

The Role of Industry in the Office-Based Lab

How an ethical collaboration between device manufacturers and office-based vascular labs can provide quality health care and improved efficiency.

BY KRISHNA M. JAIN, MD, AND JOHN MUNN, MD

In 2015, we continue to see remarkable advancements in the medical devices created for vascular intervention. Enhancements to previous technologies, such as drug-coated balloons, drug-eluting stents, and atherectomy catheters, enable physicians to perform more procedures percutaneously with better results. Simultaneously, we have seen growth in office-based vascular labs (OBLs), which allow safe, cost-effective outpatient management of vascular disease using these new technologies.^{1,2} Hence, there needs to be a strong relationship between industry and OBLs. The benefits of a close working relationship will be realized by both parties. Increased utilization of vascular devices by OBLs will help the financial bottom line for industry and bring more therapeutic options to the OBL, which will help patients and doctors alike.

OBSTACLES FOR OBLs

The care provided in the OBL is safe, efficient, effective, and cost-effective compared to the hospital system. However, one problem facing the OBL with respect to new technology is reimbursement. Payments for procedures are generally determined by the Centers for Medicare & Medicaid Services (CMS), and insurers follow their lead. The first priority for CMS is to determine reimbursement codes, which apply to in-hospital cases. There is a lag period before appropriate codes are created for OBLs, and a payment schedule is attached to each code. As a result, new technology is available to hospital patients before OBL patients.

New devices and technologies also cost more, due in part to the expense of research and development. OBLs run on a tighter budget because reimbursement for the technical component is less for OBLs than for hospitals. OBLs simply cannot afford the elevated costs of new devices and remain viable. As a consequence, devices that are approved for outpatient use may not be affordable and thus are underutilized. However, because they are more efficient, more

patients can be treated in OBLs compared to hospitals, using the same resources. This represents an area where industry is missing out on potential growth.

OVERCOMING THESE OBSTACLES

What can be done? Perhaps industry, working alongside medical societies, can demonstrate the effectiveness of new devices and their applicability to outpatient applications, which would lead to more efficient treatment of the patient population. CMS could then be persuaded to increase the technical component in reimbursement for OBLs at the same time it is done for hospitals, making these new devices more affordable to the OBL. Secondly, pricing strategies could be designed by industry to make new devices more affordable in the OBL setting.

The other asset industry has is the sales representative. Their presence in the operating room, when appropriately monitored, is supported by the legal system.³ By virtue of their training, territory, and exposure to multiple cases, sales representatives have hands-on knowledge of their products and their applicability, which can be an asset to physicians both before and during cases, particularly if the physician has recently adopted a new technology. This knowledge could, in turn, help physicians choose the right device and apply it in the most cost-effective manner. The expertise of sales reps may also help with patient safety, as they may observe unique challenges and creative solutions in one office and discuss with physicians in other practices. They may also know when a cheaper modality will be equally effective. Reps also typically carry additional inventory with them, which can help with over- or understocking. Finally, they can help minimize waste by advising on the right size or type of device for different situations.

ETHICS

We hope that all physicians will be ethical and use only the resources required to treat each patient. Unfortunately,

the temptation to abuse the system to increase personal profit exists. The sales rep is in a unique position to monitor device usage and practice patterns resulting in abuse. Increased sales are pleasing, but overusing expensive devices hurts the health care system, makes both doctors and industry look bad, and causes harm to the patient.

There are two large organizations in industry that ensure members have high ethical standards and behave accordingly. The Advanced Medical Technology Association (AdvaMed) provides guidelines to the sales force. Their mission statement is as follows: "AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation." Furthermore, AdvaMed recognizes "the obligation to facilitate ethical interactions between companies and those individuals or entities involved in the provision of health care services and/or items to patients." The Medical Device Manufacturers Association represents smaller medical technology companies, and their mission is to "promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology."

If abuse is identified by a rep, the company can restrict or stop device sales to questionable individuals or groups.

They can also notify the appropriate medical society's ethics committee.

CONCLUSION

OBLs aim to improve the delivery of health care due to their safety, efficiency, and cost-effectiveness. It is vital that doctors and the medical industry work together to provide this type of high-quality health care to our patients in an ethical manner. ■

Krishna M. Jain, MD, is Clinical Associate Professor of Surgery, Michigan State College of Human Medicine in Kalamazoo, Michigan; and Director of the Borgess Vascular Institute. He has disclosed that he is President and CEO of National Office Endovascular Labs, LLC. Dr. Jain may be reached at kjain@avsurgery.com.

John Munn, MD, is Clinical Assistant Professor of Surgery, Michigan State College of Human Medicine in Kalamazoo, Michigan. He has disclosed that he is a partner for National Endovascular Labs, LLC.

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