



MATTER is a community of healthcare innovators, an incubator of ideas, and a catalyst for change. MATTER hosts programs that address the needs of healthcare entrepreneurs and innovators.

A Salon is one of its many dynamic programs. MATTER curates a room full of experts from across the healthcare ecosystem to discuss the challenges and opportunities surrounding a specific topic. On April 20, 2016, MATTER's Salon focused on "Shift to Fee-for-Value and Impact on Medical Device Sales."

**MATTER Salon Notes
Shift to Fee-for-Value and Impact on Medical Device Sales**

The shift in provider and payer attention to fee-for-value services has been well-documented in orthopedic, cardiovascular and other medical device sales.

MATTER convened a cross-functional group of stakeholders in the medical device supply chain, representing manufacturers, payers, patients, and providers. The group was engaged in a roundtable discussion on specific trends that are impacting the medical device supply chain. Specifically, the objective of the session was to investigate how the shift to value-based models of care is impacting the sales model for medical device companies.

Cross-functional participants represented key stakeholders throughout the supply chain as well as individuals with specific exposure to fee-for-value incentives:

Manufacturers	Providers	Payers
Evan Norton, Abbott Ventures Yousuf Mazhar, Abbott Ventures Ashwin Kumar, Abbott Ventures Dan McCoy, Hill-Rom Jonathan Gunn, Briteseed Andrew Cittadine, Diagnostic Photonics	Paul Berrini, Sinai Health System	Asif Khan, CEO CareMerge
Technology/Telehealth	Sponsor	Contract and

		Procurement
Jim Ivers, Mondopoint Divya Varshney, Consilink Dave Anderson, TouchPointCare	Steven Collens, MATTER Maryam Saleh, MATTER Kelli Enright, MATTER	Bernhard Kappe, Pathfinder Tom Derrick, Open Markets Trevor Wood, Open Markets Hani Elias, ProcuredHealth Brian Fisher, Navigant

Attendees discussed the key trends that providers and manufacturers are facing. For medical device manufacturers in particular, the group explored opportunities in the changing medical device industry; midsize medical device companies should consider:

- Focusing on developing value-based service offerings to support the Affordable Care Act (ACA)
- Aligning manufacturers' interests with value-based provider networks (accountable care organizations (ACOs), etc.)
- Aligning service offerings with shift in care to outpatient settings

Executive Summary

Key trends in medical device sector

Providers are **consolidating** in key service lines that have been important growth engines for the medical device industry. Notably, more than half of physicians in cardiology and orthopedic service lines are employed. Although cardiologists and orthopedic surgeons tend to be the highest paid specialties, the employment model has and will allow healthcare systems to drive more consistent management. The Bundled Payments for Care Improvement initiative (BPCI) was a great example of the mechanisms that large providers are willing to put in place to control costs in orthopedic surgeries.

Providers are **vertically integrating**--creating opportunities for providers to enter into value-based purchasing agreements. Vertical integration allows providers to enter into financial risk for the management of their populations.

Increasingly, providers are seeking **value-based services with their medical products** to support their own initiatives. These are particularly targeted at medical devices because device utilization is closely tied to utilization of inpatient and outpatient services.

Changing customer

As physicians are consolidating, individual physicians are having **decreasing influence on medical device purchasing**. The individual physician is now a clinical expert in the medical device procurement process, but capitulated large hospital groups, integrated delivery networks, ACOs, and regional group purchasing organizations tend to involve multiple stakeholders in the purchasing process.

Value committees are often the vetting point for many devices and need to be considered in device design and marketing.

Importantly, networks are more likely to be concerned about delivering value and receptive to value stories associated with medical devices. The network, more than the hospital, will want to see the downstream effects of the device. These network improvements typically go through the *directors of population health, directors of innovation, and directors of managed care contracting* in accountable care provider systems.

