Shared Pain, Shared Gain
Creating a more collaborative supply chain for implantable devices

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Why Collaborate? Why Implantables?

Healthcare demands a new business model

Implantable devices are in your customers’ strategic survival plan

Orthopedic device manufacturers play a role in both clinical and supply chain processes

Inefficiencies and lack of visibility cost providers and suppliers
The Supply Chain is a System

…and we are all in the same boat
An Unsustainable Path

At historic growth rates, the Congressional Budget Office in 2007 projected that healthcare would consume 98% of GDP by 2082.

Even with the recent slowdown in healthcare spending, the rate of growth still outpaces overall inflation.

Source: Modeling Behavior (for illustrative purposes only)
The future is unclear, but some things are certain

*Healthcare providers must survive on declining reimbursement*

*Healthcare providers will be reimbursed on value, not volume*

The Bottom Line: Your customers need to better understand and control what drives Quality AND Cost
Turning Healthcare on its Head

Providers and suppliers need to change their business models

Providers need to make money by keeping people OUT of the hospital

Suppliers need to lower costs to serve, help create value

BOTTOM LINE: Both providers and suppliers need to work together to improve operational performance and increase visibility to key data on cost and quality drivers
Focus on Implantables

Implantable devices typically represent:
- ~30% of total hospital supply spend
- 50-80% of total costs for some procedures

Product standardization a primary strategy
- Improves contracting opportunities
- Eliminates variation, improves quality

Bottom Line: Customers are focused on trying to buy products that help drive the best outcomes from manufacturers who will negotiate the best price.

Eventually, customers will look for manufacturers that can lower total cost of ownership and help create value.
The Cost + Quality Equation

VALUE = COST + QUALITY

- What role do products play in lowering total cost, while improving quality?
- Can a more expensive product reduce hospital acquired infections or readmissions?
- How is value measured, by whom, for whom, and over what time period?

BOTTOM LINE: Data will be required on cost and quality by product, procedure, physician, facility, over specific time periods, and for individual patients and specific populations.
Total Cost of Ownership

Total cost of ownership is a philosophy for really understanding all supply chain related costs of doing business with a particular supplier for a particular good or service.

- World Class Supply Management

Price Paid for a Product or Service

Acquisition Costs
Logistics
Inventory Management and Risk
Reimbursement
Clinician Time Spent on Supply Chain
Cost to Serve
Contract Compliance
## Healthcare: An Expensive Customer to Serve

SG&A costs much higher in healthcare than other industries

<table>
<thead>
<tr>
<th></th>
<th>Pharma</th>
<th>Biotech</th>
<th>Generic</th>
<th>Medical Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segment Mean</td>
<td>33%</td>
<td>29.8%</td>
<td>23.9%</td>
<td>32.7%</td>
</tr>
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### Three-Year Weighted SG&A Expense As a % of Revenue

Gartner Cross-Industry Supply Chain Top 25
(CP, High Tech, A&D, Auto, Life Sciences, Industrial)

| Segment Mean | 17.51% |
“Hospitals need to understand what drives our costs and often we don’t. Manufacturers, on the other hand, have industrial engineers and performance improvement staff who use scientific formulas instead of anecdotal data to manage their supply chains.”

Nancy LeMaster, VP, Supply Chain
BJC HealthCare
Lack of trust between the various industry partners in the healthcare supply chain has been a hindrance to information sharing and collaboration. The result is significant cost and inefficiencies.

- Gartner Research
Trust-related Challenges

- Items not covered under Contract or Construct Pricing
- Price Synchronization/Visibility
- Commercial – Operations Alignment
- Credibility of Clinical Studies
- Role of the Vendor Representative
- Hospital-Physician-Vendor Relationships
- Product Utilization/Value Analysis
- Customer-focused R&D
- Multiple Inventory Types
- Demand Planning/Inventory Management
### Hospitals’ Supply Chain Priorities

