusions.[114,115] Early recognition and ability to promptly deal with these complications are critical to treatment plans for the management of CTOs. Appropriate clinical decision-making requires that cardiologists be aware of which patients with CTOs are best managed with various therapeutic options.[89,116,117] (knowledge, competence, and performance)

In addition, evaluations collected from attendees at the CVC meeting identified the following educational gaps:

- Appropriate patient selection
- Peripheral vascular coding
- Multidisciplinary collaboration/approach to patient care
- New tools:
    - Drug Elution technology
    - stent grafting
    - covered stents
    - closure devices
    - lasers
    - IVC filters
- New approaches and techniques
    - retrograde distal puncture
    - atherectimy
    - carotid stenting
    - angiographic imaging during doppler ultrasound
    - endovascular/AAA
    - limb salvage
    - thrombolysis
    - pedal access
    - tibial access for bedside DVT

Attendees were also asked what specific content they would like added to the CVC agenda. The topics are listed below:

- Hands-on ultrasound (femoral and pedal intervention)

- Dissections, perforation, and other complications
- More technical tips
- More case presentations
- Ischemia and necrosis after endovascular intervention
- Advances in small vessel disease
- Patient adherence/complicance
- Malpractice issues and defense management
- Managing adverse outcomes after certain procedures
- Trauma

To address these educational needs, Amedco proposes an international conference to be held July 10-12, 2019 in Chicago, Illinois. The conference will be designed for interventionalists, vascular surgeons, general cardiologists, and hospitalists, as well as fellows, residents, podiatrists, radiological technologists and other healthcare professionals interested in atherosclerotic cardiovascular disease, and will address the gaps in knowledge and competence outlined above through didactic lecture, panel discussions, debate and discussion of live case studies. We will also incorporate audience response elements whereby attendees could respond to direct questions posed by the faculty in an effort to achieve the educational goals of the program and improve patient outcomes.

LEARNING OBJECTIVES

Upon completion of this activity, participants will be able to:

- Implement clinical guidelines and case studies to the selection of medical, surgical, and endovascular treatment options for vascular disease in various patient populations
- Analyze risk assessment and diagnostic methods in peripheral arterial, carotid, and venous diseases
- Evaluate characteristics of vascular anatomy that relate to case and access site selection, and noninvasive and invasive imaging techniques
- Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases
- Identify complications that commonly occur following endovascular and surgical revascularization and develop management strategies to address these complications
- Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease
- Apply evidence-based research to the selection of the most appropriate stent for each patient
- Discuss results from recent clinical trials that may affect individual patient outcomes during percutaneous interventions

Professional Practice Gap(s)	**Type of Gap**	**Aligned Learning Objective(s)**	**Outcomes Method**
Clinicians lack knowledge and competence in the application of clinical practice guidelines to the selection of appropriate	Knowledge and competence	• Implement clinical guidelines and case studies to the selection of medical, surgical, and endovascular treatment options for	Multiple choice and case vignette questions Pre- and post-survey

individualized treatment for carotid artery disease		vascular disease in various patient populations • Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases	
Clinicians lack knowledge and competence in the application of clinical trial data (including an analysis of methodology and patient populations) and meta-analyses to clinical practice	Knowledge and competence	• Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease • Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases	Multiple choice and case vignette questions Pre- and post-survey
Clinicians lack knowledge and competence in the application of advances in vascular access management.	Knowledge, competence, and performance	• Evaluate characteristics of vascular anatomy that relate to case and access site selection, and noninvasive and invasive imaging techniques • Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases • Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease	Multiple choice and case vignette questions Pre- and post-survey

