WHITE PAPER

Current Issues in Healthcare Administration

“How Can Hospitals Significantly Reduce the Cost of Purchasing Orthopedic Medical Devices?”

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Introduction

Healthcare in the United States, while ultra-advanced and globally recognized as “first in it’s class”, is mired in excessive expense and unsustainable costs. In fact, when compared to twelve other countries in a recent report on International Health Policy, the United States was ranked the highest in cost. That same report identified that in 2009 the U.S. healthcare spending was 17.4% of it’s Gross Domestic Product (Squires, David A., May 2012). It is quite interesting to note that in 2000, our healthcare spending was at 13.2% of the GDP, and though it was predicted that we would get to the aforementioned 17% of the GDP, that prediction was for 2011 (Stanton, Mark W., 2002, p.1)! Arriving at that number two years early is clear evidence, and further demonstrates our crisis.

Statement of the Problem

Our healthcare system has been the subject of heated debate not only in the last two Presidential Administrations, but also dates back decades to the early 1970s. Based upon a great deal of research and prompting by the health policy gurus of the day, the Nixon administration not only declared our healthcare in a state of crisis, but the administration also pushed for a system overhaul and more stringent government regulation. In 1970, the U.S. spent $75 billion on healthcare, $10 billion of that was for Medicare and Medicaid. Fifteen years later, in 1985 the U.S. exceeded $400 billion, with nearly $100 billion on Medicare and Medicaid (Etheredge, Lynn, 1986). Currently, with our healthcare expenditures into the trillions, actually $1.3 trillion in 2000 (Stanton, Mark W., 2002), the debate continues on whether or not our government should be more in control of healthcare. We said hello and goodbye to $2.6 trillion in healthcare spending in 2010 and 18% of the GDP, which, once again, was earlier than our government’s
prediction. It appears that the growth of our expenditures for healthcare is exceeding our GDP growth by 2.5% (Stanton, Mark W., 2002, p.1). It is, therefore, both responsible and valuable to pursue any area of cost, such as medical devices, in order to discover viable methods of reduction, and to test those methods without delay!

**Purpose of the Study**

With the advent of the Patient Protection and Affordable Care Act (PPACA), or “Obama care”, in March of 2010, programs such as Value Based Purchasing (VBP) and Bundled Payments for Care Improvement Initiatives are being implemented and will force accountability. VBP will help to change the old pay-for-reporting program to a true pay-for-performance program. There will be a “score card” issued to hospitals for performance in identified and predetermined areas of concentration, with specific criteria designed for improvement. The Centers for Medicare and Medicaid Services (CMS) are mandating that hospitals and physicians work closer together to become problem solvers and to collaborate on patient care. In lieu of these recent changes in our healthcare system, it will become increasingly more advantageous for hospitals and physicians to work together as a team. With respect to VBP, we have already begun year two, with a base operating payment reduction of 1.25% (see Table 1, red highlights). CMS has already begun withholding a predetermined percentage of the base DRG reimbursements that are paid out to hospitals across the country (Nelson, Bryn, 2009). A simple example would look something like this: a hospital that would normally be receiving $50 million from CMS for Medicare reimbursements in year one would have a withhold deduction of $500,000 (1.0%). In year two on that same $50 million in reimbursements, $625,000 (1.25%) would be withheld. Of these withhold amounts for reimbursements, CMS will
give a percentage of VBP payment to that hospital as an “incentive”. This payment will be adjusted annually based upon the performance score from the year prior. So if the % of VBP incentive earned per scorecard is 80%, the hospital receives an incentive payment of $400,000, an actual loss of $100,000 (Nelson, Bryn, 2009, p.6).

Table 1

**Important Dates for Value-based Purchasing**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Start Date</th>
<th>Targeted Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2013</td>
<td>October 1, 2012</td>
<td>Base operating payments reduced by 1.0 %</td>
</tr>
<tr>
<td>FY 2014</td>
<td>October 1, 2013</td>
<td>1.25 %</td>
</tr>
<tr>
<td>FY 2015</td>
<td>October 1, 2014</td>
<td>1.5 %</td>
</tr>
<tr>
<td>FY 2016</td>
<td>October 1, 2015</td>
<td>1.75 %</td>
</tr>
<tr>
<td>FY 2017</td>
<td>October 1, 2016</td>
<td>2.0 %</td>
</tr>
</tbody>
</table>


In the past, the fee-for-service (FFS) arrangement for billing and reimbursement simply encouraged volume. Quality, cost accountability, and outcomes were not the focus, and so historically there has been no pressing reason for hospitals and physicians to “team up” on patient care. In fact, arguably, this has done more to encourage an adversarial relationship between the two, rather than fostering partnerships (Mitchell, Case Study, 2013; Weismann, Study, October 2012). That being said, a major opportunity and potential advantage in building these partnerships is best stated in an old saying, “timing is everything.” The time is right to identify areas of care and/or cost that can be significantly reduced with hospitals and physicians working *together* as a team to do so.
Medical Device History

Among the many areas of concentration for cost reduction and spending restraint, the subject of Implantable Medical Devices (IMD) is one that even our Department of Justice has targeted for closer investigation (D.O.J., November 2007; Study Eval., October 2011). In 1976, federal regulation of medical devices began with the Medical Device Amendments passage within the FDA. These amendments organized medical devices into three classes based upon potential risk to patients, which still exist today. Since 1976, the FDA has developed six centers of responsibility, and the FDA center responsible for regulation of medical devices (pre and post-market) is the Center for Devices and Radiological Health, or the CDRH. All manufacturing, repackaging, re-labeling and importing of medical devices in the U.S. falls under the responsibility of the CDRH. General surgical instruments, such as scalpels, retractors, blades and drills are examples of Class I devices, and are viewed as reasonably safe and effective, or low risk, and require only “general controls”. Class II devices are viewed as presenting more risk to the safety and effectiveness on patients, and therefore require “specialty controls”, such as 510K clearance before they can be marketed in the U.S. Examples of Class II devices include screws, plates, nails, joint replacement components, and spinal fixation devices. Interbody spacers and synthetic void fillers are also included in Class II devices (Buch, Barbara MD, 2007). This research deals specifically with Class II devices for orthopedic joint reconstruction and spine procedures. Figure 1 not only serves to illustrate the trend in rising prices specifically of class II devices, but it also serves to emphasize how the timing is right for both hospitals and physicians (surgeons) to work together, and possibly force more price accountability with the device manufacturers. If
you look closely, you can also conclude that with the downward trend in reimbursements, how historically surgeons and hospitals have been adversaries. However, the continuing problem of rising prices for medical devices, and the continual decrease of reimbursements to both hospitals and physicians (surgeons) reveals a common enemy. The hardship of accountability for cost is clearly affecting hospitals and physicians. So where is the accountability for the medical device manufacturers? If provider hospitals and surgeon providers can work more as a team going forward on collaborative patient care, perhaps it will shed more light (and pressure) on their perceived common nemesis, and the hardship of pricing accountability can be shared by device manufacturers as well.

This figure has been used in numerous presentations by both surgeon and hospital associations to illustrate a “disturbing trend” (source below).

