A Holistic Approach to Optimizing the Implantable Device Supply Chain

Uncovering the Hidden Links to Lower Costs, Higher Quality
For many hospitals and healthcare systems, orthopedic and cardiovascular service lines are under increasing scrutiny. Procedures conducted in the operating room (OR) and catheterization laboratory (Cath lab) have long been considered the most profitable for hospitals: they generate a lot of revenue but also considerable expenses. To maximize profitability, service line leaders need to minimize costs and maximize quality, all while understanding the interrelationships between the two. Unfortunately, as professors Robert Kaplan and Michael Porter write in their article “The Big Idea: How to Solve the Cost Crisis in Health Care,” “there is almost a complete lack of understanding of how much it costs to deliver patient care, much less how those costs compare with the outcomes achieved.”

When it comes to procedures involving implantable devices, the majority of cost containment strategies have focused on reducing the price of implants and improving the efficiency of the surgical process. These two activities have been conducted relatively independently from one another, by supply chain and clinical leaders, respectively. Meanwhile, efforts to improve processes and data related to the procurement and consumption of implantable devices have been relatively ignored, despite the fact that manual processes and lack of visibility to product demand and consumption contribute more than $5 billion in waste each year in the U.S. alone.

The price paid for implantable devices can contribute significantly to the cost of healthcare, at times accounting for more than half of the amount reimbursed for some procedures. But cost containment efforts that focus a disproportionate amount of attention on price can divert efforts to obtain information needed to achieve a more value-based healthcare system – understanding the role products play in delivering better quality care at a more affordable cost. Further, efficiency improvement efforts that are limited to surgical processes and do not include operational processes limit opportunities for future cost reduction. As Gary Botimer, MD, chairman of the department of orthopedic surgery at Loma Linda University Medical Center in California, told HealthLeaders magazine: “The best way for hospitals to reduce costs is to follow what all other successful industries have done to provide

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**Implantable Devices: Dollars and Sense**

- Manual processes and lack of visibility to product demand and consumption contribute more than $5 billion in waste each year in the U.S. alone.
- Demand for implantable devices will continue to increase from 7 to 9 percent annually.
- In 2011, U.S. insurers paid $50 billion for implantable devices and another $75 billion to providers for implanting the devices, with half of that spend for orthopedics, the fastest growing segment.
- The percentage of implant procedure costs attributed to peripheral products, e.g., cutting guides, disposable instruments, and biologics have doubled in recent years.
- SG&A costs for medical device manufacturers are on average 36 percent of total revenue.
- A 2010 study found that hospitals spend more than $36 million per year on wasted orthopedic hip and knee implants.

Read this white paper to learn more about the sources of this data, the underlying reasons for the costs, and the possible solutions to these challenges.
products at affordable rates—elimination of unnecessary expenses in their processes.”

This white paper will explore the often hidden costs associated with highly manual, disjointed and duplicative processes in the implantable device supply chain. It will also consider the interrelationships between those activities and how improvements in the supply chain can have corresponding and positive impacts on the clinical and financial aspects of healthcare.

Many of the challenges outlined below have been sources of conflict and mistrust among the various parties involved in healthcare: surgeons, other clinicians, healthcare administrators (including finance, supply chain, and value analysis leaders) and suppliers. This paper will demonstrate how greater collaboration and data sharing among the key players can improve quality in process, procedures and patient care.

We will begin with a discussion of the nature and size of the problem and shed light on the realities of rising demand in the face of falling reimbursements and widespread variation in the cost of procedures and implants.

The Problem in Real Dollars

In 2011, insurers in the U.S. market paid $50 billion for implantable devices and another $75 billion to providers for implanting the devices. Roughly half of that spend is attributed to orthopedic devices, which are the fastest growing implant segment due to an aging population and advances in medical technology and surgical procedures. Many industry studies predict the demand for implantable devices will continue to increase from 7 to 9 percent annually, which could mean the amount spent on the devices alone will surpass what is currently spent for related surgical services in less than five years. Meanwhile, reimbursement rates continue to decline.

