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Navigating the Value Analysis Committee

No matter how groundbreaking or seemingly life-saving the medical technology, the criteria serving as the barrier between innovation and clinical utilization are simple: "What does it cost and how do we calculate its value?" The gatekeepers? The hospital value analysis committees (VACs).

These committees, made up of physicians, nurses, purchasing agents, liability specialists, supply chain management and administrators, evaluate all new product purchases for the hospital or clinic setting.

"The VAC is designed to limit unbudgeted capital and to keep disposable costs to a minimum. For that reason, bringing true innovation to market is as challenging as ever," says Jim Pearson, CEO, NICO Corporation, the leading innovator in the design of automated, minimally invasive neuro and spinal tissue and tumor removal instruments.

For med-tech companies like NICO, focus on the so-called "Triple Aim" is key: Improve patient experience, improve population health and reduce cost of care. Clinical data serves as the most effective way to communicate that your technology checks all three boxes. Understanding a particular VAC process, being knowledgeable on its committee composition and knowing the challenges that the institution is facing are equally important components of the equation.

To provide medical device and technology companies with a greater perspective on successfully navigating VACs, we spoke with four River Cities' med tech portfolio companies that have dedicated countless hours to mastering the pathway to get innovative products in front of and approved by these ever-vigilant committees.

Ryan Denney
Vice President of Sales
Veran
Lung Cancer Diagnostics

Jim Pearson
CEO, President
NICO Corporation
Neurosurgical Platform

Tom Dugan
CEO
Amniox Medical
Regenerative Medicine

James Kim
Global VP of Sales & Marketing
OrthAlign
Orthopedic Surgical Navigation

Sales Strategy Considerations

- Electromagnetic navigational bronchoscopy system
- Clinical users: Interventional pulmonologists, thoracic surgeons, interventional radiologists
- 510(k)
- Fast follower with vastly improved product to Medtronic's SuperDimension
- Under DRG reimbursement

- Access, tissue excision and tissue preservation devices for intracerebral hemorrhages and subcortical primary and secondary tumors
- Clinical users: Neurosurgeons
- 510(k)
- Disruptive technology requiring new hospital and surgeon education
- Under DRG reimbursement

- Proprietary cryo-preserved human birth tissue-based products
- Clinical users: Orthopedic and spine surgeons, wound care clinicians, ophthalmologists
- 510(k) and HTP moving to BLAs
- New regenerative medicine platform with broad applications
- Under DRG for ortho; existing code in ophthalmology and wound care

- Handheld navigation unit for precise alignment and positioning in total knee and anterior total hip arthroplasties
- Clinical users: Orthopedic surgeons
- Facing CCJR dynamic
- 510(k)
- Under DRG reimbursement

What is the typical path to get in front of the VAC?

Ryan Denney, Veran: The pathway to get products in front of a VAC is dependent on the product. For capital equipment, the process can go one of two directions. In many facilities, a VAC won't put capital on their agenda until there is an established interest from a physician, and the product has been budgeted. In other instances, the VAC needs to approve prior to the hospital budgeting for the technology. Typically, physician interest is imperative if you want approval from a VAC.

For disposables or single-patient-use products, the VAC process can be very different. Traditionally, if the disposable is affiliated with a piece of capital (razor/razorblade model), then disposables will get approved/denied at the same time that capital is approved/denied. If disposables are additive to a piece of capital, physician support will be necessary if the product needs to go through the VAC. In many instances, device companies can avoid the VAC with these products if they can show a benefit to the patient, and if the cost is similar to the other disposables being used with that capital.

Tom Dugan, Amniox Medical: The first step is to identify and confirm the process, timeline and requirements for the VAC. Attempt to identify key VAC members to understand composition of the committee and areas of focus. Recognize that different types of institutions [For profit, Not-For-Profit and Government hospitals] have different approaches and objectives within the VAC.

Identify clinical product champions (three – five) willing to put forth the effort to request the product. Physicians are critical, but groups of clinicians (physicians, nursing staff, etc.) across multiple specialties would be ideal. Clinical evaluation of the product may be permitted or even required prior to VAC submission.

Ensure that all material is developed and delivered in the appropriate format [hard copy, electronic]. Proof all material and use a checklist to confirm requirements are met. Submit the material in advance of the required date [two – five days].