Figure 1

*Price & Reimbursement Comparison: Implants, Surgeons, Hospitals 1994-2006*

Orthopedic Medical Devices: Joint Reconstruction. Medical devices for joint reconstruction or replacement fall into three main segments, Total Knee Arthroplasty (TKA), Total Hip Arthroplasty (THA), and Extremities. In 2012, knee arthroplasty accounted for nearly half of the annual sales, and knees and hips combined were 91% of the joint replacement sales for the year (see Figure 2). There has been a steady rise in the cost of these procedures in the U.S. since the mid 1990s (Rosenthal, Elisabeth, 2013; Medicare Payment, FY 2007). There are two key indicators within the demographics of not only the U.S., but the

Figure 2

*U.S. Joint Replacement Sales by Segment, 2012.*

Worldwide population as well, that confirm the continuance of this trend and the need for fiscal intervention. The indicators are the aging population, which our government supposedly has been planning for over the last four decades, and the rising incidence of obesity. The growth of the aging sector will mean an increase in the number of surgeries due to either the natural occurrence of the degenerative process, or to trauma or
accidental injuries. Obesity, described by some as an epidemic in the U.S. and rampant in even the younger generation, contributing factors such as excess weight on the joints, poor physical health, diabetes, and suppressed immune response (Ortho Industry Report, 2012). Even though the U.S. has a smaller elderly population than many other countries, it ranks higher in obesity (Squires, David A., May 2012). Both surgeons and hospitals all over the world are acutely aware of these indicators. Both are preparing for a sustained increase in surgical procedures and hospital care (both in-patient and out-patient), and are forecasting accordingly. However, with healthcare expenditures exceeding 18% of their GDP to date, no other country needs cost reducing measures like the U.S. So a major challenge looms for both our government, and healthcare providers of all fields in the coming decade. To significantly reduce costs, with an expanding obesity problem and aging population, will indeed be a continuing challenge. It does, however, also create an opportunity for collaboration between hospitals and physicians in facing a new wave of accountability. Price accountability will no doubt catch up to the medical device industry as well, as our government has already begun specifically taxing medical devices (Graham, John R., 2013). Tables 2 and 3 outline some important facts to consider regarding osteoarthritis, joint replacement, obesity, and population.

Table 2

*Worldwide Miscellaneous Facts*

<table>
<thead>
<tr>
<th>Arthritis, Joint Replacement and Obesity: Miscellaneous Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Obese women ~4X and obese men ~5X risk of developing knee OA (vs. non-obese).</td>
</tr>
<tr>
<td>• 11 pound weight gain over 10 years = 50 percent increase in the likelihood of developing OA.</td>
</tr>
<tr>
<td>• Highest quintile of body weight up to 10X risk of knee OA vs. lowest quintile.</td>
</tr>
</tbody>
</table>
• Risk of knee OA up 35% for every 5kg of weight gain.

• Doctor-diagnosed arthritis in U.S.: 16% of under/normal weight people vs. 22% overweight and 33% obese.

• 99% TKR in non-obese deemed successful 6.5 years after surgery vs. 88% in obese.


Table 3
Worldwide Population Demographics, 2005 & 2020

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Population (MM) 2005</th>
<th>Population (MM) 2020</th>
<th>Average Annual Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>2,410</td>
<td>2,513</td>
<td>0.3%</td>
</tr>
<tr>
<td>20 – 39</td>
<td>2,033</td>
<td>2,286</td>
<td>0.8%</td>
</tr>
<tr>
<td>40 – 64</td>
<td>1,536</td>
<td>2,085</td>
<td>2.4%</td>
</tr>
<tr>
<td>65+</td>
<td>473</td>
<td>724</td>
<td>3.5%</td>
</tr>
<tr>
<td>Total World Population</td>
<td>6,451</td>
<td>7,608</td>
<td>1.2%</td>
</tr>
</tbody>
</table>


According to Orthoworld’s Annual Report on the orthopedic industry, the U.S. and worldwide demographics are good news for medical device makers:

“With more than 90 percent of joint replacements performed on people over the age of 45, the robust growth in these age groups will certainly bode well for the continued health of the joint replacement market.”

(Orthopedic Industry Annual Report, 2012, p.12)

Figure 3, the data for which was taken from an article in the New York Times in August of this year, loudly demonstrates not only the rising cost of hip and knee
replacements, but also that these cost increases have gained public attention. While not all patients can afford to travel to another country for their hip or knee replacement, this article summarizes one such patient’s trip, and the staggering cost differences. It’s important to note that the quality of the device is identical to that of the U.S (actually a commonly used implant manufactured in the U.S.!), and the quality of care the patient received was impeccable. This article also sparked a ferocious response from medical device makers (Rosenthal, E., August 2013; Young, R., August 2013). Device manufacturers do

Figure 3

*U.S. Pricing Trends for Hip & Knee Replacements*

not want any more attention drawn to the true cost of implantable medical devices, their profit margins, or the real picture of discounting to hospitals. In fact, hospitals have such a difficult time discerning real (actual) cost of their implants, they feel as though they are “held hostage” by the device manufacturers (Botimer, *White Paper*, 2013, p.8). Medical device manufacturers, including both joint replacement and spine, enjoy some of the highest profit margins in the industry. Figure 4 (below) reveals Security Exchange Commission data from a study in 2010 that records Medical Device Makers earning an average of 11.65% in profit margin, number two in the top five “highest profits in the healthcare sector” (US Healthcare Costs, 2013, p.3).

Figure 4

*Profit Margins by Industry Group, 2010*

**Orthopedic Medical Devices: Spine.** The manufacture of spine medical devices, or spine segment, is the fastest growing segment in orthopedics (Orthopedic Business Trends, 2012; Orthopedic Devices Market, 2011). The spine segment, while relying heavily upon the same aforementioned demographics as the joint replacement segment (over 90% of procedures performed on patients over 45 years of age), performs only 71% of procedures on the same age groups (Orthopedic Industry Annual Report, 2012). This gives the spine segment a distinct advantage because the bulk of deformity correction, minimally invasive surgery (MIS) and other complex procedures are contained within that remaining 29% below age 45 (see Figure 5). These procedures are among some of the most profitable (Millen. Res. Grp.: Insights, 2008).

Figure 5

*Spine Procedures by Age Group, 2012*

![Pie chart showing spine procedures by patient age group: 39% 45 to 64, 29% 65+, 32% <45. Source: Orthopedic Industry Annual Report (Year ending December 31, 2012). OrthoWorld. (U.S. Bureau of the Census)](image-url)
The spine segment is younger regarding time on the market compared to the joint replacement segment. This fact combined with the early interference by the FDA (pedicle screw approval), and rapid technological advances in both surgical and non-surgical treatment of spinal disorders, spine manufacturers are just beginning to deal with the deep discounting and capitation that hip and knee joint manufacturers have already been enduring (Wilson, et al., 2008). The profit margins in the spine segment therefore have been and remain higher than that of the joint reconstruction (hips and knees) segment (Millen. Res. Grp: US Market Analysis 2004, US Markets for Spinal Fusion Technologies 2008). Surgeons that perform spine surgeries in the U.S. and abroad are either orthopedic surgeons, with their general training in orthopedic surgery, or neurosurgeons, with their general training in neurosurgery. The discipline of orthopedic surgery in the spine segment deals primarily with the bones, joints, connective tissues, and nerves of the human body including the spine. The concentration is with musculoskeletal ailments, injuries, and trauma. The discipline of neurosurgery in the spine segment deals primarily with the bones, joints, connective tissues, fluids, nerves and vascularization of the brain, spinal cord, and spinal column. The concentration is with neurological ailments, anomalies, injuries and trauma. Orthopedic spine surgeons are generally regarded as better qualified in the surgical treatment of spinal deformity such as scoliosis, while spine neurosurgeons are generally regarded as better qualified in the surgical repair of intradural injuries or injuries inside the dura (e.g. thecal sac tears). Both surgeon specialties, especially those that are fellowship trained in spine, are uniquely qualified to perform spine surgery, and both are regarded as experts in the treatment of spinal disorders (Hochschuler, Stephen H. MD 2012; Wikipedia, def., 2013).
As the fastest growing segment in orthopedics, the spine segment market share trends are quite interesting. There are over 200 (240) companies manufacturing implantable devices for spine (OrthoStream, October 8, 2013). With the emergence of new companies into both the U.S market and the international market as well, there have been quite a few manufacturers that have nibbled away market share form the top five spine market leaders – Medtronic, Depuy J & J, Synthes, Stryker and Zimmer. Figures 6 and 7, taken from data for the spine segment between the years 2004 and 2008, illustrate not only shrinking market shares from market veterans, but also reveal the growth in the new arrivals. The growth in the category labeled as “OTHER”, represents those 200 plus new spine companies. Some hold up to 2% of the current U.S. market share, while others have market share so small (below 1%) they don’t make it into the reporting by name. In 2004, Figure 6 reports that category as owning 14% of the market share. Four short years later the OTHER category had grown to 23%. Medtronic, the market leader for nearly two decades, sustained a loss of 9% in market share, and Depuy/J & J a loss of 4%. Three of the top 5 realized small increases in market share. One of the top five companies enjoying a market share increase in 2008, and known all over the world as experts in trauma surgery repair implants, Synthes was about to undergo a major change.
Reducing the Cost of Orthopedic Medical Devices