Under the Affordable Care Act, hospitals are seeing their Medicare reimbursements cut by an increasing amount: up to a total of 2 percent in 2017 (the rate cut was 1.25 percent in 2013). Some hospitals will recoup a portion or even all of that money, possibly even gain a bit more, by improving clinical processes, patient satisfaction and outcomes, while others will see an even greater drop due to failures in those areas. Meanwhile, reimbursement rates for surgical procedures have declined even further. In December 2012, the American Association of Orthopaedic Surgeons published a retrospective analysis of the inflation-adjusted trends in Medicare reimbursements for orthopedic surgeons, showing the “negative gap between what orthopedic surgeons have to pay in operational and practice costs and what they receive in reimbursements has progressively widened over the 18-year period studied” with reimbursement dropping as much as 68 percent in real dollars in 1992 (See Figure 1). While physicians may be feeling more of the pinch now, the financial future of hospitals and surgeons will be increasingly interdependent, with more surgeons either employed or involved in shared risk programs with hospitals, such as co-management, gainsharing and bundled “episode-of-care” payments around orthopedic and cardiovascular procedures.

In light of increasing demand and declining reimbursement, hospital leaders have pursued a variety of strategies to reduce the price paid for implants, from hard-hitting price negotiations to purchasing collaboratives and product standardization. There’s good reason: According to a recent study, “implant and device costs associated with procedures are generally eating up at least one-third of the reimbursements.” But there is debate about whether average selling prices are going up or down. A 2013 study that looked at the average selling price for implantable devices from 2007 to 2011 across a range of categories, including cardiovascular and orthopedic, reported a “decline in inflation-adjusted prices… from 17 to 34 percent depending on the device category.” Specifically, the study...
reported a 17 percent drop for artificial knees, 23 percent for artificial hips and 34 percent for drug eluting stents. But another study published in the Journal of Bone and Joint Surgery in September 2012 cites data that shows the average selling prices of hip and knee implants have increased more than 100 percent over the past decade.

How can the data in these two reports be so far apart? Stan Mendenhall, publisher of Orthopedic News Network and the source of the data referenced in the second study, provided some additional context and insight into the source of rising costs in a paper reviewing the 2013 study. He writes: “Between 2007 and 2011, I calculated an increase in overall knee implant costs of 6% and a decrease in hip implant costs of 6%. This had followed a decade of continual price increases between 1995 and 2006.” Mendenhall says prices have come down in certain implant categories as the result of “more aggressive negotiations” but he adds, “the overall costs for the devices related to the surgery has not declined as much as claimed because of peripheral products that remain ‘under the radar.’”

The peripheral products he references are things like: “cutting guides for knees which add about $1,000 for each case, antibiotic bone cement instead of regular cement, pin guides for surgical navigation systems, disposable instruments, and biologics…. These ‘implant related’ costs have increased from about 3% of costs several years ago to 6% of implant costs in 2012.” Peripheral products have not typically been the focus of hospital cost containment discussions. As a result, lack of complete visibility into what is brought into the procedural suite and actually consumed makes it difficult for hospitals to fully calculate expenses.

One thing is clear: there is significant variation in the price paid for implantable devices, which in turn can contribute to wide deviations in the amount hospitals charge for the same procedures. The variation in hospital costs and inability of healthcare providers to tell prospective patients how much they will likely be charged has garnered increasing public scrutiny and negative news coverage as part of the national healthcare reform debate. The study referenced above and published in the Journal of Bone and Joint Surgery in September 2012 reported that “there are substantial variations in total hip replacement and total knee replacement implant costs within and across hospitals after controlling for patient diagnoses and comorbidities. This variation is responsible for the majority of variation in the overall cost of total hip and knee replacement surgery.”

