Trends in Medical Device Purchasing, Evaluation of Value, and Advice for Manufacturers

Interview with Patrick Vega

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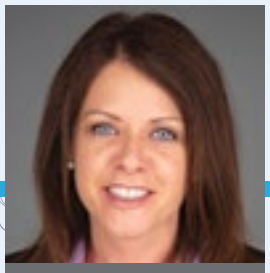
In his role at Vizient, a leading healthcare performance improvement company, Patrick Vega supports member hospitals, health systems, and physicians in musculoskeletal services with a focus on high-value care, aligning cost, and quality. He brings over 20 years of achievement in service line and business development for hospitals, health systems, and physician practices. His broad expertise in assessment, planning, and implementation coupled with highly developed physician relations abilities has resulted in a history of successes in the most challenging environments. Patrick consults, writes, and speaks on topics regarding the spine, orthopedics, and neurosciences, specifically in the areas of strategic assessment and planning, program development, and center of excellence development. He has more than 35 national conference presentations and published articles.

This interview was conducted by Ann Menzie, MS, Senior Director, Evidence Synthesis, Modeling & Communication, Evidera, in conjunction with ongoing efforts to provide relevant and up-to-date information to help our clients develop and execute their evidence generation and market access strategies.

Ann recently spoke with Patrick about the evolution of the medical device industry, maturation of hospital value analysis programs, and driving value in healthcare by improving outcomes and quality while reducing costs. While this interview focuses on the changing medical device landscape and hospital purchasing dynamics in the US, formal value analysis through health technology assessments (HTAs) or tenders is well established ex-US. Many countries in Europe, for example, have implemented evidence-based, decision-making strategies to drive quality of care in a cost-constrained environment. By encouraging manufacturers of medical devices to consider the clinical and economic value of new products and the evidence strategies to support differentiating value propositions, there is substantial opportunity to address key stakeholders'



Ann Menzie

needs in all markets. While presented from the perspective of the US, the ideas expressed in this interview have global implications for clients looking to develop successful market access strategies worldwide.

What trends have you observed over the past five years regarding changes in the medical device industry and the dynamics of surgeons and hospitals as key decision makers of medical technologies?

Historically, the process of selling medical devices to hospitals was often informal. If a physician expressed interest in a product and believed it to be safe and effective, then the hospital approved it for purchase with minimal consideration of cost. In today's environment where reimbursement rates are flat or declining, hospital purchasing decisions follow a process of value analysis that evaluates both price and performance.

Relative to purchasing, where the hospital/physician relationship was once defined by rising tensions, there is now a need to establish collaborative partnerships in acquiring new devices and technologies. This evolution is largely driven by a need to evaluate service-line performance by sharing data as well as a growing understanding of a co-dependency of physicians and their affiliated hospitals in order to thrive, or at times simply survive, in a challenging hospital environment.

Please tell us more about the value analysis programs being used by hospitals to evaluate medical devices and technologies.

Most hospitals apply the process of value analysis to address product efficacy, clinical outcome, quality of care, and safety (for both patients and staff). Focus areas for value analysis include improving outcomes, appropriate vendor standardization, pricing optimization, and implementation of cost-saving initiatives. Many hospitals also incorporate lean initiatives into their value analysis programs to aid in the identification and elimination of waste, redundancies, and inefficiencies.

Value analysis teams (VATs) are comprised of multi-disciplinary professionals including physicians, clinicians, and purchasing staff. Additional members of VATs may include nurses and representatives from finance, supply chain, infection control, central processing, and data informatics. The strategic aim of a VAT is to select products and services that promote the highest standard of care - not always at the lowest cost, but at the greatest value. The value-based procurement process followed by a VAT for medical devices is not unlike the process followed by a pharmacy and therapeutics (P&T) committee.

VATs are used by hospitals as well as hospital networks of all sizes, including integrated delivery networks (IDNs), and are typically established for each hospital service line (e.g., cardiology, orthopedics, and general surgery). Larger hospital networks may implement system-wide value analysis programs that make decisions impacting multiple facilities. Group Purchasing Organizations (GPOs) also have well-developed value analysis processes to support their members. GPOs utilize VATs that include representation from member health systems to assess the value of products and services across the continuum of care using a collaborative approach benefiting member hospitals by helping them achieve their high value, quality outcome, patient care strategies.

What is the process for bringing a new medical device to a VAT?

Physicians submit the medical device to a VAT for evaluation, typically using an online system, and may be asked to present the product to the VAT. VAT meetings are frequently closed to vendors, including medical device manufacturers; however, they may be invited by the VAT to provide additional information if needed. The VATs evaluate requests for products and services and critically evaluate the influence on clinical outcomes, safety, processes, and total cost of care compared to what is currently being used.

Medical device manufacturers may provide physicians with evidence-based materials to help them prepare for VAT meetings and advocate for the new medical device. These materials communicate "value" [Value = (Quality + Outcomes)/Cost] and may take the form of evidence reviews; value briefs; or dossiers, economic models, etc.