Clinicians are lacking in their ability to optimize outcomes for patients following diagnostic and interventional vascular procedures and fail to employ methods of identifying and managing high-risk patients to reduce bleeding complications	Knowledge, competence, and performance	• Evaluate characteristics of vascular anatomy that relate to case and access site selection, and noninvasive and invasive imaging techniques • Identify complications that commonly occur following endovascular and surgical revascularization and develop management strategies to address these complications	Multiple choice and case vignette questions Pre- and post-survey
Clinicians often fail to utilization all appropriate, evidence-based treatments that are available	Knowledge, competence, and performance	• Implement clinical guidelines and case studies to the selection of medical, surgical, and endovascular treatment options for vascular disease in various patient populations • Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases	Multiple choice and case vignette questions Pre- and post-survey
Clinicians lack knowledge and competence in the risk assessment of patients with peripheral vascular disease	Knowledge and competence	• Analyze risk assessment and diagnostic methods in peripheral arterial, carotid, and venous diseases	Multiple choice and case vignette questions Pre- and post-survey
Clinicians fail to apply clinical guidelines and risk stratification methods in the prevention of stroke associated with venous thromboembolism and deep vein thrombosis	Knowledge and competence	• Implement clinical guidelines and case studies to the selection of medical, surgical, and endovascular treatment options for	Multiple choice and case vignette questions Pre- and post-survey

		vascular disease in various patient populations • Analyze risk assessment and diagnostic methods in peripheral arterial, carotid, and venous diseases	
Clinicians fail to employ appropriate treatment and monitoring with oral anticoagulants to improve outcomes in patients at risk for thromboembolism	Knowledge, competence, and performance	• Implement clinical guidelines and case studies to the selection of medical, surgical, and endovascular treatment options for vascular disease in various patient populations • Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases • Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease	Multiple choice and case vignette questions Pre- and post-survey
Clinicians lack knowledge and competence in the screening and appropriate treatment selection to improve outcomes in patients with aortic aneurysm	Knowledge, competence, and performance	• Analyze risk assessment and diagnostic methods in peripheral arterial, carotid, and venous diseases • Evaluate characteristics of vascular anatomy that relate to case and access site selection, and noninvasive and invasive imaging techniques • Compare and contrast medical,	Multiple choice and case vignette questions Pre- and post-survey

		surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases • Identify complications that commonly occur following endovascular and surgical revascularization and develop management strategies to address these complications	
Clinicians fail to utilize appropriate stents for percutaneous interventions	Knowledge, competence, and performance	• Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases • Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease • Apply evidence-based research to the selection of the most appropriate stent for each patient	Multiple choice and case vignette questions Pre- and post-survey
Clinicians fail to take into account the limitations of existing stents	Knowledge and competence	• Compare and contrast medical, surgical, and endovascular treatment options for peripheral arterial, carotid, and venous diseases • Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease	Multiple choice and case vignette questions Pre- and post-survey

		• Apply evidence-based research to the selection of the most appropriate stent for each patient	
Clinicians fail to consider patient characteristics that may influence outcomes	Knowledge and competence	• Identify complications that commonly occur following endovascular and surgical revascularization and develop management strategies to address these complications • Apply evidence-based research to the selection of the most appropriate stent for each patient • Discuss results from recent clinical trials that may affect individual patient outcomes during percutaneous interventions	Multiple choice and case vignette questions Pre- and post-survey
Risks, benefits, and techniques in treatment of CTO	Knowledge, competence, and performance	• Analyze risk assessment and diagnostic methods in peripheral arterial, carotid, and venous diseases • Analyze recent clinical trial data comparing various treatment modalities in the management of vascular disease • Apply results from current clinical trials to determine patient characteristics that may affect patient outcomes during	Multiple choice and case vignette questions Pre- and post-survey

		percutaneous interventions	

CVC 2019 OVERALL MEETING DETAILS

In 2018, over 600 participants attended the conference and were represented by a number of specialties.

Physician Breakdown by Specialty

44% Interventional Cardiology
13% Vascular Medicine
14% Interventional Radiology
9% Cardiology
3% Cardiovascular
9% Podiatry
2% Neurology
6% Phlebology

PROPOSED FACULTY

IAHB, in collaboration with the CVC Program Committee, determines the faculty members for this activity. Names of potential faculty members are identified in a variety of ways, including in-depth literature searches, internal recommendations, or by other faculty. Assessments also include the following criteria.