Here are some excerpts from that report:

“There is almost a complete lack of understanding of how much it costs to deliver patient care, must less how those costs compare with the outcomes achieved.”
— Robert Kaplan and Michael Porter
“The Big Idea: How to Solve the Cost Crisis in Health Care”

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- The cost of the device represented a large share of the total cost of each procedure, ranging from 13 to 87 percent for total knee replacement and from 15 to 87 percent for total hip replacement.
- Implant costs varied by a factor of almost seven, from $1,797 to $12,093 for total knee replacement and by a factor of more than five, from $2,392 to $12,651, for total hip replacement (in 2008 U.S. dollars).
- Total procedure costs varied by a factor of more than three for total knee replacement and for total hip replacement.

Additional research points to a relatively ignored component of implant pricing: significantly high SG&A (selling, general and administrative costs) incurred by manufacturers. According to Supply Chain Insights research, SG&A costs for medical device manufacturers are on average 36 percent of total revenue. Gene Kirtser, president and CEO of ROi, the supply chain company for St. Louis-based Mercy, the sixth largest Catholic health care system in the U.S., told HealthLeaders magazine in October 2013 that “providers now face device costs that represent nearly 50% for sales and general administration, while only a small percentage, about 6%, accounts for research and development designed to improve devices.” Like many healthcare executives, his
hope is that better comparative effectiveness research will help guide product selection based on evidence as to which products deliver the best patient care at the best price.

Mercy has worked with the U.S. FDA MDEpiNet initiative to understand what kind of data and technology infrastructure is necessary to effectively evaluate the impact that specific clinical product attributes have on patient care, (e.g., do drug eluting stents, or the different drugs used in various brands, have a better outcome than bare metal stents). In the process, Mercy has also discovered that better data collection at the point of care can improve real-time inventory visibility and reduce time spent on periodic inventory counts. Better data can also help suppliers understand which products, or product attributes, work best for different patients and use that information to guide their R&D and sales efforts.

**What increases operational costs for providers and suppliers?**

- Manual processes
- Lack of visibility into product demand, consumption and inventory
- Low inventory turns
- Excess and expired inventory
- Long procedure to payment cycle times

**The Hidden Costs of the Implantable Device Supply Chain**

The factors contributing to higher SG&A costs for suppliers often increase operational costs for providers as well: manual processes, lack of visibility into product demand, consumption and inventory, low inventory turns, excess and expired inventory, and long procedure to payment cycle times. Addressing many of these factors can also help shed light on the kind of data hospitals and healthcare providers need to drive more evidence-based decisions.

Following are some of the biggest challenges facing the implantable device supply chain. Most if not all of the issues outlined also have close causal relationships impacting the most important elements necessary to improve financial and clinical performance: automation, visibility, evidence and trust. For example, manual processes reduce visibility into when cases are scheduled, what is needed for a case, what is actually brought into the surgical suite and what is consumed. These can create a myriad of problems, including inaccurate charge capture and billing, higher labor costs, and off-contract purchasing that can erode trust among the parties.

**Before the Case**

- The selection and use of implantable devices, especially in the orthopedic world, is a source of tension between hospital administrators, manufacturers and physicians. Often, administrators blame vendors for convincing surgeons to use more expensive products that may not result in corresponding improvements in patient care, while surgeons contend some administrators are interfering with their ability to determine what is best for their patients.
- Late notification about when a case is scheduled or what changes are made makes it difficult for both providers and suppliers to efficiently prepare for the procedure. Surgeons generally schedule elective procedures weeks in advance, but suppliers and hospitals may not be notified about cases or changes to the schedule until days, or even hours, before. This can increase the burden on clinical staff, logistics costs for rush orders, and risks related to the wrong product being delivered or used in a case.
- Although the technology exists, (e.g., digital templating) to help determine which products will be needed for non-emergent cases, vendor representatives may or may not have this information in advance and bring in more product than is actually necessary, which can increase waste during the case (see During the Case section).
- Nurses often prepare for cases using outdated physician preference cards and have to spend time restocking a large portion of the products (while not always recording that those items have been returned to inventory).

