Peripheral Vascular Care: A Clinical and Administrative Perspective

Michael R. Jaff, DO, answers questions posed by Gary M. Ansel, MD, FACC, and Koen Deloose, MD, on the challenges of his new role as hospital president and how new regulatory and reimbursement models might affect vascular care delivery.

Dr. Ansel: Why did you decide to leave your prior full-time academic and clinical life to become president of a community hospital?

There were three major reasons, in increasing order of importance. First, it was an incredible challenge, one that I never had the opportunity to try before, and I figured, how many people at my age and position get to step out of their comfort zone into something new?

Second, part of my job is working at the system level, and my system is one of the largest in the country. So, having a chance to actually be at the table for some of the most important discussions happening in health care in the United States seemed like a tremendous opportunity. I'm listening to and learning about the incredible challenges facing the federal and state health care systems.

Finally, over the course of the few years before I took this job, I had noticed that many of my colleagues were becoming more disillusioned with the practice of medicine and overwhelmed by the requirements they faced to just get through the day. I figured that it would be very hard for me to have any material impact on improving their professional lives as a single doctor at Massachusetts General Hospital. But, as president of a hospital with a large medical staff, I might have a much greater opportunity to bring some joy back to the practice of medicine.

Dr. Ansel: What are some of the advantages and disadvantages you identify in having a physician as hospital president?

I think that the advantages clearly outweigh the disadvantages. The most important advantage is that nowadays, so many decisions must be made at the leadership level of any hospital or health system. If you don't have someone who has sat across from a patient worried about losing a leg, having a stroke, or dying—if you don't have someone with that experience helping guide the decisions—then decisions will be made for the wrong reasons and could potentially have unintended consequences. It's critical to have a physician who is actually taking care of patients ultimately responsible for decisions around a hospital.

Of course, the disadvantage is that it's a very complicated job. You have to be able to recognize right off the bat that, for many subjects, you likely will not be anywhere near the smartest person at the table. So, you have to surround yourself with people who have skills you don't have, and you have to be willing to listen and allow them to run with their expertise.

Dr. Ansel: Do you think physician participation in high-level institutional meetings is important? If so, in what ways?

I think this is true for any major decision that occurs in a hospital or health system. It is very hard for me to imagine many decisions that wouldn't benefit from at least the insights and opinions of a care provider—whether that's a committee, a facility strategy issue, a finance issue, or a prioritization issue. I think there is always a benefit in having clinical input.

Dr. Deloose: In your opinion, does the process of material procurements restrict physicians' free choice, or is it an essential means of limiting costs?

This is another example in which, if a decision is not arrived upon thoughtfully, it could have an unintended

consequence. If a decision on device or product selection is driven solely by price without an appreciation for clinical advantages or disadvantages, the rigor of the associated scientific data, the regulatory approach—all the stuff that we as vascular physicians deal with every day—if those are not included in the decision making, it could have a very serious negative impact on physician choice and even patient outcomes.

I think there is a way to marry the clinical and scientific data with the economic data so that when evaluating devices of similar safety and efficacy, then it's entirely reasonable not to stock everything on your shelf. But, again, how informed would the decision be without having clinical expertise at the table?

Dr. Ansel: What are the three biggest challenges you are currently facing in your role?

The biggest challenge is that we're running a business in which we don't know the rules on how to make a living. I'm being a bit glib, but the truth is, at the federal level, the system is clearly not working, and we don't know what the system will look like in the future. At our state level, up until very recently, we didn't know what the governor's budget regarding health care or Medicaid coverage would be. It is very hard to strategize on your financial survival when you don't even know what the rules of the game are.

The second challenge is—and I'll speak only for Massachusetts—the explosive growth of Medicaid patients due to the decision of small business employers to remove commercial health insurance from their employees and have them enroll in Medicaid. This has caused havoc in the marketplace. It is very tough to take care of all these patients who clearly deserve health care in a way that's both effective and financially salvageable.

The third challenge is that it's just a competitive world out there. I'm in an awfully competitive health care environment in which I really need to focus on what is going on to allow my hospital to thrive and flourish, and it's a big challenge to know what bets to place.

Dr. Ansel: Are you optimistic about the future of community-based health care in the United States?