Customer's definition of value in medical devices

Providers and payers are becoming more aligned and want to understand the true value of medical devices that they use in terms of *impact on cost, quality, and outcomes specific to the customer's populations*. For many customers, that means that manufacturers will have to *invest in demonstrating the long-term value of a product* across a single institution or across a single patient population.

Among customers adopting accountable care models, bundling seems to be a growing trend which significantly impacts decisions to use innovative medical devices. Driven by successful pilot programs like BPCI in orthopedics, many providers and payers are trying to develop a *capitated, episodic, post-acute payment model for specific patient procedures* in orthopedics, cardiovascular, and other therapy areas.

Value-based service offerings

Typically, new stakeholders are aligned to quality incentives and requirements resulting from the ACA. Therefore, any service offerings that demonstrate the following may have the greatest impact on the medical device buying process:

- Reduction in readmissions
- Improvement in care coordination
- Increase in patient satisfaction

Financially, medical device manufacturers can enter into financial risk in achieving the outcomes associated with different value-based contracts. *Risk-sharing agreements* with providers and payers can take the form of value-based purchasing, or in some cases, guarantees for reduced surgeries or other utilization. For example, a stent manufacturer entered into risk-sharing programs where the payment is conditional upon the patient not getting readmitted for a defined period of time. Entresto™ from Novartis utilized this tactic in their drug pricing with inconsistent effectiveness.

Partners in value design of devices

Medical device manufacturers are challenged to provide the appropriate value messages to their customers for three key reasons:

- Customer skepticism around data and metrics coming from manufacturers
- Lack of infrastructure to develop outcomes data necessary for the value story
- Significant variability among customer organization design and maturity with respect to value

Manufacturers who have experience in developing value-based messages and services have noticed a ***lack of replicability and repeatability*** of model, which can have financial implications for device manufacturers. ***Third-party service providers*** are better suited to provide value-based services and can be good partners for manufacturers.

Data and analytics

Many manufacturers are already collecting and analyzing medical device data. However, ***a number of architecture platforms exist*** which can use medical device data; choosing the right platform for their data can be confusing for manufacturers. The platform providers may not provide any flexibility in altering the platform and, therefore, ***choosing a platform can limit the utility of data*** generated by the devices.

Still, many manufacturers, payer, and providers see medical devices moving toward providing ***more connected and interoperable devices***. A critical design requirement of the medical device data is that it will be ***incorporated into the patient's electronic medical record***.

To be competitive in the future environment, manufacturers will need to understand the expectations of ***evidence within disease-specific or protocol-specific populations*** that payers and providers embracing value-based purchasing would expect. Generating the evidence to support value may only require ***case studies and real-world examples instead of randomized clinical trials***.

However medical device manufacturers decide to incorporate value into their products or portfolio of offerings, it is important to get input from payers and providers well in advance so that value can be part of the design process.

Detailed Notes

Background

The medical device industry is undergoing several changes. Five years into the Affordable Care Act, providers are more and more inclined to shift to a value-based model of healthcare delivery, which --among other things -- has had significant impact on the medical device sales process.

For less commoditized devices, the typical sales approach involves working with clinicians to influence the purchasing decision of the hospital. However, medical device companies are finding that the clinician's sphere of influence over purchasing decisions is decreasing. The medical device companies are left to search for another means to influence purchasing decisions. Another potential sales channel could be via ACOs and regional capitated hospital groups. In order for medical device companies to make their products valuable to these new target customers, their value proposition needs to go beyond delivering the most safe and effective products. They need to show that they can deliver better overall outcomes. In order to deliver better outcomes, their devices are now bundled with services to track patients after their operations to ensure they adhere to care plans and that there is proper follow up after surgery.

Key trends within medical device sector

Three key themes within the medical device sector are driving the shift from volume-to-value. First, the medical device industry is experiencing increasing consolidation, leading to a market with fewer, but more powerful, players who have broad portfolios. Second, manufacturers are vertically integrating to lower costs and increase efficiency. For example, Medtronic's acquisition of Cardiocom, a disease-management and patient-monitoring firm, gives Medtronic access to downstream distribution channels for their devices. Third, manufacturers are increasingly bundling relevant services with their products to achieve more favorable positioning with payers and providers.