**During the Case**

- Supply chain processes during the procedure, which occur in a highly complex and critical environment, are typically handled in a manual, disjointed and duplicative manner. For example, orthopedic implants are usually carried by hand into the OR by the vendor representative, and their consumption is documented manually by multiple parties (e.g., the circulating nurse and the vendor representative) for various purposes (e.g., the implant log, charge capture, purchase orders, etc.) (See Figure 2). Even hospitals...
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Clinical Supply Documentation at the Point of Care: What Causes the Problems?

Supply Documentation is a Disjointed Process Involving Variety of Staff, Tasks, and Systems

Survey conducted with OR nurses attending the 2011 AORN Conference
N = 326

Fig. 2

ranked as some of the most technologically sophisticated still do the majority of clinical supply documentation at the point of care manually (See Figure 3).

- Manual data capture often leads to errors around which products were used in patient care. This can create problems downstream (e.g., billing, inventory management, recalls, etc.)
- Lack of interoperability makes it difficult to share data across clinical, financial and supply chain systems, requiring the same data to be captured multiple times.
- Lack of product data standards and provider use of auto identification and data collection (AIDC) technology (e.g., barcodes and scanning technology) makes it difficult to automate processes and report on products purchased, stored and consumed in the delivery of patient care. The U.S. FDA UDI rule, which mandates that manufacturers assign and label their products with unique device identifiers and display that information in both human and machine readable formats, (e.g., an AIDC carrier such as a barcode or RFID, etc.) will help, but many providers lack the technology and/or processes to capture the AIDC information.
- Vendor representatives who bring in off-contract products that are used without hospital knowledge until after the procedure can increase costs for the provider or manufacturer (depending on which party ends up absorbing the expense). This also perpetuates the mistrust that is blamed for a lack of provider-supplier collaboration required to address many of the challenges discussed in this paper.
- Costs associated with wasted products (e.g., dropped and damaged; opened but not used and not usable for another patient) are often overlooked and underestimated expense. A 2010 study found that hospitals spend more than $36 million per year on wasted orthopedic hip and knee arthroplasty implants. In the study, nearly three-fourths of the occurrences were caused by surgeons or operating staff, with vendor representatives responsible for the balance. Manual documentation during the course of a procedure often makes it difficult to determine responsibility after the fact and can result in confusion and disagreements over who ultimately bears the costs for those products.

After the Case

- Circulating nurses and vendor representatives compare their individual documentation of which products were actually consumed during the case. Manual data entry often leads to errors and/or discrepancies in their respective reports and higher labor costs due to the time required to reconcile the differences.
Supply chain transactions, (e.g., purchase orders and invoices) around implantable devices are usually handed manually, due to the need to capture additional data (e.g., lot number, expiration date, patient and procedure information), which can delay purchase orders to suppliers. Discrepancies between purchase orders and invoices also require human intervention, resulting in additional labor costs and a reduction in the ability of providers to take advantage of early pay discounts.

Use of construct or other complex pricing structures designed to help providers control costs can mask details about all of the various products, (e.g., individual screws and plates) that were used in a given case. This level of detail is needed for recall management, comparative effectiveness research, and demand planning and replenishment.

In order to reduce their costs, many hospitals and healthcare systems have pushed responsibility for inventory management to their suppliers, resulting in a myriad of inventory models. Based on GHX research, manufacturers are currently managing many different types of inventory:

- Owned and stocked in hospitals (40 percent)
- Consigned and stocked in hospitals (25 percent)
- Trunk/bill-only stock held by sales reps (28 percent)
- Other field inventory, excluding distributor (14 percent)

This makes it more difficult to accurately account for supply levels, location, ownership and usage, which further complicates billing and replenishment. Vendor representatives also spend a considerable amount of time managing inventory on behalf of customers.

Without demand signals, it is hard for hospitals and suppliers to accurately manage inventory levels, resulting in the same facilities experiencing simultaneous stock-outs and excess product that expires before it can be used.