- National recognition and expertise in the activity's content area
- Extensive publications in content area
- Board certification
- Recommendation from an expert in the field
- Date of last publication

The names below are faculty members who will serve as advisors and/or program committee chairs for this meeting and who will also identify/invite additional presenters based on the final curriculum developed.

Advisory Board

Jaafer Golzar, MD, FACC, Founcer
Mid America Cardiovascular Consultants
Advocate Christ Medical Center
Oak Lawn, IL

Zvonimir Krajcer, MD
Texas Heart Institute
Baylor College of Medicine
Houston, TX

Paul Jones, MD, FACC, FACP
Chicago Heart Vascular Consultants
Mercy Hospital and Medical Center
Chicago, IL

Amir Motarjeme, MD
Midwest Vascular Institute of
Illinois Advocate Good Samaritan
Hospital Downers Grove, IL

Patricia Thorpe, MD
St. Lukes Medical Center
Phoenix, AZ

AGENDA AND FORMAT

The CVC is a 4-day, interactive, regional conference that will address the educational gaps identified in our needs assessment.

The live program consists of pre-recorded patient cases taped around the country, integrated with discussion, debate and didactic lectures. Audience response system (ARS) technology will support audience participation and engagement in the live meeting. ARS will also be used to support a pre-activity test, in-activity questions, and a post-activity test. Pre-activity ARS questions will assess the range of participant practices. Aggregate responses will be displayed for the participants and provide the faculty with an overview of the clinical practices of the activity participants.

Faculty will present interactive case challenges, and attendees will be asked to make clinical assessments and decisions via multiple-choice ARS questions throughout each case. Following each decision point, but before the audience responses are displayed, the faculty provides commentary with appropriate supporting evidence. Participants will view the ARS data after the faculty provides his or her decision rationale. A question-and-answer session will occur at the end of each session.

Below is a list of topics presented at CVC 2016. The topics below represent the content that would be developed for the 2016 conference but are not necessarily intended to constitute a final agenda. All content is to be developed in collaboration with the faculty chosen for this activity.

<u>The Business of Medicine</u>

- Physician-Hospital Alliance: Future or Fad?
- The Revival of Hospital-Physician Employment: What's Different This Time?
- What Every Physician Should Know to Ensure the Best Possible Outcome With a Hospital Alliance
- 2016 Updates and Case Reviews on Billing & Coding on Peripheral Vascular Interventions

<u>Aortic Disease– Aortic Aneurysm</u>

- AAA: Screening and Natural Progression
- Total Percutaneous AAA Repair: Why, When, and How?
- Quick Tip: Pre-close Step-by-Step Approach (Prerecorded Live Case)
- XTREME PVD: Total Percutaneous AAA Repair (Prerecorded Live Case)
- Hybrid Procedures: Combined Open and Endovascular Repair of Complex AAA
- Tips and Tricks During EVAR in Patients With Challenging Infrarenal Neck Anatomy
- EVAR for Ruptured AAA
- What Does the Future Hold for Femoral Artery Access Site Repair During EVAR & TEVAR?
- Next Generation Technologies for EVAR
- EVAR Surveillance After Repair
- Endograft Failure and Management
- Evidence-Based Evaluation of EVAR

<u>Atherosclerotic Aortic and Iliac Disease</u>

- Percutaneous Treatment of Aortoiliac Occlusive Disease – Is Aorto-Bifemoral Grafting Needed Anymore?
- Tips for the Use of Re-entry Devices in the Aorta and Iliac Arteries
- DIY: Step-by-Step Approach to Revascularization of Aortoiliac Chronic Total Occlusions (Prerecorded Live Case)
- Percutaneous Treatment of Iliac Artery Aneurysm
- Endovascular Treatment of Erectile Dysfunction
- XTREME PVD: Prerecorded Live Case
- Recent Innovations in Access and Closure