Current sales model for medical device companies

In today's market, many medical device companies have one key product that they use heavily in negotiation and contracting with hospitals for their commodity-based products. For example, Abbott leverages its two highly-differentiated products, MitraClip[®] and Absorb[™], in negotiations for their commodity-based stent business.

Market positioning strategies for medical device companies

Excluding competition based solely on price, medical device companies differentiate by offering their customers:

- A broad product portfolio
- Highly-differentiated products

- Value-based service offerings with their products

Large medical device companies have greater capabilities to offer a broad portfolio. Highly-differentiated products offer superior technological innovation or outcomes over competitor products.

With the shift towards value-based care, it is no longer sufficient for manufacturers to rely solely on product features to drive sales. Instead, customers are looking to companies that can demonstrate the value of their products in terms of cost, quality, and outcomes. For instance, St. Jude's Medical has been able to successfully differentiate its heart monitoring system, CardioMEMS™, by demonstrating proven outcomes in reducing heart failure hospital admissions.

Changing customer

With provider consolidation and the increasing shift to employed models, individual physicians are experiencing decreasing influence on medical device purchasing. New stakeholders are having increasing influence on purchasing decisions. They include:

- Clinical department heads
- Chief financial officers and finance departments
- Purchasing departments and group purchasing organizations
- Payers and care managers
- Health systems
- Accountable Care Organizations (ACOs)

In approaching these new customers, manufacturers should tailor their value proposition to each stakeholder's unique incentives and priorities. Take readmissions, for example. Clinical department heads are focused on developing care models that facilitate lower readmissions while maintaining patient satisfaction and quality of care. Hospital finance departments, payers, and purchasing departments are interested in cost-effective products that maximize clinical outcomes. ACOs are interested in solutions that address quality and outcomes metrics around readmissions.

Customers' unmet needs

Customers are looking for service offerings that address incentives and requirements resulting from the ACA, such as solutions to:

- Reduce readmissions
- Improve care coordination post-discharge
- Increase patient satisfaction
- Shift care to lower-cost settings

Hospital partnership opportunities for manufacturers

The ACA's focus on outcomes provides opportunities for medical device manufacturers to act as hospital partners and not just as suppliers. Providers are not equipped for enabling and managing value-based care themselves. They are looking for outside partners that can help them track data and understand a product's impact on outcomes and reduction of ACA penalties.

Taking cost out of process

To overcome the consistent downward pressure on price in the medical device sector, manufacturers should invest in quality outcomes of products or add services to address customers' unmet needs.

Changing the sales approach

Historically, medical device companies have experienced high selling, general and administrative expenses. With increasing pressure to control healthcare costs, companies will need to adjust their sales model. In the current model, large organizations have specialty sales forces for most of the different divisions or product lines. Companies could reduce expenses by creating specialty sales teams for just high-touch products. However, a more sustainable approach would be to structure incentives around outcomes and quality metrics rather than sales.

Challenges in manufacturers owning service solutions

It is challenging for a manufacturer to be the natural provider of service solutions for the following reasons:

- Customers are looking for solutions to track metrics across service areas
- Customer skepticism around data and metrics coming from manufacturers
- Lack of infrastructure to develop outcomes data necessary for the value story
- Significant variability among customer organization design and maturity with respect to value

As a result, third party service providers may be better suited to provide services and can be good partners for manufacturers.

Risk-sharing agreements with payers and providers

Following the pharmaceutical industry's lead, manufacturers are starting to enter risk-sharing partnerships with payers and providers. By guaranteeing their products to hospitals, manufacturers hope to differentiate their products based on clinical value. For example, Novartis entered an outcomes-based contract with Cigna and Aetna for its heart failure drug Entresto™ earlier this year. Similarly, orthopedic implant and stent manufacturers are entering into risk-

sharing programs where the payment is conditional upon the patient not getting readmitted for a defined period of time.