Lack of detailed consumption data also makes it difficult to compare costs and quality by physician and determine the root causes for the differences. Variation in costs can result from a wide range of reasons, some of which are product related, such as a physician who prefers a more expensive product than his or her peers; an orthopedic surgeon who uses more cement in a total knee replacement; even a doctor that frequently opens more implant packages than are actually used, rendering some of them as wasted. Without good data on costs and quality, it is hard to have meaningful discussions with surgeons. Further, when data is not available or not shared, decisions can be made based on a narrow frame of reference. For example, financial leaders may only base their decisions on the price paid for a product and not know if a more expensive product could reduce readmissions or infection.

"The best way for hospitals to reduce costs is to follow what all other successful industries have done to provide products at affordable rates elimination of unnecessary expenses in their processes." — Gary Botimer, MD, Chair, Department of Orthopedic Surgery, Loma Linda University Medical Center
rates, thereby improving profitability in the long run. Doctors, meanwhile, may not see when a less expensive product or clinical process can achieve similar or even better outcomes. None of these broader perspectives are achievable without good data on total costs and clinical outcomes.

Speaking at the GHX Healthcare Supply Chain Summit in 2013, Vanderbilt* chief supply chain officer Teresa Dail, RN, BSN, called for more openness and collaboration among the various parties involved in decision making. “We all share a desire to utilize products that provide the very best patient outcomes,” Dail said. “But in the absence of good evidence, product selection is often based on preference and relationships. By working together, clinicians, supply chain professionals, healthcare administrators, and manufacturers can gather and share the kind of information needed to make decisions that result in better outcomes, improved operational efficiencies and lower costs for all.”

Tom Faciszewski, MD, an orthopedic and spine surgeon with the Marshfield Clinic and Ministry Healthcare, joined Dail on stage, adding, “Many supply chain strategies are limited to attaining the best price for a given product. However, what we need is a fully functional strategic supply chain program involving cross functional, multidisciplinary teams with specific and written team charges. Supply chain’s role is to propose and facilitate the entire supply chain strategy (right product, right price, right time, right physician, right patient) with all the efficiency possible and all the waste removed.”

**Recommendations**

The following are steps that hospitals and healthcare systems can take to address many of the challenges outlined in this paper and to achieve the clinical, financial and supply chain objectives so clearly articulated above by Dr. Faciszewski and Teresa Dail.

- Expand efficiency improvement efforts beyond surgical processes to include operational activities related to the implantable device delivery, procurement, usage documentation, replenishment and payment.
- Work with physicians to provide more advance notification of scheduled procedures to improve demand signals for both hospitals and suppliers.
- Automate processes to improve both the efficiency and quality of data around product usage in the OR and Cath Lab.
- Communicate the longer term value of process automation/change to nurses, e.g., better data capture reduces time spent reconciling cases after the fact, reporting on inventory levels.
- Ensure data can be collected and shared with multiple systems for multiple purposes, e.g., the implant log, charge capture, electronic medical record documentation, purchase orders and billing, etc.
- Capture data on all products used in patient care, including peripheral products, not just the implantable device itself.
- Create dashboards that allow you to do comparative analysis of procedural costs and quality, by physician and product usage.
- Analyze data collected to understand total costs for procedures, by patient, by physician, by facility and the relationship to the clinical outcomes achieved.

*Both Mercy and Vanderbilt are among the healthcare systems participating in a collaborative effort with GHX and major orthopedic and cardiovascular implant manufacturers to automate the implantable device supply chain to eliminate much of the waste described in this white paper and to increase visibility and data sharing among the parties involved in specific procedures and transactions. Automation in pilot studies has already demonstrated significant reductions in labor and cycle times and the ability to capture and transmit data electronically between trading partners. Further product development and broader technology adoption will bring the industry closer to many of the other imperatives of a value-based healthcare system discussed herein, lowering costs and improving quality for all.
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About the Author: As executive director for industry relations with GHX, Karen Conway works internationally with standards bodies, government agencies, industry analysts, academic researchers, trade associations, and suppliers and providers to optimize clinical and business performance through supply chain excellence.