Figure 6

Spine Market Share, U.S., 2004
By Competitor Comparing 2004 to 2008

![Pie chart showing market share in 2004.]  
- Medtronic: 45%
- Depuy J&J: 14%
- Synthes: 17%
- Stryker: 11%
- Zimmer: 6%
- Biomet: 3%
- OTHER: 4%


Figure 7

By Competitor Comparing 2004 to 2008

![Pie chart showing market share in 2008.]  
- Medtronic: 36%
- Depuy J&J: 23%
- Synthes: 6%
- Stryker: 8%
- Zimmer: 12%
- Biomet: 13%
- OTHER: 2%

As in any business, any company that is capital, revenue, and cash rich may choose to pursue an opportunity for merger or acquisition. The SEC, our government watchdog for preventing companies from acquiring too much market share and an unfair competitive advantage, has long battled unfair and illegal business strategies. One such unfair strategy is “if you can’t beat them, consider buying them”. Figure 8 reveals that by 2012, Depuy/J & J and Synthes had merged (still being monitored by the SEC and the FTC), and the new entity reported 28% market in share, which was actually only a small increase in market share collectively. While Medtronic and Biomet both suffered small losses, notice that the OTHER category is still gaining (Ortho Industry Report, Orthoworld, 2012).

Figure 8


![U.S. Spine Market Share 2012](chart)

**NOTE:** Depuy/Synthes combination per Depuy's acquisition of Synthes in 2012.

It’s important to note here that some of these same companies manufacturing spine devices are also orthopedic industry leaders for joints internationally. When considering the *worldwide* market share for the entire orthopedic segment, four of the top ten worldwide manufacturers share top spots in market share in both joint replacements and spine sub segments (see figure 9). Zimmer holds the number one spot, with the Depuy/Synthes giant and Stryker following close behind, and Biomet enjoys the number four spot when orthopedic segments are combined. While Medtronic doesn’t appear on the leader board, they are included in the 6% OTHER spot (Ortho Industry Report, *Orthoworld*, 2012).

**Figure 9**

*Worldwide Orthopedic Market Share, 2012*

![W.W. Orthopedic Market Share 2012](chart)

Definition of Terms

ACO: Accountable Care Organization. Hospitals group together for quality/cost initiatives.

Bundled Payment: Hospital receives a “lump sum” payment for care/services rendered, and pays physicians involved in care.

CMS: Centers for Medicare and Medicaid Services.

CDRH: Center for Devices & Radiological Health. Department within the FDA that regulates manufacturing & labeling of medical devices in the U.S.

Class II MD: Class Two Medical Devices. One of three classes; includes hip & knee replacement components and spinal fusion components (plates, screws, rods, connectors & spacers).

DRG: Diagnosis Related Group. System to classify hospital cases into one of originally 467 groups. FFS related.

FDA: Food & Drug Administration. Governmental approval authority for products including medical devices.

FFS: Fee For Service; method of payment based upon volume.

FTC: Federal agency charged with responsibility of regulating and monitoring fair competition among rivals in the market place.

GPO: Group Purchasing Organization. Volume pricing leverage.


IMD: Implantable Medical Devices. Inside the body; artificial.
<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interbody Device</td>
<td>Artificial spacer inserted into a disc space to restore height.</td>
</tr>
<tr>
<td>NDA</td>
<td>Non-Disclosure Agreement. Mutual legal document.</td>
</tr>
<tr>
<td>OA</td>
<td>Osteoarthritis. Degenerative bone condition.</td>
</tr>
<tr>
<td>OIG</td>
<td>Office of Inspector General. Within the Department of Health &amp; Human Services, the OIG inspects and monitors issues of fraud and is the investigative arm of the FTC.</td>
</tr>
<tr>
<td>OR</td>
<td>Operating room; surgery suite.</td>
</tr>
<tr>
<td>POD</td>
<td>Physician owned distributor. Physicians purchasing and involved in selling medical devices (IMD).</td>
</tr>
<tr>
<td>PPACA</td>
<td>Patient Protection and Affordable Care Act; Obama care. New healthcare initiative enacted by President Obama in March of 2010. Goal of providing all U.S. citizens with affordable healthcare, and reducing healthcare costs.</td>
</tr>
<tr>
<td>PPI</td>
<td>Physician Preference Items. Favorite, most used implants.</td>
</tr>
<tr>
<td>S, G &amp; A</td>
<td>Selling, general administrative; cost component.</td>
</tr>
<tr>
<td>Spinal Fusion</td>
<td>Hardware inserted to stabilize a section of the spine.</td>
</tr>
<tr>
<td>THA</td>
<td>Total Hip Arthroplasty; hip replacement.</td>
</tr>
<tr>
<td>TKA</td>
<td>Total Knee Arthroplasty; knee replacement.</td>
</tr>
<tr>
<td>VBP</td>
<td>Value Based Purchasing. A scoring program based on quality, cost reduction, and patient outcomes.</td>
</tr>
</tbody>
</table>
Literature Review

There are several areas of concentration that must be explored in order to gain a qualified and adequate understanding of the research. A list of terms, acronyms and definitions has been included on pages 20 and 21, just prior to this review.

In the past two decades, hospitals and physicians have been free to bill for services rendered under a Fee-for Service (FFS) arrangement, which has allowed both entities to be compensated on volume of procedures. Not only has this arrangement contributed to the excessive and unsustainable healthcare expense (including the failing financial position of Medicare/Medicaid), but it has also prompted (or, allowed) our government to become more involved. FFS encouraged neither hospitals nor surgeons to work more closely together in treating patients. In fact, it actually produced more adversarial relations between the two (Mitchell, Case Study, 2013; Weisman, Study, October 2012). Resentment between hospitals and physicians over billable services, compensation and reimbursement runs deep throughout the U.S. (refer to Figure 1 on page 8).

President Obama, in March 2010, put the Patient Protection and Affordable Care Act (PPACA) or “Obama Care” officially into play. Besides having the goal of providing all U.S. citizens with affordable health care, the program will also replace the former FFS volume based system with the new Value Based Purchasing, officially starting in October of 2011 (Affordable Care Act, 2011). Value Based Purchasing (VBP) is the first area of concentration to be explored.

There is actually a great deal of information on VBP available starting in 2009. There are two very important concepts in VBP pertinent to this research. The first is that
hospitals and physicians (especially certain surgeon specialties) will be encouraged to work together under several structures, such as bundled payments for care initiatives, and collaborate on patient care. The concentration is now on reduced cost (value), quality and patient outcomes. The second key concept of VBP is that both CMS (Medicare) providers and private insurance providers will begin to “steer” patients toward, or away from, hospitals and physicians based upon their “scores (Jarousse, May, 2011; Kowalczyk, February, 2011; Nelson, 2009)”.

The area of implantable medical devices (IMD), or implants, has a long history both in the U.S. and abroad internationally. Again, the old FFS system did little to affect pricing, especially of orthopedic reconstruction and spinal fusion (Weisman, October, 2012; Roadmap, 2007). Device manufacturers have not only controlled the pricing the last three decades, they’ve fiercely defended their territories by allowing very small discounts. Even when the hospitals banded together to form group purchasing organizations (GPO), and developed “capped” or “construct” pricing, or preferred vendor lists to force deeper discounts on these devices, the companies rallied by enlisting the help of the implanting surgeons (U.S. Gov., January, 2012). There is much information to support this research from a cost and necessary initiatives standpoint.

