Competing Responsibly: A Venous Industry Roundtable

Representatives from industry provide their perspectives on training, ensuring ethical use of venous products, and industry's role in value-based care and collaborating with societies to establish best practices.

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Dr. Elias: Responsible vein care has been a topic that has been discussed by a group of vein specialists in *Endovascular Today*[1] and other publications such as *VEIN Magazine* over the last few years. Ethical, responsible vein care and overuse (or abuse) is something everyone—vein specialists, payers, industry, and, most importantly, patients—cares about. We thought your perspectives would help shed some light from the venous industry side. What do you feel is the ideal relationship between industry and practitioners in the venous space?

Mr. Heil: For years, industry has felt that its "relationship" with the provider was the single-most important aspect in its ability to compete and be successful. Although this still remains somewhat true today, the nature and motivations of the relationship(s) have migrated from those that have been more superficial and professionally personal to those that are centered around the patient and delivering the most appropriate therapy and care. I think this reinforces the level of trust between industry and practitioners. None of us are completely naive to the fact that establishing long-lasting relationships are critical in today's competitive environment, but anything short of delivering what is in the best interest of the patient is questionable. It is the ethical obligation of both the practitioner and industry partner to think and act collaboratively when it comes to delivering the "right care, with the right therapy, for the right reasons."

Mr. Goodman: The relationship between industry and physician is essential. There can be no real innovation without a close collaboration between both, and there should always be a mutual goal to work together for the benefit of patients.

Ms. Lesenfants: At Medtronic, our mission is to alleviate pain, restore health, and extend life. Health care practitioners are critical partners in our ability to fulfill our mission. The relationship between industry and physicians is incredibly important, as it drives medical innovation, new treatment approaches, global awareness, and, ultimately, better patient care. With venous disease, vein stripping is still the standard of care in many countries around the world, and often, patients with venous disease go undiagnosed or are misdiagnosed. Therefore, it is important that we come together to help enhance education of the disease state, improve global access, and drive further education to those who diagnose and refer that patient.

Dr. Elias: When it comes to training best practices for patient selection and optimal uses of your devices, what works well? What types of programs or initiatives have been less effective?

Mr. Goodman: When formulating our medical education strategy at Philips Volcano, we think carefully about the learning curve of our customers. The goal is to bring a customer from the initial point of interest to a level of competence and confidence where they

can deliver safe and quality care. For each indication, we have defined a "clinical pathway," drawing from the same term used to describe the standardization of a patient's clinical course to improve consistency of outcomes.[2] Depending on where our customers are on the clinical pathway for a particular therapy, we have created a variety of programs to address varying levels of understanding, as well as different channels to deliver content. We have found it to be less effective when our customers dictate their own learning pathway because the use of intravascular ultrasound in venous disease is still relatively new. They simply don't know what they don't know; this way of working together and commitment to a mutually agreed upon path works very well.

Mr. Heil: Again, I must reiterate the need for the right procedure/therapy for the right patient. As we know, when treating venous disease, especially from an interventional perspective, there can be multiple variations in anatomic structure, location, and complexity. Each patient should be considered unique when it comes to delivering care, and for this reason, it's important to create a comprehensive training curriculum with this in mind. It's critically important to not only describe and identify the types of patients that are most appropriate or ideal for a therapy/procedure, but also do the same when it comes to those who would not be served well by a particular device or procedure.

With so many new therapies on the market, it is not uncommon to meet some resistance when trying a new modality. To help with this, we find that peer-to-peer and preceptorship programs are ideal. With these programs, we match experienced practitioners with new users for training and support during the adoption phase. Some simply speak over the phone, while others complete in-person and hands-on training. We have also found that having a clinical support team to accompany a practitioner during their first few cases (or however long they would like) is a fantastic way to optimize the procedure and ensure proper patient selection. Along with delivering a comprehensive training program, using real-world examples, such as individual case studies and case reviews, provides a practical approach to treatment and the types of patients who would be best suited. Any type of real-world and/or hands-on training approach has been most effective.