What communication takes place between a potential vendor and VAC prior to the initial meeting?

Ryan Denney, Veran: This is very dependent on the relationship that the sales representative has with the physician and with hospital administration. If a good relationship exists, there is typically some good dialogue between the vendor and the individual presenting the new technology to the VAC (typically the physician champion), as the individual presenting tends to trust the vendor to provide all relevant information that will be needed for the VAC meeting. Obviously, this enhances the chances of approval for the vendor. If the relationship is limited, the VAC will do most of their research and due diligence without the help of the vendor.

James Kim, OrthAlign: There typically isn't much of an opportunity to interface with the VAC prior to the initial meeting, however, it should be noted that there is no one standard way of a hospital operating a VAC.

Jim Pearson, NICO: Typically, there is limited or no vendor-to-VAC communication. Discussions take place through the physician via completing questions on a template or form. The VAC typically does not permit the vendor to be in any meetings or to communicate directly with the committee. Our job is to educate the sponsoring physician as best we can – we can review and contribute to documents the physician submits to the VAC and we help adequately prepare the physician prior to the meeting so they can comprehensively defend their request in front of the committee.

Tom Dugan, Amniox Medical: Typically requests for many data points: ATTB, FDA, insurance verification, scientific/technical information, clinical studies, manufacturing info (latex free?), pricing and GPO/IDN contracts. If in-house clinical evaluation is required, there is often an agreement re: the number of cases and standard/metric to be used in the evaluation.

Is it at all similar to meeting with the FDA?

James Kim, OrthAlign: No. The FDA focuses on the clinical side of a product. The VAC emphasizes the economics behind something. As VACs are playing a bigger role in the need to "fix" hospitals' financials, I believe they are purely focused on cost-cutting. Eventually, as the cost-cutting exercise runs its course, clinical importance and value will begin to play a bigger role as all of the "waste" is identified and extracted out of hospitals.

Ryan Denney, Veran: No, I don't believe it is very similar to meeting with the FDA. I have worked with FDA in previous roles regarding product approval (PMA and 510k), and the VAC has different objectives when considering product approval. As most are aware, FDA is concerned with patient safety first and then efficacy after. Because of that, most VACs do not have to concern themselves with patient safety (they rely on the FDA for that). On the other hand, they do spend significant time on outcomes and efficacy, and how those relate to their overall ROI. In other words, if the product gets approved, how does that help patient outcomes, and how do those outcomes affect the bottom line for the hospital? With the above said, VACs definitely consider any and all published data and information that provides negative product feedback (infection rates, readmission rates, product failure rates, etc.), but the bigger concern seems to be the overall patient benefit when compared to cost and reimbursement.

How do you prepare for such a meeting?

Ryan Denney, Veran: Traditionally, vendors are not allowed to participate in VAC meetings. That said, there are special circumstances when members of the VAC ask vendors to attend to answer questions and/or to address potential concerns or issues.

It is also of great importance if the vendor can get his/her physician champion to the VAC meeting. Without a "voice" in the room, many VACs assume that physician support is minimal, and therefore, usage will be minimal as well. This will almost certainly result in the VAC voting to prevent the product from being accepted into the institution.

James Kim, OrthAlign: We have a Value Analysis Committee Kit that our sales reps can use as a full resource that includes all information required by various VACs. Content includes:

- Formal Letter Template that Surgeon Champion can use for submission to VAC
- FDA documents
- Product Description
- Instructions for Use
- Product Codes
- Clinical Studies
- Case Studies
- Cost Benefit Tools
- Marketing Brochures
- Education Brochures
- Surgeon Education Program

- Staff Training Overview
- Pricing Information
- Reimbursement Information
- Product Warranty Information
- Key Contacts

Jim Pearson, NICO: We developed a VAC form about two years ago after reading more than 35 VAC overviews and selling over 50 products that required review and approval by VACs. The form, once completed by the physician, answers the most common questions asked by VACs and is then submitted by the physician to the VAC.

Tom Dugan, Amniox Medical: Up-front probing to determine VAC process, composition and issues/challenges at the institution. Review the proposed submission with the product champions and work with them to ensure that they fully understand it and can effectively communicate it. Get their feedback so that the package can be revised as appropriate based upon their prior experience or knowledge of VAC process/issues.