The area of physician fee reduction and decreasing surgeon compensation is rife with data as well (See Figure 1), but the area of physicians’ involvement with manufacturers for financial gain is growing. The Department of Justice (DOJ) and our government’s emphasis on medical devices and kickbacks are bringing more light on this subject (D.O.J., November, 2007; Study Eval., October, 2011). One school of thought is that the area of fee and compensation reduction for physicians, and the increasing
financial involvement of physicians with manufacturers are “cause and effect”. There are articles that point to and prove that manufacturer sales representatives presence in the OR many times results in more implants, or more premium implants (or both) in a large percentage of the surgeries performed (Seaman, July 2013). There is also much controversy on the subject of physician owned distributorships (POD), where physicians are directly involved with not only the buying and selling of IMDs, but also the sharing of the resulting profits. While this new trend can affect a price reduction for hospitals (Weisman, October, 2012), the controversy centers on conflict of interest (OIG, Special Fraud Alert, March 2013; Kelly, John E., McNamara, Anne P., October 2012).

The area of “profit sharing” between hospitals and physicians also has much data available. One particularly interesting discovery made in this review is that the DOJ actually sanctioned what is called Co-Management Service Agreements between hospitals and physicians. This is extremely valuable because should the surgeons and hospitals begin to work more closely as teams in patient care, and significant cost reductions are realized, there will be incentives issued! If there is an agreement in place, the physicians and hospitals may legally divide the incentives (Ashton, 2007; Reidboldt, 2013).

Hospitals recognize this, and they are purchasing physician practices like never before; physicians see the need, and they are either relenting to purchase or working closer with hospitals. One of the most profitable groups of surgical procedures, and under great scrutiny, is orthopedics. This research will take one discipline (orthopedics), and simple singular procedures for knees, hips (TKA, THA) and single-level spine fusions (with implantable hardware), and explore one method of cost reduction in purchasing
these implants "directly" to determine if there can be significant savings achieved. Both surgeons and hospital administrators will be interviewed on this subject with pre-planned questions. Among the data available on the subject, a very recent white paper published in Loma Linda, CA by the University Medical Center is a very positive indicator of future attention and success.

The last area of concentration in the literature review is in Change Management. The concept is difficult, it demands a team approach, and requires a deep commitment from both physician and hospital administration (Mitchell, Case Study, 2013; Kotter, 2012, original, 1996; Askenas, April, 2013). The data is broad on the subject, but there are a good amount of resources available. One such source, Becker’s Hospital Review, sums up managing change in order to become a true innovative health system this way:

“True transformation starts with a deep understanding of the severity of the problem and a formalized process to execute ideas. You actually have to change the operating structure, culture and strategic vision so people understand it at every level of the organization. This is not incremental change. This is transformational.” (Gamble, Molly, September 2013)

A white paper, submitted for publishing, and authored by Gary Botimer, MD at Loma Linda University Medical Center in California is the first of it’s kind, and became available for review in August of this year. This article is very compelling because it not only examines the concepts of unsustainable cost, value-based initiatives, and direct purchasing, it also breaks down the implant cost components, revealing a very obvious area of attention (see Figure 10). This white paper also demonstrates the findings in a
small study at the medical center. It records the results and proves significant savings can be achieved, but it also shows both the importance of team commitment and the education and training of the hospital personnel. These are crucial to ensuring the success and on-going progress of affecting real change. The importance of total commitment from both upper hospital administration AND from the selected participating surgeons cannot be overstated. The absence of which will most surely guarantee failure of the endeavor. (Botimer, *White Paper*, 2013; Kotter, John P., 1996 & 2012).

**A Controversial Cost Savings Concept**

It is important to note that while they may not be framed as the innovative cost savings concept of this research project, Physician Owned Distributorships (POD), aforementioned on page 24 of the Literature Review, are pertinent to explore, and warrant mentioning. The concept of the POD, a physician owned enterprise that buys, distributes and profits from the sale of their medical device inventory, is gaining both attention and momentum at many levels. Attention gained at the federal level is precisely the reason why the POD is excluded as an alternative in this research. In March of 2013, the OIG in a Special Fraud Alert Bulletin regarding Physician-Owned Entities stated that besides being “inherently suspect under the anti-kickback statute,” there is also noted “the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers (OIG, Dept. HHS, March, 26, 2013).” The concern over conflict of interest by the OIG has resulted in a ‘heightened scrutiny’ of the activities and proliferation of the POD model. The idea of
Reducing the Cost of Orthopedic Medical Devices

physicians/surgeons performing more surgeries, and with their preferred implants of choice was also clearly summed up in the bulletin:

“The financial incentives PODs offer to their physician-owners may induce the physicians to perform more procedures (or more extensive procedures) that are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate devices. We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are ‘physician preference items’ (OIG, Dept. HHS, March, 26, 2013).”

The OIG was very specific in outlining their criteria for “suspect characteristics.” This is not to say that PODs cannot be operated legally if properly structured. However, even if structured to mitigate minimum risk, it will not exclude PODs from being fully investigated in order to prevent conflict of interest, overutilization, unfair effects on competitors, increase in cost or decrease in quality, and kickbacks (Kelly, John E., McNamara, Anne P. October 2102). All that being said, the cost savings initiatives and claims are not to be ignored. There are claims that this business model “…may substantially reduce hospital implant costs by reducing the need for sales and marketing efforts while also improving the efficiency of distribution functions (Steinmann, DO, John, et al.).” Specific focus on reducing ‘the need for sales and marketing efforts’ while attempting to find ways to reduce the price of orthopedic medical devices is especially interesting to note here because, first of all, it was made by a surgeon who was presenting his orthopedic group’s POD study results to the American Academy of Orthopedic Surgeons (AAOS) in 2009. Second, that very same specific focus will be used to
introduce the innovative cost-reducing concept in this research, but without the concern over the OIG, federal investigation, and possible fines and/or jail time.

The study submitted to the AAOS by John Steinmann, DO, et al. was based upon results from 544 cases performed in three hospitals between May of 2006 and May of 2008. The POD distributed implants for these 544 cases, and the breakdown of procedures and implants used was 155 TKAs, 62 THAs, 199 posterior lumbar fusions with instrumentation, and 128 anterior cervical fusions with instrumentation. There were three participating hospitals, all of which reported their average contracted prices for these types implant systems. Figure 10 reflects the findings of the study, a savings to the hospitals (had they chosen to purchase the POD implants) of 34%, or $1,040,974.

Figure 10

*Figure 10*

*POD vs. Hospital Pricing Comparison, 2009*

<table>
<thead>
<tr>
<th>Average Contract</th>
<th>Surgeon Distributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>$3,500,000</td>
<td>$3,099,192</td>
</tr>
<tr>
<td>$3,000,000</td>
<td>$2,058,217</td>
</tr>
<tr>
<td>$2,500,000</td>
<td></td>
</tr>
<tr>
<td>$2,000,000</td>
<td></td>
</tr>
<tr>
<td>$1,500,000</td>
<td></td>
</tr>
<tr>
<td>$1,000,000</td>
<td></td>
</tr>
<tr>
<td>$500,000</td>
<td></td>
</tr>
</tbody>
</table>

Two conclusions that the orthopedic surgeon owners drew and presented from the study were as follows:

1. Surgeons CAN organize and run a “legally compliant” physician owned distributorship capable of providing “preferred” implants.

2. Their POD can be an effective cost reducing tool for hospitals willing to purchase their implants.

They also concluded that:

“Based on Medicare payment methods to hospitals and based on Medicare reimbursement formulas, annual escalations in orthopedic implant prices eroded both hospital profitability and exert a negative influence on surgeon reimbursement.” And “the costs of implant sales, marketing and distribution, on the other hand, adds questionable value when considering the expense associated with these functions (Steinmann, DO, John, et al., 2009).”