Yes, I'm very optimistic. In fact, I think that community-based health care could be one of the major pathways to a successful health care plan in the United States. I think the majority of first- and second-tier care needs to be done in the community hospital, and that tertiary and quaternary care ought to be done in highly specialized, large academic centers. If we had an efficient process for ensuring that patients were getting care in the right place, at the right time, and at the right price, it could have a highly positive impact on health care quality, outcomes, and costs.

Dr. Deloose: How do you feel the new European regulations concerning clinical trials and device approvals will affect long-standing differences in the endovascular landscape between Europe and the United States?

I think that this was to be anticipated. The same thing has happened in other regions of the world where it used to be very easy to get first-in-human feasibility and even approval. The advantage in the United States is that the US Food and Drug Administration has clearly said that in certain situations and for certain percentages of patients in trials, they'll accept data from outside the United States. If data are now being generated in Europe with more rigor than what was previously requested, companies might be able to use more of that for their trials in the United States for ultimate approval. I think that it will delay certain devices coming to the United States, and it will pose more of a financial challenge for companies, which might make companies think twice about investing in certain technologies or certain pathways. So, there are pluses and minuses to it, but I don't think any of it is surprising.

Dr. Ansel: Do you envision significant changes in the model of delivery of vascular care over the next several years? How important will the volume-to-value vision be in the future, or is this all a pipe dream?

First, I think the strategy for health care delivery will evolve, whether it's vascular care or any other kind of care. Vascular care has a unique opportunity to participate in a value-based plan. What any of these types of episodic care plans does is force systems to better coordinate care and to choose the pathway of care that's most effective for the least cost. I think those are good things—better coordination of care across specialties, across facilities, at a value-based price, and with outcomes that can be demonstrated to improve quality. I view these as positive steps.

I also think that if a true risk-based contract were developed with providers, whereby they stood to lose if they didn't provide efficient and value-based care, they could be out of a market. It's going to force everybody to raise their game, and if it's done the right way and if quality is a major benchmark as opposed to price, then I think it will be good for patients as well.

Dr. Ansel: How active do you predict health care delivery entities such as yours will become in developing stricter institutional guidelines regarding the treatment of superficial femoral artery (SFA) disease, in particular?

There are two reasons we're going to become much more aggressive in the treatment of SFA disease. One is that variability in practice results in a higher cost, and that has been shown across the board, not only in vascular care, but also in orthopedics, cancer, and other chronic diseases. We are going to try to develop pathways that represent best practice, and practitioners will have to document a rational reason why they varied from the established pathway.

Second, we are going to be much better at measuring outcomes, not only acute procedural outcomes, but outcomes that are meaningful to patients over time. For example, for claudicants, it would be walking distance, and for critical limb ischemia patients, it would be the salvage of a limb that's actually a functioning limb. I think hospitals and health systems will become much more proficient at measuring outcomes and using that information to feed back to practitioners about who is doing well in their system and who is not.

Appropriate use of real-time, accurate data are critical to any of these models of care, but it's even more important in a value-based, episodic care system where you are on the line for a certain amount of money for care, and if you exceed that limit, you are on the loss side. In addition, as an individual practitioner, you will want to know how your practice patterns meet the guidelines for cost compared to your colleagues.

Dr. Deloose: As the president of a hospital, what is the most essential outcome of an SFA treatment: objective peak systolic velocity ratio–based patency rates or semisubjective freedom from target lesion revascularization?

Neither. For me, the most important outcome would be: Can the patient walk farther and faster than they did before the procedure?

Dr. Deloose: What can you tell us about the importance of cost-effectiveness analyses in trials and how these will affect decision making at the hospital level?

This is really important because cost-effectiveness analyses are very infrequent in our world of vascular care. The IN.PACT SFA study did report cost-effectiveness data as part of a randomized, clinical, prospective, multicenter trial. That sets the bar—that's exactly what we need. The other type of statistical modeling that I and others have participated in only gives you signals—they really don't allow a hospital or a health system to make decisions around purchasing. However, cost-effectiveness in a prospective, multicenter, randomized trial—that's gold. I think we will see more cost-effectiveness analyses, and the results will likely be included in purchasing decision-making committees. ■

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