Although online or self-study programs serve a purpose, these alone cannot and will not deliver the type of education and technical training needed to appropriately deliver the care/treatment for many of the interventional treatments. In addition, 1- to 2-day training courses that are a part of interactive conference symposia have a place, but if you do not practice the technique repeatedly on your own patients upon return, those skills are not retained. Without the real-world, hands-on training provided through preceptorships, peer-to-peer case observations, and on-site training by an appropriate credentialed practitioner or trainer, the physician is putting themselves and the patients at risk.

Ms. Lesenfants: Training is important. We know that not everyone is at the same level, nor do they learn the same way. We offer several different types of training events to accommodate the different backgrounds and skills of our customers. At Medtronic, physician training is a key focus in order to meet our commitment to provide world-class training and education on the safe and effective use of our products and therapies to health care professionals. Physicians who use minimally invasive therapies for venous closure should have meaningful experience in diagnosing and treating venous reflux disease with endovenous techniques.

Dr. Elias: After initial training, what, if any, is industry's role in reassessing the quality of care for individual providers?

Ms. Lesenfants: Training is a continuum. No matter how complete and thorough an individual training event may be, there are times when a refresher of the content is required. As mentioned previously, we have training events for physicians at every level of their adoption of our procedures. We partner with our physician customers to continually assess if they have the knowledge and skills they need to use our products safely and effectively and achieve superior clinical outcomes.

Mr. Heil: We all too often take for granted the fact that once we gain competency in a specific area of interest or expertise, there is no longer the need or desire to learn. Although the quality of care provided can sometimes be subjective and even debated, the fact remains that there is always a postprocedure/postcare "outcome" for the patient. Depending on the quality delivered or the appropriateness of therapy provided, the outcome is at risk.

Industry must take an active role in ensuring that its providers/users of products maintain clinical competency. There are a number of ways to provide for this, and those of us in industry have the obligation to our physician customers to deliver ongoing training and learning opportunities. Additionally, the consistent surveillance for safety and efficacy outcomes, whether through adverse event reporting or scientific publica-

tion preparation, allows for the identification of "hot spots" of successes or diminishing quality. Having access to these data helps industry to continually monitor the quality of care.

Mr. Goodman: As you know, industry does not have any responsibility for credentialing. If the US Food and Drug Administration (FDA) approves a device through the premarket approval process, they may mandate a training program as a condition of the approval of that device. Under these circumstances, metrics can be included in this process. However, for the 510(k) clearance process, no such mechanism for control exists. An FDA-cleared device can be prescribed at the discretion of any physician. It would also be difficult to ask industry to assess the clinical skills of a physician, as that should be left to their own institutions and respective medical societies.

Dr. Elias: Should industry have any remedial training for physicians who have not performed many procedures after initial training?

Mr. Heil: We tend to shy away from tough questions like these, but they are the most important. For the sake of the patient, and even the reputation of the physician, procedure, or device, a minimum standard of training and/or procedure count must be met before integrating a modality into one's practice. It is not just about performing a procedure, but rather it is being familiar with the expected patient outcomes following the procedure and knowing how to handle the unexpected and follow-up care. These all come with experience.

Additionally, it is not uncommon for physicians to trial or evaluate a specific procedure/product for a period of time, have good results, and then either abandon or use it on a limited basis for one reason or another. Certain aspects of the technique might have been forgotten during the lag. Taking time to ensure that the physician refamiliarizes him/herself with the procedure is another example of industry's ethical obligation to the patient and the provider. Assuming there is still interest and desire in using the product or performing the procedure, there must be an understanding and mutual agreement that ongoing or additional training needs to be provided before the product would be used again.