Regardless of the potential cost savings reported by any POD, the concern voiced by the OIG has caused hospitals across the country to pause over two primary issues, and more often than not, walk away from engagement with PODs. First of all, the perception communicated by the OIG that there could be risk to the patient. After all, patient safety and well-being are supposed to be the primary concern of both hospitals and surgeons. The second issue will be overutilization, and the potential for hospitals to be enjoined as partners to in a potentially harmful impression. In fact, there is already evidence that the OIG’s concern, described by some as a “crusade”, has “caused a substantial number of hospitals to stop doing business with physician-owned businesses (PRNewswire,
Reliance, October 9, 2013).” Even though there may be a significant cost savings to realize, hospitals and physicians alike will have to weigh out the potential for stiff consequences for any violation, including a maximum fine of $25,000 or up to 5 years in prison for felony charges, or both. If hospitals and/or surgeons choose to engage, great caution should be exercised (Kelly, John E., McNamara, Anne P., October 2012; OIG, Fraud Alert, March 2013).

**An Innovative Cost Saving Concept**

Both cardiac and orthopedic surgeries can be the most profitable surgical procedures for hospitals, and crucial to their success (Botimer, White Paper, 2013). While having both the cooperation and alignment of the surgeons is important, selecting and purchasing the right IMD at the best possible price is even more important. With respect to Total Knee and Total Hip Arthroplasty (TKA and THA) devices and single level spinal fusion devices (both Lumbar and Cervical), there are hundreds of products for sale that are FDA approved and not only cleared for use, but have significant and positive history for positive quality outcomes for patients. A key piece of information is that their patents, or intellectual property, have expired. This means that these devices *could* be manufactured by any qualified company, and sold at greatly discounted prices (much like generic drugs). Figure 11 illustrates a simple cost breakdown of an IMD at a selling price of $6,000. This example reveals a Selling and General Administrative (SG&A) cost to the manufacturer of 43% of the total cost of the implant. This component represents the markup by the manufacturer for selling and distributing this implant, a cost that is passed on to both the hospital, and patient customers (Maguire, et al., *White Paper*, 2013).
Historically, hospitals have had a difficult time discovering the true manufacturing costs of implants they are purchasing. Consequently, this means the hospitals are missing a key piece of information for negotiating pricing discounts with manufacturers (Botimer, \textit{White Paper}, 2013). Manufacturers train their representatives to sell their products to the surgeon first, and when the surgeon decides to use the implants in surgery, the representatives often solicit the assistance of the surgeon to get the implants approved at the hospital. Representatives then attend cases in the operating rooms and are there as part consultant, part liaison for the surgeon and his team of assistants in the case (who are either hospital employees, surgeon employees, or both). Hospital approval is based upon price, and FDA approval of the device(s). Hospitals have several pricing discount structures, or models, available. Some examples are a simple discount off the current or previous years manufacturer’s list price, preferred vendor pricing (limited list of
vendors), a construct price, or a capped pricing model (Robinson, James C., 2008; Linder, Heather, August 2013).

With a cost component of 43% for S, G & A, what if hospitals were able to negotiate the purchase of select orthopedic IMDs directly from a select group of willing manufacturers? What if a select group of surgeons, who all felt that in specific cases, such as simple TKA, THA (select patient population, no revisions) or single level spine fusions (both cervical and lumbar) that a representative was not needed in these cases? What if the hospitals and surgeons were guaranteed that their OR assistants would be equally or better trained than the representatives who attend these cases? A 43% reduction in price would give the hospital a significant price reduction opportunity, and the manufacturer (without the cost of S, G & A) would still have a great profit margin opportunity (Mitchell, Case Study, 2013). While a 43% potential price reduction sounds exciting, depending upon the segment (joints or spine) and the manufacturer, that 43% could be even higher. Table 4 lists five spine companies that advertised their annual sales, their gross profit, and select expenses including their S, G, & A for 2012 in a well respected orthopedic publication (Young, Robin, September 2013). When four of the five companies’ S, G, & A components were averaged together, the figure equaled 55%. With a potential cost savings to hospitals above the 50% mark, and still the opportunity for manufacturers to make a great deal of profit, and both surgeons and hospitals are guaranteed high quality training for essential O.R. personnel, this concept certainly warrants investigation.
Table 4

*Expense Breakdown including Administrative Expense, 5 Companies, 2013*

<table>
<thead>
<tr>
<th>$000s</th>
<th>LDR</th>
<th>NuVasive</th>
<th>Globus</th>
<th>Alphatec</th>
<th>Baxano</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012 Sales</td>
<td>$90,918</td>
<td>$620,255</td>
<td>$385,994</td>
<td>$196,278</td>
<td>$14,570</td>
</tr>
<tr>
<td>Gross Profit %</td>
<td>83.8%</td>
<td>75.3%</td>
<td>43.7%</td>
<td>59.2%</td>
<td>70.4%</td>
</tr>
<tr>
<td>Selling &amp; Marketing %</td>
<td>57.0%</td>
<td>60.0%</td>
<td>43.7%</td>
<td>59.2%</td>
<td>237.1%</td>
</tr>
<tr>
<td>Operating Profit %</td>
<td>(1.4%)</td>
<td>6.0%</td>
<td>29.7%</td>
<td>(0.5%)</td>
<td>(204.1%)</td>
</tr>
<tr>
<td>PSR</td>
<td>NA</td>
<td>1.65</td>
<td>4.05</td>
<td>0.94</td>
<td>5.69</td>
</tr>
<tr>
<td>PEG</td>
<td>NA</td>
<td>2.45</td>
<td>1.43</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>P/E</td>
<td>NA</td>
<td>20.63</td>
<td>25.54</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Includes Administrative Expenses</td>
<td>(S, G, &amp; A)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


The next step would be, after obtaining signature of a mutual non disclosure agreement (NDA), to acquire the necessary data from a willing hospital participant regarding the number of THA, TKA, single level posterior lumbar, and anterior cervical spine fusions with instrumentation over the last one to three years. This data will provide the foundation for making a business case for a pilot study, and an accurate forecast of potential cost savings per case, and in total savings. The selection of a core team of key executives that will not only commit fully to the project, but will also see it through to a true change in process, and culture is vitally important (Botimer, White paper, 2013). Key departments such as finance, supply chain, materials management, sterile supply and the operating room must all be members of the leadership team. A very select and elite group (small number) of surgeons, who have demonstrated the ability to work with
hospital leadership, will be selected based upon their procedural volume and clinical expertise in the use of identified medical devices.

A closer look at how this new proposed “model” of implant purchasing would function is illustrated in Figure 12. While the concept seems simple enough, to remove the cost of S, G & A that has always been controlled by the Supplier, and give both the control and the savings to the Provider, there are several major challenges encountered.

Figure 12

*Traditional Implant Purchase Model vs. OrthoDirectUSA® Purchase Model*

First, is compiling a list of willing manufacturing companies that agree to manufacture implants identified as “stable technologies” for a very low price. Stable - Technologies™ are defined as products cleared by the FDA “that have been used effectively for years with positive clinical outcomes” and “their intellectual property protections (patents) have lapsed” (Mitchell, Case Study, 2013, p. 4). It’s important to note that when these companies factor out their S, G & A cost, there is still ample room
for both company profit and provider discount (Mendenhall, Stan, 2010; Botimer, *White Paper*, 2013). The difficulty in finding “willing” companies to sit down and discuss cutting out their S, G & A (and their representatives) was seen first hand by Dr. Botimer, and referenced in the Loma Linda 2013 Case Study:

“It was definitely a frustrating process. Time and time again it was made clear that my values were not in line with those of the companies I was reaching out to. In fact, the only people I was really allowed to speak with were in the sales divisions of these companies. And they certainly weren’t interested in me telling them to reduce the price of their orthopedic implants because that meant putting them out of a job” (Mitchell, *Case Study*, 2013, p 2).

Obviously, as evidenced in their case study, meeting this challenge, as well as others, and successfully implementing these measures to study IS possible!

