Supplying Demand

Vascular surgeon Sean P. Lyden, MD, discusses his role as the Medical Director for Clinical Supply Chain Management and the multifaceted decision-making process involved in selecting the devices used at the Cleveland Clinic.

In addition to your role as a vascular surgeon at the Cleveland Clinic, you also have a new title and position. What can you tell us about your role as Medical Director for Clinical Supply Chain Management?

Our former Chief Medical Officer Dr. Marc Harrison asked me to take on this position approximately 2 years ago. The idea was that with declining reimbursement, the only way we were going to survive in tomorrow's marketplace was to have physician integration in Supply Chain to make clinically oriented value decisions about what we bought and used. I had been working directly with Supply Chain to manage costs for vascular surgery since 2002, so I knew many of the individuals involved. When Supply Chain was asked about physician integration, I think they actually suggested me to Dr. Harrison. My official title is Medical Director for Clinical Supply Chain Management, but I am now assisting with nonclinical as well as clinical spend areas across the Cleveland Clinic.

What are the responsibilities included in this position?

When I accepted this job in January 2010, Supply Chain and I were tasked to remove $45 million in operational expenses in 2010 and a total of $100 million by the end of 2011. In the first year, we embarked on 180 different clinical projects and, in 2011, more than 200 clinical projects. We looked at just about every single thing the Cleveland Clinic buys, from physician preference items all the way down to our copier supplies, natural gas utilities, travel expenses—everything. My job and goal was to make sure that clinicians were involved with Supply Chain and keep our analysts informed about what products were available and the value the products add to patient outcomes. Most clinicians can tell you whether an item is a luxury or necessity and the value it adds to the care of the patient. This knowledge helps Supply Chain develop and negotiate strategies.

By what criteria do you make your recommendations on which devices should be on the shelves and which should not?

There are multiple criteria. First and foremost, we consider the caregivers' input in terms of how each device provides value. We look at any data regarding outcomes as well as cost. The cost of most products will vary depending on the volume of product used and how much competition exists. We depend on physician input regarding how competitive the clinical space is, how many physicians would have to switch if we chose a different product, and how highly the physicians value the product in question or whether it is a commodity.

We also sometimes ask companies to explain how their products match up against another company's. Using that information and physician input, Supply Chain will negotiate one of many types of strategies. In some areas, we have used a single vendor; in other areas, we have used two vendors. Sometimes, we come up with what we consider a fair market price, and then any company that meets that price is accepted as a vendor. Finally, in physician preference items, we limit voting approval of the strategy to the physicians who use the products being evaluated.

It is important to note that Supply Chain conducts all of the negotiations. Physicians do not negotiate the price but rather help steer how the contracts are made and then vote to approve a contract. Contracts always contain escape clauses for issues involving patient safety. For example, if we sign a contract, and then later a device is recalled and an alternative from the same company does not meet our clinical needs, we can withdraw from the contract. During the last 2 years, we have renegotiated contracts for many physician preference items such as endomechanical stapling devices, orthopedic hip and knee implants, spine and trauma implants, pacemakers, defibrillators, heart valves, stents, and angioplasty balloons.

How are decisions made in cases when comparative effectiveness data are minimal, if they exist at all?

Unfortunately, only limited data are available regarding comparative effectiveness in most clinical areas. When a company receives US Food and Drug Administration approval for a product, it has shown safety and efficacy for specifically labeled indications. The US Food and Drug Administration is tasked to look at each device application individually and not comparative devices and data. Marketing departments then develop strategies to

gain adoption of new devices. Cleveland Clinic has tried to push back to industry on this lack of comparative data. When a company introduces a new device with similar indications to an existing device without improving outcomes, we expect the device to have a similar price. To justify a cost increase, the data should show the increased value of the new product. We ask our physicians to review and scientifically validate data regarding device performance and outcomes and not rely on marketing claims of uniqueness and superiority.

Industry today spends a lot of money on research, development, and marketing, but not on comparative effectiveness. As we begin to see shifts in health care policy, I believe that the United States government is going to force companies, hospitals, and physicians to show comparative effectiveness for procedures and devices to receive reimbursement.

For example, the Agency for Healthcare Research and Quality has already recommended limiting or eliminating reimbursement for renal artery stenting based on the lack of efficacy data. Personally, I believe there are some patients whom renal artery stents benefit, but not every patient benefits, and I know it is difficult to determine who those individuals are preoperatively. If physicians and industry do not start working together to produce comparative effectiveness data, many of our new procedures and technologies could be taken away from us if the Centers for Medicare & Medicaid Services decides to not provide reimbursement.

What advice would you give to a hospital center that is looking to have a physician take on a position such as yours?

Find someone with thick skin. Tough choices in this era of declining reimbursement are not easy, and they have required a culture change among our physicians. The key is emphasizing and defining value based on patient outcomes to drive decisions on cost and spending. You do not want to stop innovation; you need your physicians to help define the relative need for each technology and/or device. Our motto at Cleveland Clinic is "patients first," so we try to use the right product at the right price for the best outcome.

An important factor in our success was providing transparency for our physicians on the costs of materials and devices. Many are surprised that similar items may differ vastly in cost but not value in terms of the care of the patient. We have found that the cheapest item is not always the worst, and the most expensive item is not always the best. Challenging physicians to better understand and consider costs in their choices is very important. If products are equal in outcome, the cost should be equal; however, if they are of better value in terms of patient outcomes, expecting those items to cost more is not unreasonable. When devices do not have direct competition, market forces will allow a premium price.

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In a device-driven field and a climate of scrutiny toward conflicts of interest, what steps has your institution taken to ensure that physicians can participate in development and testing, yet are not making decisions based on financial interests?

The Cleveland Clinic believes that medical innovation significantly benefits patient care. We maintain comprehensive conflict-of-interest policies and procedures for staff physicians and other employees that are designed to ensure that all potential conflicts are clearly visible, promptly considered, and properly addressed by Cleveland Clinic executive leadership. Our policies require our staff physicians to regularly disclose and update interests that may pose a conflict.

These policies also apply to purchasing. When we have involved physicians in product or device review, updated disclosures are required. Individuals with significant conflicts are invited to those discussions but are unable to participate in voting or decision making. We do not want to hamper innovation, but we want to make sure that we are very transparent about those conflicts so that they do not affect our choices or decisions. Our formal policies are available on our public Web site.

To what degree do you feel conflicts of interest are a problem in the field of vascular intervention?

Without industry's help, no great innovative product would have ever gotten to market. The key is transparency. I think where people have gotten in trouble is when they try to hide or not disclose what their conflicts are. ■

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