<table>
<thead>
<tr>
<th>Objective</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimize prices by standardizing products and creating physician / hospital alignment</td>
<td>18%</td>
</tr>
<tr>
<td>Track usage, location and maintenance of assets</td>
<td>15%</td>
</tr>
<tr>
<td>Create <strong>strategic partnerships with suppliers</strong> and provide <strong>real-time visibility into demand and consumption</strong></td>
<td>18%</td>
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<tr>
<td>Develop a recruitment strategy to ensure right talent is in place</td>
<td>8%</td>
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<tr>
<td>Track products until point of use by integrating patient records systems</td>
<td>7%</td>
</tr>
<tr>
<td>End to end electronic contracting / procurement and invoicing</td>
<td>7%</td>
</tr>
<tr>
<td>Implement a supply chain performance management and metrics program</td>
<td>8%</td>
</tr>
<tr>
<td>Enhance organizational commitment to environmental protection</td>
<td>7%</td>
</tr>
<tr>
<td>Centralize distribution activities &amp; optimize warehouse operations</td>
<td>12%</td>
</tr>
<tr>
<td>Most Successful</td>
<td></td>
</tr>
</tbody>
</table>

**Main Supply Chain Objectives Today**

13. What are your company’s main supply chain objectives today?

14. List those mentioned in Q13. Which one is your company most successful at today?

*Source: Gartner AMR Supply Chain, Healthcare Providers*
The Collaborative Healthcare Value Continuum

- **High Quality**
  - Focus on products that deliver the best outcomes at the best price
  - Negotiate Best Price

- **Low Cost**
  - Increase internal collaboration for better efficiency and visibility
  - Internal and external patient-centered collaboration

- **Implantable Supply Chain Focus**
  - Degree of Collaboration/Data Sharing

- **Patient-Centered**
Better Demand Visibility, Better Profitability

- Improved Supply Chain Costs
- Improved Manufacturing Productivity
- Lower Inventory levels
- Better Perfect Order Performance
- Enhanced Success in New Product Launches (time to value)

Source: 2008 AMR Healthcare Study
A Shared Problem

PPI supply chain is $5B+ annual problem – shared equally by providers and suppliers

$3,000
$2,500
$2,000
$1,500
$1,000
$500
$

$2,625 M
Revenue Leakage

$2,725 M
Low-Value Sales Tasks
Loss & Expiration
Low Inventory Turns
Back-Office Labor

Provider
Manufacturer

Sources: PNC Healthcare; GHX Quantitative Research Study (Aug 2010; n=136 & n=25)
A Shared Opportunity

PPI supply chain is $5B+ annual problem – shared equally by providers and suppliers

Automation, process change and better data visibility required to realize shared savings.

Sources: PNC Healthcare; GHX Quantitative Research Study (Aug 2010; n=136 & n=25)
Opportunity Areas: Providers

For providers, improving billing and inventory management are most important

Regarding implantables, which of the following are Most Important to you? (Rank 1-5)

- Increasing accuracy of patient billing
- Reducing hospital based inventory
- Reducing losses due to expired products
- Reducing losses due to wasted product
- Increasing procedure suite set-up efficiency
- Reducing out-of-stocks
- Reducing expedited deliveries
- Reducing invoice payment disputes
- Increasing inventory turns
- Reducing clinicians product usage reconciliation time
- Reducing losses due to lost product
- Improved regulatory compliance (e.g. HIPAA)

Sources: GHX Quantitative Research Study (Aug 2010; n=136 & n=25)
For manufacturers, improving inventory management and regulatory compliance are most important

Regarding implantables, which of the following are Most Important to you? (Rank 1-5)

- Increasing inventory turns
- Improving regulatory compliance (HIPAA, FDA, etc.)
- Reducing in field inventory management costs
- Reducing out-of-stocks
- Reducing losses due to expired products
- Increasing payment cycle time from date of procedure
- Reducing expedited deliveries
- Reducing losses due to product obsolescence
- Reducing losses from lost product
- Reducing invoice disputes
- Reducing hospital based inventory
- Reducing product usage reconciliation time

Sources: GHX Quantitative Research Study (Aug 2010; n=136 & n=25)
Many Players, Many Manual Processes

Roles in the OR

- Surgeon - Performs surgery
- Assistant - Physician’s assistant aids surgeon during the procedure
- Scrub tech, a.k.a. Sterile Tech - In charge of handing items and supplies to the surgeon in the sterile field
- Vendor Rep - Provides consignment implants, advises the surgeon and documents what is used for the supplier
- Circulator, a.k.a. Circulating Nurse - Documents what is used in surgery, brings in items from outside the OR, passes items into the sterile field
Supply Documentation in the OR Still Highly Manual

Even with electronic implant recording capability, most nurses use paper and stickers for recording usage during procedure.