It is not uncommon for VATs to conditionally approve a new medical device with a trial period before fully approving it for use. Hospitals may wish to test the impact of the product within their system to evaluate if claims of improved outcomes and/or cost savings are fully realized before committing to purchasing the product. To be successful with VATs, medical device manufactures must seek and deploy a strategic understanding of their customers, both physicians and facility, that blends price, product efficacy, and patient functional outcomes.

What do VATs use to inform their decision making?

VATs leverage a wide range of inputs to inform their decision making, including the following:

- Physician evaluation of clinical efficacy and safety
- Evidence published in peer-reviewed journals – often independent, outside services may be leveraged to assess the strength of the evidence base
- Reimbursement coding, coverage, and payment - Is the medical device reimbursed using existing coding? Does the reimbursement payment for the procedure adequately cover any incremental costs?
- Manufacturers' brochures, evidence briefs, white papers
- Economic models that show cost savings, cost effectiveness, and/or cost offsets resulting from using the medical device or technology

- Data collected through electronic medical records (EMR) and other internal sources evaluating surgical site infections, transfusions, readmissions, costs, and patient satisfaction to assess unmet needs for new products or services

VATs evaluate the medical device or technology in comparison to existing products. Therefore, it is imperative that materials supplied by the manufacturer demonstrate meaningful differentiation from existing products, and that these claims are supported by evidence.

There is variation in the level of sophistication of VATs within US hospital systems that is related to the level of clinical supply integration. VATs that are less sophisticated do not have a rigorous, evidence-based process for reviewing requests and are more of a "rubber stamp." Those that are more sophisticated are physician led and use financial, clinical, and operational data to drive their decisions. Many VATs fall somewhere in between the two and are looking to continually evolve in order to increase their level of sophistication.

Many manufacturers are looking beyond medical devices, such as surgical implants, and are developing robotic and digital platforms. How do hospitals evaluate these new technologies that often add cost to the system without incremental reimbursement or long-term data showing improvement in patient outcomes?

To date, the evidence supporting long-term clinical outcomes of robotic-assisted procedures is limited. Published studies have varying designs and report a range of outcomes making it challenging to draw meaningful conclusions from the literature. Many papers report improvements over open procedures, but evidence is mixed compared to minimally invasive procedures using existing technology. Manufacturers have developed brochures and white papers reporting short-term clinical outcomes with a strong focus on cost improvements from implementing robotic programs. Making evidence-based decisions regarding robotics programs is challenging given variation in costs and opportunities for improving efficiencies between different hospital systems.

Value analysis of robotic programs often extends beyond the traditional VAT to include additional hospital stakeholders responsible for strategic purchasing decisions related to return on investment. Physicians will evaluate robotic programs based on intra-operative and clinical improvements, such as enhanced visualization, less blood loss, faster recovery, and the potential for better outcomes. Service-line leaders and hospital C-suite executives may evaluate robotic programs based on the ability to grow market share by attracting patients seeking robotic technology. Physicians may be attracted to hospitals that offer advanced technology as well by building their practice and referral base through leveraging their expertise in and access to robotics. Hospitals may also invest in robotics programs to build their residency programs to train the next generation of surgeons using the most advanced robotics technologies available.

Robotic programs introduce additional costs to the system through capital equipment, disposables, maintenance contracts, etc., often with no incremental reimbursement. However, the expectation is that the increased volume will drive revenue. This demand for advanced technology by patients and physicians coupled with clinical evidence purporting the procedures are equivalent in safety and efficacy often drives hospital decision making in favor of establishing a robotics program.

What advice would you give to manufacturers looking to approach a hospital with a new medical device or robotic technology?

Develop a robust go-to-market strategy for ***both*** physicians and providers, specifically:

- Develop an advocate (most often a physician) who will champion the product on behalf of the manufacturer to the VAT
- Be transparent regarding all costs, including non-product costs, such as disposables, maintenance, and additional equipment
- Develop a VAT strategy and evidence-based tools that communicate clinical and economic value (e.g., value analysis briefs, cost calculators)
- Demonstrate an understanding of the reimbursement landscape for the procedure and/or product and the impact on the hospital contribution margins
- Offer product trials, as needed
- Invest in evidence generation to substantiate differentiating value propositions and claims
- Seek a strategic partnership between vendor, hospital, and physician by approaching hospitals as key stakeholders
- Consider pricing strategies that reflect the clinical and economic value the product delivers to providers and patients, not just covering costs of manufacturing and factoring in a profit
- Build capabilities within the field organization to facilitate evidence-based discussions with hospitals and develop a trusted relationship

The opportunity for vendors in an increasingly sophisticated purchasing environment lies in not just serving physicians but also understanding more holistically the many buyer considerations: price, performance, differentiation from current products, and long-term value. This level of understanding is not easily acquired, requiring manufacturers to develop and deploy a strategy that addresses all key purchasing elements. ■