After locating manufacturers willing to accommodate this concept, the next challenge is bridging the gap between the participating hospital, and the surgeon, or surgeons, willing to also listen and participate. I believe that this is where OrthoDirectUSA® (ODUSA) has three distinct advantages offered by no one else to date. First, their list of participating manufacturers is impressive and there is no monetary tie, which eliminates bias. ODUSA simply offers the list to its potential clients, and lets THEM make their choices. Next, ODUSA has already selected companies that can and will provide the same orthopedic medical devices most surgeons have either already used in the past, or are currently using, thereby heading off the objection some surgeons may voice as “sub-standard” implants. Often when discussing non-premium implants, or
generic implants, there is a feeling that quality is sacrificed, and the surgeon is implanting an inferior product (Rhode, Blair, MD, October 2012). Third, and most important, ODUSA has an organized, fully functioning and modular training program for the operating room device technician (ORDT™). This program “provides long-term on-site Mentors to support surgeons in the OR” until they are confident in their new staff arrangement (Mitchell, *Case Study*, 2013, p.3). This is crucial in assuring the participating surgeons that their OR staff attending the case will be equally or better trained than the “reps” they have become so accustomed to being present (Maguire, et al. 2013; Mendenhall, 2010).

Although ODUSA appears miles ahead in forging their path as the premier change management consultants for this concept in reducing the cost of medical devices, there no doubt will be more entrants. I found one device manufacturing company, Wright Medical that has decided to form a “Direct” branch of their company, and sell their implants at a discount to interested parties. “In the WrightDirect model, the implant inventory and instrumentation would be purchased and held by the hospital” (Johnson, Brian, May 2013).

**Methodology**

First, an extensive search of the literature was performed to ensure an adequate understanding of the healthcare issues at hand, the pertinent areas of concentration, and to acquire appropriate qualitative and quantitative data. In order to locate and discover both current and historical data on the research subjects, the following sources were accessed via the Internet, library and personally collected books and periodicals:

**Government Sources:**
• Agency for Healthcare Research and Quality (AHRQ)
• Centers for Medicare and Medicaid Services (CMS)
• Food and Drug Administration (FDA)
• Office of Inspector General (OIG)
• Securities Exchange Commission (SEC)
• U.S. Government Accountability Office, Committee on Finance
• U.S. Department of Health and Human Services (USHHS)

Trade Organizations:
• ABA eSource
• Healthcare Industry Distributorships Association (HIDA)

International Research Group Reports:
• Millennium Research Group
• OrthoWorld
• The Commonwealth Fund
• Medical Mutual
• Kroll Advisory Solutions/Compliance Week

White Papers:
• Advisory Board Company
• Allscripts
• Orchid
• OrthoDirect
• Surgical Directions

General Sources:
• Internet Searches:
  1. Medical Journals
  2. Industry Magazines & Quarterlies
  3. Newspapers

• Books

**Threats to Validity**

In order to control history, perceived as a minor threat to the validity of this project, every effort to keep the interview questions as identical as possible was made. Also, while still tailoring between administrator and surgeon, the selection of participants was random selection. Since this concept is a new approach, the aim was primarily to find commonality in the answers to signal whether the participants would be for, or against real testing of the research, i.e. a case study. This was done to eliminate the threat of testing.

**Research Design**

After building a solid foundation for the primary research by collecting, reviewing, summarizing, and organizing the data, interview questions were created. The questions would be centered on the primary research question and proposed concept of “How Can Hospitals Significantly Reduce the Cost of Purchasing Orthopedic Medical Devices?” The interview questions would be as congruent as possible, but specifically designed for the area of expertise of the interviewee. The ability to present a brief summary of the data supporting the research concept is vitally important for two key reasons. First, it sets the stage for, and establishes credibility in the discussion. It’s important for both the surgeon and hospital interviewee to feel their time is important,
and their entrepreneurial expertise can be appreciated (Bea, Javon R., July 2013). Secondly, it can potentially encourage the participants toward a joint project and business case for a case study, thereby furthering, and even proving (or disproving) the research (Mitchell, Tommy, 2013; Botimer, White Paper, 2013). The interviewees would be both Hospital Administrators and Orthopedic Surgeons.

**Participant Selection**

In order to appropriately narrow the scope of the interviewees in both hospital administration, and orthopedic surgery, it was necessary to first define some specific qualifications in both provider groups. First hand knowledge of the specific medical devices (THA, TKA, single level spine), the pricing structures, purchasing practices, and the clinical use of these devices. Decision making power was also considered crucial.

**Delimitations (Inclusionary).** The hospital administrators were selected based upon the following criteria:

- Chief Financial Officer (CFO), or Vice President (VP) level in Finance, Governmental Affairs, or Supply Chain.
- Minimum of ten years experience in the position.
- Employed within either a large medical center, or system of hospitals.
- Position of influence in order to move a project forward (i.e. Case Study or White Paper).

**Delimitations (Inclusionary).** The surgeons were selected based upon the following criteria:

- Director, Managing Partner, or President of their P.A. or Institute, in order to move a project forward (i.e. Case Study or White Paper).
• Minimum of ten years experience of implanting orthopedic medical devices.

• Specific experience implanting for THA, TKA (joint replacement), or single level spinal fusion devices for both lumbar and cervical area (spine instrumentation).

• Residency in either Orthopedics or Neurosurgery.

• Fellowship trained in Spine, Adult Joint Replacement, and/or Reconstruction preferable.

Data Collection

Upon final selection of surgeon participants, hospital administrator participants, and alternate participants, a Letter of Invitation (see Appendix A) addressed to each potential participant was either sent via mail, or hand delivered. The Webster University IRB Consent Form (see Appendix B) was included with the Letter of Invitation. After participants’ agreement to be interviewed is confirmed by mail or by phone, and proper consent was documented, appointments were scheduled for the interviews. Upon completion of proper introduction, and assuring each interviewee of confidentiality, the interviews were conducted with the selected surgeons (see Appendix C for Questions) and Administrators (see also Appendix D for Questions). The questions were asked clearly, and the participants’ answers were reviewed and/or discussed, and recorded. After the pre-planned questions were answered and recorded, each participant was asked for his/her personal opinion and comments on two additional subjects: physician owned distributorships (POD) and co-management agreements. Both of these subjects were previously introduced in the Literature Review (page 24), and POD was addressed in further detail in the Controversial Cost Savings Concept (pages 27-31).
Data Analysis

The answers recorded from the interviews were reviewed and examined for commonality, congruence, opposition or disagreement.

Data Recorded for Questions 1 – 12:

**Question 1**
How many cases per year?

<table>
<thead>
<tr>
<th></th>
<th>&gt;200</th>
<th>&gt;300</th>
<th>&gt;500</th>
<th>&gt;1000</th>
<th>&gt;2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin2</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td></td>
<td>X</td>
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</tr>
<tr>
<td>Surg3</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

% Of Respondents 33 17 0 50

**Question 2**
How many vendors have you worked with/are under contract?

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<thead>
<tr>
<th></th>
<th>&gt;5</th>
<th>&gt;10</th>
<th>&gt;15</th>
<th>&gt;20</th>
<th>Other</th>
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<td></td>
<td></td>
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<td>Admin2</td>
<td></td>
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<td></td>
<td></td>
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<td>Admin3</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td></td>
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<td>X</td>
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</tr>
<tr>
<td>Surg3</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
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</tr>
</tbody>
</table>

% Of Respondents 17 17 67

**Question 3**
Are you involved in fee bundling?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Admin2</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Surg1</td>
<td></td>
<td>N</td>
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<td>Surg2</td>
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<td>N</td>
</tr>
<tr>
<td>Surg3</td>
<td></td>
<td>N</td>
</tr>
</tbody>
</table>

% Of Respondents 33 67

**Question 4**
Do you prefer one device company, or prefer alternatives?

<table>
<thead>
<tr>
<th></th>
<th>Single</th>
<th>One to Three</th>
<th>Alternatives</th>
</tr>
</thead>
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<td>Admin2</td>
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<td>Y</td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td></td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

Reducing the Cost of Orthopedic Medical Devices  40
### Question 5
Do you feel current device representatives bring value to the/your OR?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>Y</td>
<td>N</td>
<td>Don't really see the need</td>
</tr>
<tr>
<td>Admin2</td>
<td>Y</td>
<td>N</td>
<td>Feel that our staff can do what they do</td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td>N</td>
<td>Not really Keep docs happy</td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td>N</td>
<td>They keep my staff on track with me</td>
</tr>
<tr>
<td>Surg2</td>
<td>Y</td>
<td>N</td>
<td>Whenever I Need them</td>
</tr>
<tr>
<td>Surg3</td>
<td>N</td>
<td>Y</td>
<td>Only with complex cases; only occasionally</td>
</tr>
</tbody>
</table>

| % Of Respondents | 33  | 67  |

### Question 6
On a scale of 1-10, 10 the most important, how important is the sales rep in the room for routine/primary THA, TKA, single level lumbar or cervical fusions?