Every VAC is different so the preparation is individualized and specific to that institution. However, our marketing team is preparing a standardized toolkit to provide comprehensive information that can be tailored to the specific institution/VAC.

What is required of a vendor's physician sponsor(s)?

Jim Pearson, NICO: It requires several commitments and deliverables from them. Number one: It requires their time, which is very limited. Number two: It requires that they complete their own VAC form and provide estimates on product usage and value. Third: It requires that they attend the VAC meeting to represent and defend their product selection. I must add that for replacement products or perhaps a new product with a simple new aspect, this is typically not as big of an issue. However, when you have a truly innovative product that is a breakthrough technology, it's important to think about what the VAC is asking and comprehensively respond so that they have a true understanding of product value, both clinically and economically, and they can see differentiation between existing products and the innovative product they are being asked to review. They want to know:

- How is the product or technology better?
- What does it replace?
- How is it innovative?
- How does it or can it save cost or improve hospital economics?

The VAC process, for this reason, is terrible for truly innovative technologies. It's okay for day-to-day products, but for truly innovative products and technologies, I think there is a need for a specific "innovation track" that analyzes these innovative technologies through a different lens. Without this, I fear innovation will significantly suffer or stagnate.

James Kim, OrthAlign: He/she needs to be a user of the product and present to the committee why it should be brought into the hospital's portfolio of products. That is why a tool such as the VAC Kit is important: A surgeon needs help in building the story on why.

Ryan Denney, Veran: In most instances, there is not much required from the physician champion. If the sales representative is good, and he/she understands the process, the physician effort should be minimal. If possible, it is ideal if a physician can do a bit of due diligence prior to the VAC meeting to help justify the approval.

Observing a case or two with the new product provides a bit of legitimacy to the request for new technology. At the same time, physician peer-to-peer conversations can help the requesting physician explain the justification for new technology. There seems to be a higher likelihood of approval when physician champions invest a bit of their own time in an effort to gain VAC approval.

What are the clinical data requirements for 510K devices in the eyes of the VAC?

Jim Pearson, NICO: Proof that there is clinical improvement while making the hospital money is an essential aspect. This is the new "Triple AIM" in which healthcare institutions are being measured by today. When you can consistently show exemplary patient outcomes using a technology that all surgeons can use after training that allows for significantly improved hospital economics, you've made a great case for meeting Triple AIM. NICO has several examples of patient stories that support Triple AIM, such as Blakely Murphy's tumor removal story and Gigi Gelvosa's stroke treatment story.

Tom Dugan, Amniox Medical: Level I-II clinical evidence – randomized, controlled trials. High level health economic data – from Level I-III studies and publications in peer reviewed journals.

Is the clinical data requirement growing more onerous?

Jim Pearson, NICO: Yes, I believe so.

Ryan Denney, Veran: It would seem that VACs are assessing clinical data more thoroughly than in the past. I would say that most VAC members are asking for more data, and they do seem more interested in the quality of the data. At the same time, they are definitely interested in the efficacy of a device when compared to similar devices. Not to state the obvious, but if the cost is the same or higher, and if the data is similar to an already approved device, the odds of approval go down. If the cost is the same or higher, and if the efficacy is deemed to be better, the odds of approval increase drastically.

In the past, you could often use case studies or "white papers" to help with the VAC approval process. Although those can still be submitted for review, they don't seem to carry as much weight as they once did regarding approval.

Tom Dugan, Amniox Medical: Yes, but it typically depends on the account and the level of champion.

What are the must have's to get VAC approval?

Tom Dugan, Amniox Medical:

- A committed sponsor
- A "story" about why the product should be utilized in the institution: clinical, economic and user benefits vs current practice
- Some form of clinical data from a peer-reviewed journal
- Possibly an in-house clinical evaluation with documented results
- Cost-benefit analysis and pricing – possibly annual cost to institution based upon projected volumes. Sometimes replacement cost for current product.
- Detailed product specifications
- FDA status and cleared indication for use
- Information re: on-going clinical trials

What does it take to get your device approved for initial use or trial at an average hospital?