Ms. Lesenfants: Physicians have discretion in choosing what devices they use to treat their patients. At Medtronic, if we received feedback from our customers that they are not comfortable with their level of skill needed to use our product, we work to provide additional training to increase their confidence level.

Mr. Goodman: Similar to my previous answer, the concept of remedial training would mean that we are asking industry to assess the clinical skills of the physician, which would be challenging and something that would be more appropriately assessed by the physician's institution and respective medical societies. As a part of our clinical pathways process, we offer a number of options for training, education and awareness, and skill set development. Depending on the individual needs of the physician, we can offer resources to help facilitate device training and education, as well as skill set development.

Dr. Elias: With differences of opinion prevalent in venous intervention and throughout the medical field, on what criteria do you base your standards for what constitutes appropriate care?

Ms. Lesenfants: As I mentioned previously, in some countries around the globe, the standard of care is vein stripping. However, in the United States, thermal ablation is considered a standard of care. As a global company, we need to look at each market differently and collaborate with physicians and societies to help set standards of care. For example, in the United States and Europe, there are endovascular treatments for chronic venous insufficiency (CVI) included in key societal and global health technology assessment recommendations.

- American Venous Forum (AVF)/Society for Vascular Surgery (SVS) 2011 clinical guidelines for patients with varicose veins and associated CVD: Recommend endovenous thermal ablation (laser and radiofrequency) for the treatment of saphenous incompetence rather than high ligation and inversion stripping (grade 1B)
- AVF/SVS 2014 venous leg ulcer clinical guidelines: To prevent recurrence, they recommend ablation of the incompetent superficial veins in addition to compression therapy in patients with venous leg ulcer and incompetent superficial veins (grade 1B)
- American College of Physicians (ACP) 2015 clinical guideline for superficial venous disease: Endovenous thermal ablation (laser and radiofrequency) is the preferred treatment for saphenous and accessory saphenous vein incompetence (grade 1B); it also suggests mechanical/chemical ablation may be used to treat truncal venous reflux (grade 2B)
- United Kingdom (UK) National Institute for Health and Care Excellence (NICE) 2013 clinical guideline: Recommend endothermal ablation (laser and radiofrequency) as an interventional treatment for

patients with confirmed varicose veins and truncal reflex. If endothermal ablation is unsuitable, recommend ultrasound-guided foam sclerotherapy
- UK NICE interventional procedures guidance 2015: Recommend cyanoacrylate glue occlusion for varicose veins with proper informed consent
- UK NICE interventional procedures guidance 2016: Recommend endovenous mechanochemical ablation for treatment of varicose veins on standard arrangements

Mr. Heil: Guidance on appropriate care can come from a variety of sources (ie, medical societies, payers, technology assessment organizations, clinical trials, and industry through FDA-labeled indications). These all play some part in determining the criteria that should be used when assessing and determining appropriate care. One of the hot topics in our space is around appropriate care versus overutilization. Several societies, along with physician experts such as Jose Almeida, MD, are on a quest to bring awareness to this issue. Industry has a role to play in this as well. Commercial interests are clear, but the long-term viability of those interests are at risk if patients no longer have access to those therapies due to payer restrictions. The criteria are relatively straightforward and for the most part are driven by the payers, society guidelines, and the FDA-labeled indications.

Mr. Goodman: I don't think it is industry's responsibility to assess appropriateness of care. We can provide information within our labeled indications as it relates to therapy; however, we are not in a position to assess the outcomes and/or quality of the care administered by the physicians who utilize our technology. This should be left to the discretion of the physicians' institution or the respective medical societies.

Dr. Elias: What do you consider the role of industry to be in ensuring the ethical use of its products?

Mr. Goodman: I think industry can play a large role here. Our training and education is aimed at enabling the proper use of our technology; this is the essence of our field force's daily responsibilities. All of our sales and clinical professionals undergo extensive training and are documented to be competent in all the technical aspects of our devices; thus, they are the front line to help enable the appropriate use of our technology.