Only 10% of entry is based on barcodes or RFID.

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

Providers and Manufacturers still use separate, manual processes to collect usage data that must match

Example: Hospital Version

Example: Manufacturer Version
Manual Processes Create Costly Delays

- One provider had 8 touch-points before the PO was released

- Cycle Time Frames (based on GHX provider pilot baselines):
  - Procedure Date to PO Release Date: 4.7 days AVG/164 days MAX
  - Procedure Date to Invoice Receipt/Release Date: 14.5 days AVG/165 days MAX
  - Invoice Receipt/Release Date to Invoice Payment Date: 13.7 days AVG/162 days MAX
  - Procedure Date to Invoice Payment Date: 29.3 AVG and 190 days MAX

For an electronic Bill Only or Bill/Replace, 
>75% of the time we will be able to release the PO:

- 14% Same Day
- 29% Within 24 hours
- 43% Within 48 hours
- 14% Same Week
- 0% Can't Guarantee Timing

Process improvements are critical and can be supported by automation
Interest in New Usage Capture & Reporting System

...if it could reduce reporting/time:

- Very High: 22%
- High: 26%
- Moderate: 18%
- Low: 3%
- Very Low: 3%
- No Response: 6%

Survey conducted with OR nurses attending the 2011 AORN Conference
N = 326
What is the likelihood that your organization would adopt the use of a manufacturer-specific solution for point-of-use capture? For inventory tracking?

Strong support for industry-wide model vs. one-to-one
A Word about UDI

Idea dates back to *To Err is Human* report

- Led to FDA Barcode Medication Rule
  - Based on existing NDC standard
- CDRH realized lack of similar identifier for medical devices
- UDI included in the FDAAA of 2007
- Proposed rule imminent

The Secretary shall promulgate regulations establishing a **unique device identification system for medical devices requiring the label of devices to bear a unique identifier**, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately **identify the device through distribution and use**, and may include information on the lot or serial number.
After the Proposed Final Rule is Issued

1. 90 day comment period
2. Possible public meetings
3. Review and analysis of comments
4. Response to comments
5. Development of final rule (with responses)
6. Then complete review again
7. And finally publication of the final rule

~ 12-18 months

Timeline for Compliance

Based on premarket risk class:
- class III – 12 months after final rule (implants)
- class II – 36 months after final rule (equipment)
- class I – 60 months after final rule (disposables)
A Three-Part System/A 4-Step Process

1. Allocate the code (GS1, HIBCC) to covered products at each UOM
2. Label the products with human and machine readable code or DPM if necessary
3. Populate and maintain the UDI Database(s)

UDI (2 parts)
- Device ID (Static)
  - plus (if applicable)
- Production ID, e.g., lot, serial #, expiry (Dynamic)
- Human readable label

UDI Database
- Contains static data elements
  - Device ID
  - ......
  - ......
- Device ID is the key

AIDC
- Machine readable carrier
  - Linear barcode
  - 2-D barcode
  - RFID
  - Other
UDI Designed to Provide Global Visibility

- Medical device recalls
- Adverse event reporting
- Track and trace
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Medical errors (e.g., bedside scanning)
- Device information for patients and clinicians
- Product and epidemiological databases
- Comparative effectiveness
- Documenting device use in EHR, HIS, and claims data
- Sentinel Initiative and other postmarket surveillance activities
Key Takeaways

• Healthcare demands a new way of doing business
• We share the same problems; we can share the same solutions
• Automation and supply data capture at the point of use are key
• Standards and standardized processes improve efficiencies and visibility
• Data sharing and trust go together
• Objectives and processes must be aligned
  • Internally and across trading partners
• Collaboration can improve clinical, financial and operational performance for all

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