<table>
<thead>
<tr>
<th></th>
<th>1 to 2</th>
<th>3 to 4</th>
<th>5 to 6</th>
<th>7 to 8</th>
<th>9 to 10</th>
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<tr>
<td>Admin1</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Admin2</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Surg1</td>
<td>Y</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td>Y</td>
<td></td>
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<td>Surg3</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

| % Of Respondents | 100 |

### Question 7
What is your opinion of the current pricing of your medical devices?

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>Fair</th>
<th>Too High</th>
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</tr>
<tr>
<td>Admin2</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg3</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| % Of Respondents | 100 |

### Question 8
Are you familiar with Stable Technology and/or Patent Expiration?

<table>
<thead>
<tr>
<th></th>
<th>Stable Tech</th>
<th>Patent Exp</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>N</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Admin2</td>
<td>N</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td>N</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Surg3</td>
<td>N</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>
Question 9
Do you know/can you explain the current method of purchasing your devices?

<table>
<thead>
<tr>
<th></th>
<th>Familiar</th>
<th>Not Familiar</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>Y</td>
<td></td>
<td>All familiar with the process</td>
</tr>
<tr>
<td>Admin2</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg3</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Question 10
Have you heard of these devices being manufactured elsewhere, private labeled, or sold "directly"?

<table>
<thead>
<tr>
<th></th>
<th>Man. Elsewhr.</th>
<th>Priv. Label</th>
<th>Sold Direct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Admin2</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Surg2</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Surg3</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

Question 11
IF: You were confident in the ST offered (familiar, favorable, used before), and your OR Technical Staff were properly trained to assist you, and you were confident that a significant savings would be achieved, would you consider/allow operating without a rep present?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>Y</td>
<td></td>
<td>Surgeons MUST approve the implants</td>
</tr>
<tr>
<td>Admin2</td>
<td>Y</td>
<td></td>
<td>Surgeons must approve the process</td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td></td>
<td>Must be pre-approved &amp; must have backup</td>
</tr>
<tr>
<td>Surg2</td>
<td>Y</td>
<td></td>
<td>Don’t need to be there</td>
</tr>
<tr>
<td>Surg3</td>
<td>Y</td>
<td></td>
<td>Sure, we do it now</td>
</tr>
</tbody>
</table>

Question 12
If there were a way to profit share with each other in this process which is actually sanctioned by the DOJ, would it interest you?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin1</td>
<td>Y</td>
<td></td>
<td>Money shouldn't be the only incentive</td>
</tr>
<tr>
<td>Admin2</td>
<td>Y</td>
<td></td>
<td>Would like to know more</td>
</tr>
<tr>
<td>Admin3</td>
<td>Y</td>
<td></td>
<td>Attractive idea physician align</td>
</tr>
<tr>
<td>Surg1</td>
<td>Y</td>
<td></td>
<td>I'm interested; need to know &quot;how&quot;</td>
</tr>
<tr>
<td>Surg2</td>
<td></td>
<td>N</td>
<td>Not participating at present</td>
</tr>
<tr>
<td>Surg3</td>
<td>Y</td>
<td></td>
<td>Need a lot of info; if mutual benefit</td>
</tr>
</tbody>
</table>
Results

Original assumptions and expectations, based upon both the literature review and on personal knowledge of the industry prior to the interviews, were that wider gaps in philosophies and more areas of disagreement would be discovered. I was, however, pleased to discover that this was not the case. While there were some definite areas of disagreement such as fee bundling, representatives’ value in the OR, and PODs (all expected), there were some key areas of mutual agreement that would support the concept offered in this research. Examples are as follows:

Figure 13

Results from Question 4

- Figure 13 reveals that 83% of respondents (both groups) agreed that alternatives (more choice) in manufacturers and their products were better than a limit of one to three vendors.
- Both groups indicated more choice as necessary not only for the surgeons’ ability to perform as desired, but to keep competition in place for price accountability.
• Both groups stated that the lists of approved vendors to be allowed into the hospitals should be based upon their agreement to meet the designated pricing structure as well.

Figure 14

Results from Question 5

Figure 15

Results from Question 6

• A key issue was the ranking of the importance of a representative in the OR for primary TKA, THA, single level posterior lumbar, and single level anterior cervical procedures. While there were a small percentage of respondents that
expressed value in what the reps add to cases (see Figure 14), all respondents agreed unanimously that with primary knee and hip cases, and with single level spine cases (both lumbar and cervical) the ranking was a 1 or 2 on a scale of 1 to 10 (see Figure 15).

- All agreed their (reps’) presence was not required in the OR as long as the implants were available and sterile.

Figure 16

*Results from Question 7*

- In Figure 16 another key question over the price of these medical devices reveals significant results. All respondents agreed that the current prices were too high, and that the companies would have to come down on pricing dramatically.

- Note: The hospitals represented in this project all had different pricing structures. Some are viewed as among the lowest in their service geography, and some among the higher in pricing (participant interviews).
Still another key issue was the discussion of co-management agreements between the hospitals and surgeons to co-mingle incentives (see Figure 17). All respondents were pleased to hear that the DOJ has sanctioned these agreements, and all respondents were interested in knowing more about this arrangement.

Eighty-three percent of respondents were willing to consider participation if the co-management agreement was mutually beneficial.

A significant note of interest is of the 17% indicating “No” as their response, they were not interested in participating even though agreements were actually in place at their hospitals of choice (participant interviews).
The most significant result (see Figure 18) found from the questions and discussions in both groups was centered around the question: If both groups were confident in a Stable-Technology™ acquired for a select surgeon or surgeon group, and it was guaranteed that the OR staff was properly trained to assist, and a significant savings could be achieved, would you both agree to (administration), and perform (surgeons) a number of cases without a representative in the OR (Question 11)? The answer was unanimous with a condition for both groups. Administration answered “yes”, with the condition that the surgeon(s) were involved in the selection process, and on board with the cases. The Surgeons answered “yes”, with the condition that they are involved in the selection of the technologies and the training is appropriate, and that a sterile back-up set of their first choice be available.
As stated before, where physicians and hospitals stand currently regarding reimbursements, and with the coming changes to healthcare (especially Medicare), the timing may be right for both sides to work together in a cost savings project such as this.

**Discussion**

It is important at this point to reference four key courses taken during my graduate experience. These courses I consider to be foundational in their application, not only in this research, but in any business relating to healthcare as well. They are as follows:

**Course Application**

This section deleted from the original per Administrative request.

**Application in Other Areas of Specialty**

With respect to additional areas of focus to investigate the relevance and validity of this concept of cost savings, as previously noted on page 31, cardiac procedures were mentioned as some of the most profitable for hospitals. It stands to reason that the medical devices, especially stents, in this area may warrant study as well since there is already evidence that the presence of the representatives in the rooms has resulted in increased costs. Apparently the representatives routinely suggesting additional supplies, drugs or premium implants have driven up cost in these procedures notably when compared to cases when the rep is absent (Seaman, Andrew, July 2013). Cardiac, along with orthopedic devices have been climbing at a higher rate than any other area of medical care, and can account for anywhere between 30% to 80% of a hospitals reimbursements from both public and private insurers (Botimer, *White Paper*, 2013).
Even the area of general operating room instruments and disposables could be reviewed and perhaps studied to evaluate a direct purchasing model (Mitchell, *Case Study*, 2013).