<u>Renal/Mesenteric Disease</u>

- Renal Artery Intervention: Current Indications
- Role of Embolic Protection During Renal Artery Intervention
- Tips for Optimal Outcomes in Renal Artery Stenting
- Contemporary Treatment of Resistant Hypertension: The Role of Renal Denervation
- Renal Protection for CIN– Where Do We Stand?
- Mesenteric Acute and Chronic Ischemia – Patient Selection and When to Treat
- Revascularization of Mesenteric Arteries – Tips and Tricks
- Tackling Aneurysms of the Mesenteric and Renal Arteries

<u>Superficial Femoral Artery Summit</u>

- Is Femoral Popliteal Bypass Still the First Choice or Is Percutaneous Repair of Long SFA CTO Now the Standard of Care for Most Patients?
- Thrombolysis of the SFA – Drip Before You Fix
- Endovascular Tools to Stay True Lumen
- DIY: Step-by-Step Subintimal Tracking and Reentry (Prerecorded Live Case)
- Excimer Laser CTOCrossing Techniques
- Now That I'm Through, What Do I Do?
- Directional Atherectomy
- Orbital Atherectomy
- Rotational Atherectomy

- Point/Counterpoint: Debulking Is Necessary Before You Stent vs Debulking Wastes Time and Money Before Stenting
- XTREME PVD: Prerecorded Live Case
- Update of SFA Stent Data
- Update on Covered Stent Data

Infrapopliteal Disease: Below the Knee CTO Summit

- Podiatrists: Who They Are and How Are They Trained?
- Screening in Office for Adequate Blood Flow?
- XTREME PVD: Prerecorded Live Case
- Role of Plaque Modification Angioplasty
- Infrapopliteal Stenting – DES or Self-Expanding Stents
- Infrapopliteal Use of Drug-Coated Balloons
- Infrapopliteal Bioabsorbable Stents
- Specialty Team Blood Flow and Wound Care
- Developing Solid Relationships Between Vascular Specialist and Podiatrist
- Drug Therapy During Infrainguinal Revascularization
- Role of Atherectomy in Infrapopliteal Disease
- When to Use Distal Protection During BTK Revascularization

Carotid Disease

- Carotid and Intracranial Anatomy – How Much Do I Really Need to Know?
- Carotid Stent – One Year After CREST: What Have We Learned?
- Tips and Tricks for Accessing the Carotid Artery for Carotid Artery Stenting
- CEA vs CAS – Show Me the Data!
- Building a Multi-Disciplinary Approach to Treating Carotid Artery disease
- Advances in Prevention of Distal Embolization
- Point/Counterpoint: Distal Protection or Proximal Protection for the Prevention of Embolic Events During Carotid Stenting
- CAS: Patient Selection – At the End of the Day, Who Should I Stent?
- Dealing With Disaster: Carotid Artery Stent Complications
- Carotid Stent – Tips and Pitfalls

Venous Disease

- Treatment of Acute and Chronic DVT
- Mechanical and Pharmacological Lysis of DVT
- Use of Retrievable IVC Filters During
- Mechanical Treatment of DVT
- Tips for Optimal IVC Filter Placement:
- Minimizing Filter Migration and Tilt
- Bedside Placement of IVC Filters
- Treatment of Cerebral Venous Insufficiency in the Treatment of Multiple Sclerosis – Could We Be on the Brink of a Cure?
- Imaging and Treatment Strategies for Superficial Venous Insufficiency
- Medical Management of Infected Venous Ulcers
- Treatment of Venous Ulcers With Case Studies
- Treatment of a Patient With Cerebral Venous Insufficiency and Multiple Sclerosis

Nurse/Technologist Symposium

Advanced Wound Care Symposium

OUTCOMES

Outcomes for the symposium address Moore's Level 1 through Moore's Level 5, and will utilize ARS to ask factual, procedural, and case-based questions of the participants before and after the activity to measure change in knowledge and competence (Moore's Levels 3 and 4).[68] Knowledge questions will address both what the participants have learned and how it would be applied. Competence questions will be developed in the form of case-based vignettes to demonstrate the degree to which participants show they can apply to clinical practice what they have learned in the educational setting; case vignettes have been shown to be an effective predictor of clinical performance and are recognized as a valuable educational tool to measure change in competence.[69-71] Questions and case vignettes will be designed by the faculty to reflect the educational objectives of the symposium.