Ms. Lesenfants: Medtronic provides some of the best product training programs, and we work diligently to constantly communicate information to our customers, such as labeling and new data relating to our products and clinical outcomes.

Mr. Heil: We must all be accountable when it comes to the ethical use of our respective products. Industry has a responsibility to its physician customers, hospitals, and, most importantly, the patients to ensure that its products are used in the manner in which they were developed and approved as well as in the appropriate patient populations.

Dr. Elias: What protocols does your company have in place to this effect, and how are these conveyed to all types of employees (eg, marketing, sales)?

Mr. Heil: First of all, at BTG International, we ingrain our core values in every aspect of the business. Our core values underpin what we do and center around patient care and delivery. Our commercial, clinical, and medical teams are keenly aware of the challenges, and each function receives ongoing training related to appropriate use and communication. When it comes to promotion, we have established clearly defined guidelines and best practices around what can be communicated, by what mechanism, and by whom. Strict adherence to these are mandated and monitored by a number of internal and external means.

Mr. Goodman: All of our marketing, sales, and clinical specialist professionals undergo a documented certification process, which is focused on clinical and technical training, along with quality systems training that is required by the FDA. All sales, clinical support, and marketing employees are required to recertify on these training programs on an annual basis.

Ms. Lesenfants: Medtronic has Global Business Conduct Standards and other policies that we adhere to, and employees receive education and training on these standards and policies. More information on our Global Business Conduct Standards can be found at http://www.medtronic.com/us-en/about/corporate-governance/global-business-conduct-standards-policy.html.

Dr. Elias: Do you feel the training responsibilities of a company differ if their product is new to the market versus a more established line? Or, if their product might see its "standard-of-care" status decrease after new products or data emerge?

Mr. Goodman: The responsibilities, or what we refer to as "the clinical pathway," are not solely based on

the newness of the product, but rather on the technical aspects of the product and its associated learning curve. Each medical device will have its own clinical and technical aspects for appropriate use based on product design, anatomic challenges, and the complexities of the disease in which the product is being used. In developing the clinical pathways, the goal was to be able to take an individual from "interested" in a therapy or device to "confident and competent." The concept of the clinical pathway is consistent, but the approach within it may vary based on the complexity of the device. The path along the continuum is an opportunity to develop resources of all types and in all mediums to reduce the learning curve or fill in information gaps.

Ms. Lesenfants: Regardless of a product's classification or life cycle, it is important to offer physician training and education. What may differ is the type of training program based on regulatory requirements. Additionally, we have a dedicated Office of Medical Affairs and are committed to helping to support ongoing education on new clinical data.

Mr. Heil: In some instances, there may be an FDA training requirement or obligation regardless of the time in which the product has been on the market. The overall training responsibilities and obligation should be the same. Whether a product is well established and utilized in the market or is considered standard of care should not determine the type of training available to a health care provider. If the product impacts patient care, then those that are responsible for delivering it deserve to receive the needed education and training on its appropriate use.

Dr. Elias: Where do you see industry's role in the concept of value-based health care where all parties—patients, physicians, industry, and payers—share in risk/benefit?

Ms. Lesenfants: With the transition to outcome-based reimbursement for hospitals and physicians, Medtronic is exploring new business models where we share direct accountability for the performance of our therapies on patient outcomes and health care costs. However, we understand that we must do more than share risk. We believe it is our role to work collaboratively to (1) develop new services and solutions to help payers and providers better manage patients across the care continuum, (2) generate clinical and economic evidence to demonstrate the value of our therapies, (3) collaborate with key opinion leaders and societies to identify best practices and optimal care pathways, and (4) engage and drive conversations with policymakers and key opinion leaders around how we can transform the incentives in health care today to focus on outcomes.