Jim Pearson, NICO: It typically takes three to six months. Free product supplied during the trial and a physician champion demonstrating clinical and economic value is what we are seeing as typical at most institutions. Here's an example of a favorable product trial that helped support and validate the need for our product in the hospital: The first case for the Seton Brain and Spine Institute using NICO's BrainPath tool resulted in the successful removal of an otherwise non-survivable brain hemorrhage.

Ryan Denney, Veran: FDA approval and physician interest will typically get an evaluation or trial set up at a hospital. Interestingly, most facilities are open to evaluations of new equipment, and the road blocks to starting a trial aren't overly challenging as long as the vendor has a physician champion. That said, a successful evaluation used to almost guarantee a purchase, and that is not the case anymore. Knowing the appropriate time to schedule a trial is paramount to success when considering the sales process.

In many instances, hospitals will ask for free product for the trial, but that is negotiated with each facility independently. Most hospitals will also ask for some administrative/legal paperwork to be filled out prior to any sort of evaluation involving patients. Most of this is intended to indemnify the hospital of any potential adverse events and to eliminate all responsibility to the hospital and their staff regarding any "breakage" associated with the equipment or device.

As expected, training and support are required from the vendor, and most vendors would never set up an evaluation without providing proper clinical coverage.

What does it typically take to get paid for consistent use?

Jim Pearson, NICO: Typically, if you have consistent use, it's actually better. Hospitals are done buying products/devices for doctors that don't get used as often as they thought they would. If we're able to achieve the Triple AIM as vendors, we're in a great position with VACs because they don't typically see system value – they only see expenditure value. Utilization is largely based on personal preference, market size, who's on call, and so on.

Tom Dugan, Amniox Medical: In-hospital use is covered under the DRG for the particular procedure. Reimbursement is required for the outpatient or office setting.

Has the power of the VAC increased, decreased or stayed the same over the past 24 months?

James Kim, OrthAlign: The VAC approval process is currently in the "panic" mode state, and it has been for the past two years. With CCJR/bundling upon us, that "panic" state is going to continue, with hospitals just looking to cut any kind of spending. The emphasis today, and I believe for the next 12 months, will be on pure cost cutting and not bringing in new variables/products. As more sophisticated hospitals begin to recognize that they are being too extreme, they will begin listening to the surgeon again and clinical outcomes will play a bigger role in the decision process. Today, too many VACs are being driven by financial people who do not have the in-depth knowledge to know everything about each vertical in the hospital.

Ryan Denney, Veran: I don't believe that we have seen a significant change over the course of the last 24 months. That said, I am primarily dealing with a very disruptive technology, and the perceived benefits of the technology are well accepted by the VAC.

For commodity driven products, I would assume that the VAC has become significantly more challenging regarding approval. Most hospitals are making a concerted effort to minimize the number of vendors on the shelf, and there has definitely been an effort to limit "similar" or "me too" products.

Regardless of GPO and/or hospital system size, hospitals have continued to push for and enforce standardization for devices that are considered to be commodities. Hospitals have also leveraged market consolidation to their advantage on commodity product negotiation. In addition, a substantial shift and increase in hospital employed physicians has obviated the need to cater to these physicians. Hospitals are not faced as often with the threat of a private practice physician to take their cases to another facility that will acquire their desired technologies or devices.

Tom Dugan, Amniox Medical: Pressure has increased, which is ultimately designed to slow or stop the sales process, limit vendors and give the institution more control over product selection and cost. This will continue for the foreseeable future.

Preparing for Tomorrow

The general consensus remains that hospitals increasingly are acting more like Fortune 2000 corporate America as it relates to their focus on cost reduction and institutional profitability. As reimbursement trends change the healthcare landscape, hospitals are simultaneously controlling costs and demanding concrete value from their vendors. With Value Analysis Committees serving as the gatekeepers to clinical spend, providing health economic data supporting claims for lower cost, better outcomes and happier patients is paramount.

River Cities is one of the most active healthcare investors in the US with a 22-year track record of funding successful medical device companies. We take pride in supporting some of the most innovative technologies and entrepreneurial teams in the device category and applaud their success in navigating the path to hospital adoption. Some of our most recent exits in the medical device category include: Surgiquest, sold to Conmed (NASDAQ:CNMD) for $265M in 2015; OrthoHelix, sold to Tornier (NASDAQ:TRNX) for $135M plus potential earn-out in 2012; and OrthoScan, sold to ATON US in 2011.