To be successful in the future landscape, manufacturers will need to understand what level of clinical evidence payers and providers are looking for to support value:

- Case studies
- Real-world examples
- Randomized clinical trials

Increasingly, payers will want manufacturers to demonstrate the long-term value of their product and improved patient outcomes for value-based payments. It is highly likely that patient satisfaction and quality of life (QoL) metrics will factor into Medicare device reimbursement in the future. In developing appropriate service solutions, manufacturers can look to QoL metrics used by the National Institute for Health and Care Excellence for evaluating medical devices.

Developing outcomes-based product messaging

With the shift to value-based models of care, manufacturers will need to change their business framework from 'putting in an implant' to caring for the patient. They will need to develop disease- and population-specific value propositions for their customers. For example, Hill-Rom has transitioned their messaging away from features of their beds to how their beds can help reduce hospital-acquired conditions and prevent patient falls.

More IT companies are trying to create architecture

A number of architecture platforms exist which can use medical device data, such as Allscripts, Amazon, IBM Watson, and Apple. However, it can be rather frustrating and difficult for manufacturers to build on these platforms due to a lack of flexibility in altering the platforms. To be competitive in the future environment, manufacturers should focus on device interoperability and data linkage into the patient's EMR.

Data monitoring can help support PPACA initiatives

Data monitoring can help providers reduce readmissions and direct patients to more appropriate care settings through:

- Identification of patients who are at a higher risk of readmission
- Development of better care management standards and protocols
- Earlier disease detection and prevention, leading to downstream cost savings

Appendix

Key Questions Provided to Stimulate Discussion

Systems Procurement

- In what ways do you purchase capital and services similarly/differently?
- What criteria are used and who is included in the decision? Is it a benefit for them to be bundled or a nuisance?
- Does a service component enhance a product in your mind, or is it an ancillary not to be addressed in the selection process?
- Are your goals and financial incentives at all tied to patient outcomes/quality care metrics?
- How do you consider the economic value of an improved patient outcome tied to a product or process as part of the total value of the product you are buying?
- How do you measure the economic value of an adverse event or a readmission?
- How do you account for “soft costs/benefits” like efficiency, risk, staff/patient satisfaction, training, maintenance, and long-term patient interaction as part of your purchasing process?
- What has changed in the idea of involving clinical in the decision process, or in driving projects rooted in expressed clinical need over the last few years?
- What is the weighting of clinical value versus financial savings in your purchase decisions?
- Who is responsible for bundled payments in your organization and are they at the table for product purchases that can potentially affect outcomes?
- Do you measure costs at a product level, or medical condition level? What metrics do you use to track success in your role?
- Are they similar or vastly different to those used in other sectors of the health system?
- How many people are usually involved in a purchase decision? How many functions?

Clinicians and Providers

- Is it better to have a product, procedure, or condition specific outcomes tracking service, or an all-encompassing, more general outcomes tracking service in your mind?
- How do you go about assessing patient condition and adherence post-discharge?

- Do you access utilization data from payers to seek incremental costs associated?
- How often do you discharge to a home health agency or SNF versus leaving follow-up solely to the patient? How do your patients communicate with you on their progress?
- What type of outcomes tracking mechanism is best? Human call service? IVR? Web-based self-reported? Automated web-based?
- How do you translate medication adherence efforts to outcomes tracking tied to devices?

Payers

- In the hospitals/clinics you own/manage, are you using outcomes data and correlating it to products used in procedures to find the most cost and quality effective solutions to healthcare problems?
- How do the incentives you provide healthcare providers for quality trickle down to the procurement level?

Device Manufacturers

- What clinical evidence do you use to prove outcomes today? How is it received?
- How do you propose to use bundled services to make tracking of outcomes more readily available to your customers?