Mr. Heil: Industry is taking a hard look at these value-based models and those that specifically share in the risk/benefit from an outcomes and adverse event perspective. We need to be prepared to face the shift from volume to value-based health care delivery, in an effort to improve outcomes while reducing costs. Orthopedic implant manufacturers and those in the cardiac rhythm management space with implantable cardioverter defibrillator and pacemakers have been at the forefront of some of these initiatives. Industry partners are the experts in how their products may affect clinical outcomes, and this expertise gives them the specialized knowledge into programs that could improve outcomes and reduce adverse events and the associated costs. Data will absolutely drive these models, and much of it resides within industry and/or can be produced through corporate-driven initiatives with payers, providers, institutions, and societies if the right motivational drivers are in place. Again, if the objective is to provide patients with access to therapies that the providers feel are most appropriate, then it's incumbent upon us to find solutions for all parties involved from a cost/benefit perspective.

Mr. Goodman: Most people think of clinical outcomes as the most important aspect to go at-risk with, and it certainly affects the cost of care, but providers and industry should look at going at-risk on operational and financial outcomes as well. If companies claim their products can shorten procedure time or can help reduce readmissions or procedure costs, then the risk-sharing model would allow the companies to put their money where their mouth is and go at-risk for delivering those improvements. There is a lot of good technology already in the market today, but is it being used optimally? That is where training can affect "value" as well.

Dr. Elias: How can companies collaborate with professional societies to establish standards and further ensure optimal care?

Mr. Heil: Industry has always welcomed the opportunity to work and collaborate with societies. Whether it's with position statements or treatment guidelines related to specific therapies, patient selection, or diagnosis, there is always value in collaboration. The real challenge has been around keeping the bias and corpo-

rate interest from influencing practice standards and guidelines.

Each organization has a significant amount of data, science, and real-world evidence that should be leveraged for these purposes. With the right governance structure and oversight in place, societies have a significant opportunity to use these vast data sets to update and refine guidelines to reflect the latest scientific and real-world evidence. With the advent of large registries by the SVS/AVF and the ACP that collect data directly from electronic medical records, I think we are going to see a drastic, but important, change in standards of care that are based on real-world evidence and experience.

Mr. Goodman: More and more, this is becoming essential. Societies can determine credentialing and appropriate care standards and partnering with them allows alignment of programs and resources. In close collaboration with industry, it is incumbent on societies to determine what's appropriate once the technical aspects of devices, the labeled indications (which can be used to effectively market our devices), and the clinical data supporting the outcomes of the technology are known.

Ms. Lesenfants: Over the past 30 years, our industry has learned a lot about CVI. Today, CVI can be treated with minimally invasive treatment options such as venous ablation procedures using radiofrequency and laser ablation, medical adhesive, and foam sclerotherapy. New technologies are entering the market to treat this condition, and there is a growing body of data to support minimally invasive options. It is important that we work together with societies and our industry partners to establish standards to ensure the best care for the patient. For example, Medtronic recently participated as part of an industry coalition, which includes Medtronic, Vascular Insights, Boston Scientific Corporation, Bard Peripheral Vascular, Inc., and AngioDynamics, to commission a review on peer-reviewed literature on endovascular therapies. These results were presented at the Medicare Evidence Development & Coverage Advisory Committee panel last July.

Dr. Elias: Thank you to the participants in this roundtable. Speaking as an "industry person" about a topic such as this can be challenging. Your overall openness will help our readers better appreciate the seriousness in which you and your respective companies think about the issue of responsible vein care. This is not just about selling a product—that is clear. One thing you have highlighted and certainly something that vein specialists have identified is the need for all of us to work together for the good of the specialty and ultimately the best care of our patients. ■

1. Almeida JI, Elias S, Khilnani NM. The Joint Venous Consortium: rationale and proposed goals. Endovasc Today. 2017;16(3):40, 43-44.
2. Panella M. Reducing clinical variations with clinical pathways: do pathways work? Int J Qual Health Care. 2003;15:509-521.

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