**Conclusion & Recommendations**

There is most certainly a need to find, test and implement methods to significantly reduce our healthcare costs, as evidenced in countless sources. Whether these methods are old and familiar, or new and even radical, reducing cost in what is now approaching 20% of our nation’s GDP (U.S. Healthcare Costs, Med. Mutual, 2013) is extremely important for our future as a country. And with increasing market drivers such as our aging population, the subsequent rising age-related conditions like osteoarthritis, the obesity crisis, increased incidence of degenerative pathologies, and diabetes (Orthopedic Bus. Trends, BioMED Trends, 2012), more cost accountability must be imposed on orthopedic medical devices. As Gary D. Botimer, MD stated in the LLMC *White Paper*,

> “By transitioning from subjective to objective decision-making, purchasing Stable-Technologies’ directly from manufacturers and relying on OR device technicians (ORDTs’) to provide high-value surgical support, Providers will significantly reduce costs while maintaining quality of care (Botimer, *White Paper*, 2013, p.9).”

Continuing research in this concept is recommended as follows:

1. Identify other hospital systems engaging in both joint replacement and spine, which are willing to gather procedural information and listen to an in-depth presentation of this concept.
2. Contact a Learning Development & Change Management entity such as OrthoDirectUSA®, and together, conduct a thorough analysis of the procedural data.

3. Work with that entity to select both a leadership team, and an implementation team and include key surgeons who are hospital friendly in the process. Surgeon buy-in and input are essential for success.

4. Develop a template for a case study to test this concept in all aspects, and then commit to publish the results.

   It is imperative to work with an expert firm that already has a list of known manufacturers in play – not working merely working on one. And this entity must have a credible, organized and credentialing OR training program, with on-site coaching or mentoring that can be specifically designed for each hospital.
References


Reducing the Cost of Orthopedic Medical Devices


Appendix A: Letter of Invitation

October 4, 2013

Hospital Administrator/Surgeon
XXXXXXXX XXXXXXXX XXXX
XXXX XXXXXXX XX
XXXXX

Dear Administrator #1/Surgeon #1

I am currently a student in the Master of Health Administration (MHA) program at Webster University. For my final Capstone course, I am hopeful that you will participate in my research study by allowing me to conduct a very brief interview (approximately 10 questions). The purpose of this project is to discover methods of significant savings with regard to medical devices.

I will be interviewing surgeons (general orthopedic and spine) and hospital administrators (C-level executives and VPs in finance, and supply chain). Your participation will be completely voluntary, and your name and address will not be revealed in any way. All responses will remain confidential and anonymous.

Your participation does not include any risk, benefits, or monetary rewards. Should you have any questions or concerns about the interview, please do not hesitate to contact me personally at (XXX) XXX-XXXX. I am also providing a Webster University contact should you want or need to voice a concern directly to the University: Professor _____________ (XXX) XXX-XXXX.

Thank you in advance for your support and contribution to my research thesis!

Sincerely,

Jay K. Whitaker, Graduate Student
Cell Phone: (XXX) XXX-XXXX
George Herbert Walker School of Business & Technology
Webster University, North Orlando Campus
2180 W. State Rd. 434, Suite 5100
Longwood, Florida 32779
Appendix B: IRB Consent Form

Institutional Review Board

Letter of Consent for Research at a non Webster University Site

Principal Investigators are required to obtain approval/permission from a site administrator granting authorization to allow the Principal Investigator(s) to conduct his/her research involving human subjects. Authorization may be withdrawn without any cause at any time by contacting the Principal Investigator(s) and Instructor.

Principal Investigator(s):

Phone Number:

Email:

Faculty Sponsor:

Phone Number:

Email:

I, ______________________ hereby grant permission to the aforementioned Principal Investigator(s)

(Print Name)

to conduct research at ____________________________.

(Site Name)

________________________________________

Authorized Administrator(signature) Date

Title

Email

________________________________________

Address City, State, Zip

Print Form

111010
Appendix C: Interview Questions: Surgeon

Interview Questions

Surgeon
NOTE: These questions are asked with regard to routine TKA, THA, and single level spine procedures ONLY. Complex, revision or MIS procedures are not being considered.

1. How many procedures (TKA, THA, or Single Level Spine with Instrumentation) do you perform per year?
2. How many different medical device companies have you worked with in the past 5 years?
3. Are you involved yet in “fee bundling” with your hospitals for these procedures?
4. Do you prefer to use one company or do you prefer options or alternatives?
5. How does your current medical device representative bring added value to your operating room?
6. On a scale of 1 to 10, 10 being the most important, how important is the sales representative in the operating room during these routine procedures?
7. What’s your opinion of the current pricing for these medical devices?
8. Are you familiar with the terms “stable technology” and “patent expiration”?
9. Do you know how your hospitals presently purchase these implants?
10. Have you heard of these devices being manufactured, privately labeled, and sold directly? To whom?
11. If you were confident in the stable technology offered (familiar and used before), and your OR technical staff were properly trained to assist you, and you were confident that a significant savings would be achieved, would you consider operating and implanting these devices without a representative? Would you object to your hospitals purchasing directly?
12. If there were a way to profit share with the hospitals in this process, which was actually sanctioned by the DOJ, would it interest you more?
Appendix D: Interview Questions: Hospital Administration

Interview Questions

Hospital Administration
NOTE: These questions are asked with regard to routine TKA, THA, and single level spine procedures ONLY. Complex, revision or MIS procedures are not being considered.

1. How many procedures (TKA, THA, or Single Level Spine with Instrumentation) are performed in this hospital(s) per year?
2. How many different medical device companies are currently under contract in this hospital(s)?
3. Are you involved yet in “fee bundling” with any surgeons for these procedures?
4. Would you prefer to use one manufacturing company/supplier, or do you prefer options or alternatives?
5. Do you feel the current medical device representatives bring added value to the operating rooms? Why, or why not?
6. On a scale of 1 to 10, 10 being the most important, how important is the sales representative in the operating room during these routine procedures?
7. What’s your opinion of the current pricing for these medical devices?
8. Are you familiar with the terms “stable technology” and “patent expiration”?
9. Could you explain to me how your hospitals currently purchase these implants?
10. Have you heard of these devices being manufactured, privately labeled, and sold directly? To whom?
11. If a select number of your surgeons were confident in the stable technology offered (familiar and used before), and your OR technical staff were properly trained to assist them, and you were confident that a significant savings would be achieved, would this select group of surgeons consider operating and implanting these devices without a representative?
12. If there were a way to profit share with the surgeons in this process, which was actually sanctioned by the DOJ, would it interest you more?
Appendix E: Participant Thank You Letter

October 2, 2013

Surgeon #1
Florida XXXXXX
XXXXXXXX Street
XXXXXXXXXXX, FL XXXXX
(XXX)XXX-XXXX

Dear Dr. XXXXX (Surgeon #1)

I would like to personally thank you for allowing me the opportunity to meet with you, and to discuss my research interest. You were very generous to allow time out of an extremely busy work schedule and to spend that time with me, and I am forever grateful. Your willingness, your insight, and your candor are very much appreciated. Should you have any questions, or need to contact me for any reason, my cellular number is (XXX) XXX-XXXX.

On behalf of myself, and the Webster University Capstone faculty, thank you again for your participation!

Respectfully,

Jay K. Whitaker, Graduate Student
Management; Health Administration
Webster University – North Orlando Metro Campus
George Herbert Walker School of Business & Technology
2180 W. State Rd. 434, Suite 5100
Longwood, Florida 32779