Participants will be provided with individual ARS keypads to facilitate the collection of data. The faculty will present one or more short case vignette(s) and, prior to beginning the content presentation, query the participants on their knowledge of the clinical aspects of the case and how they would respond to each clinical situation. The same case vignette(s) and questions will be asked again at the end of the symposium. The faculty will review the responses and share the change in aggregate competence with the participants. The University at Buffalo, in collaboration with ACHL, will report the educational outcomes as follows.

Level 1 (participation): Data collected will determine the description and demographic of the audience compared with the target audience, including the breakdown of participants by discipline, specialty, and geographic location of practice.

Level 2 (satisfaction): The sponsors will assess participant satisfaction with an evaluation form that participants must complete to obtain credit. The evaluation asks participants to rate and comment on

- Balance and objectivity
- Achievement of objectives
- Faculty performance
- Overall activity quality
- Quality of the educational experience

Level 3 (change in knowledge): Data collected will assess the aggregate change in responses relating to comprehension of the didactic material presented.

Level 4 (change in competence): Data collected will assess the aggregate change in responses relating to the case vignettes, and will be summarized in graphic form.

Level 5 (change in performance): A 3 month follow-up survey will be conducted to assess if learners changed their performance following their participation in the conference.

The sponsors will analyze the Level 3, 4 and 5 data to determine whether the educational objectives of the activity were achieved, and provide a report 90 days following the conference, upon request..

CERTIFICATION

Certification
IAHB certifies this international conference for physicians will apply for certification for nurses, podiatrists and radiologic technologists.

IAHB has commercial support policies for CME activities that are based on the 2007 ACCME Updated Standards for Commercial Support of Continuing Medical Education, which require fair balance with all our CME activities. This is achieved by ensuring that all content developed is based on learning objectives designed to meet the educational needs of physicians and other medical professionals, includes a balanced view of therapeutic options, is evidence-based, and indicates the sources and types of evidence used during the activity.

This activity is planned and runs in accordance with

- OIG Guidelines
- ACCME Standards for Commercial Support
- PhRMA Code on Interactions With Healthcare Professionals
- AdvaMed Code of Ethics on Interactions with Healthcare Professionals
- AMA Ethical Guidelines for Gifts to Physicians From Industry

AUDIENCE GENERATION

Audience generation for this activity includes

- Direct mail invitation to target audience members across the U.S.
- E-mail and fax blasts to purchased list
- Phone outreach at clinic level to prospective attendees
- Journal advertisements
- Supplemental rep distribution (if approved by commercial supporters)

TIMELINE

August 2016	Advisory Board planning meeting
November 2016	Advisory Board/Program Committee planning call Venue contracting
December 2016	Grants disseminated Educational design finalized Faculty recruitment begins Audience Generation materials development begins Outcomes planning Site selection/contracting

January- May 2017	Audience generation begins Exhibit space rental begins Registration opens Advisory Board planning call
June 2017	Compliance reviews completed Scientific validation completed Final Advisory Board/Program Committee planning call
July 2017	Faculty on-site review Live Meeting: July 18021
October 2017	Final reconciliation (90 days) Outcomes measurement report provided to grantors

** Timeline may change based on approval date, faculty availability, and/or revisions.*

GRANT REQUESTED

IAHB is requesting a grant of $125,000 for the development, management, and execution of the conference. See budget summary attached.

All industry representatives must abide by IAHB's policies regarding a Pharmaceutical Representative's Role at CME Activities. Commercial supporters will be provided a copy of this policy in advance of the conference and agree to the terms outlined.

All commercial supporters will be recognized on the CVC website, the print syllabus, onsite signage, and by the Conference Chair during opening remarks.

Exhibits are completely separate from CME/CE events and no preferential treatment will be given to any commercial supporter underwriting a CME activity.

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