Industry Representatives’ Influence in the Cardiac Catheterization Lab

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Abstract

Medical device companies spend millions of dollars a year trying to influence physicians and hospitals to use their products. This study was conducted to see when a company vendor representative made a visit to the cardiac cath lab at Hillcrest Oklahoma Heart Institute, did the physicians use that company’s stent more frequently than the physicians did when that company’s representative did not make a visit to the cath lab. The study also looked at whether the physicians stayed within the contract buying agreements that were set up with two of the stent companies. The DES and BMS stent usage and all the visits by the three competing companies were tracked for 12 months. The physicians did not appear to be influenced on their usage of DES stents but did appear to be influenced on their usage of BMS stents though it was unclear if it was a positive or a negative influence. The physicians did not meet the buying agreement contracts on the DES stents but did on the BMS stents. Further studies are recommended to see if any other interventional products may be influenced.

Introduction and Statement of Purpose

Statement of Purpose

The purpose of this project was to discover if the cardiologists working in the cardiac catheterization laboratory at Oklahoma Heart Institute at the Hillcrest Medical Center campus in Tulsa, OK, were influenced by the presence of medical industry vendor representatives in their product selection of percutaneous coronary intervention. The information collected to accomplish this study was obtained by acquiring data from two different tracking systems, from January 1, 2012 through December 31, 2012. Reptrax logs were used to track vendor representatives’ dates in the cath lab. Physician utilization reports were generated by accessing the Xper Inventory Coordinator for both coronary intervention supplies and vascular closure devices. This information was believed to show if any of the cardiologists were affected by the vendor reps presence and how it impacted the compliancy of the established vendor contracts for device usage and if any action was necessary to maintain the compliancy of the contracts.

Setting of the Problem

The physicians that were exposed to medical vendor representatives were the cardiologists at Oklahoma Heart Institute (OHI). OHI, the name of the Heart Pavilion at Hillcrest Medical Center in Tulsa, OK, has been the region’s largest and most advanced hospital dedicated to the treatment of heart disease. The cardiologists worked in the heart catheterization laboratory (cath lab) at OHI. OHI has utilized a lot of the latest technology that has existed in the treatment of cardiovascular disease, which has necessitated the involvement of medical industry representatives in the cath lab. The vendor representatives have provided valuable information about their respective devices and have assisted the physicians in the proper utilization of their respective devices. The physicians had the
responsibility to choose the best treatment for each individual patient, the vendor representative supplied the products that were used for treatment and the hospital had the facility for the physicians to work at and the responsibility to provide the products and stay in budget. All three parties worked together but at the same time each had a uniquely different motive.

**History and Background**

Before 2008, OHI was a private practice group of cardiologists in Tulsa, OK, that practiced at Hillcrest Medical Center and had privileges at other facilities. In 2008, Hillcrest Medical Center bought OHI just months before it was to open its new Heart Pavilion. The merger brought the most advanced cardiac technology in the region with nationally recognized cardiovascular physicians. This allowed the physicians to spend more of their time practicing medicine and use a lot less resources at running a business. The merger also brought about some loss of autonomy for the physicians and leverage for physician preference devices. Physicians no longer could use the threat of taking their practice elsewhere to be allowed to order the supplies they wanted. OHI, like most facilities around the country, has had to negotiate with vendor companies to get strategic pricing. Some of these negotiations require agreements that state what percentage of usage the company was guaranteed for a particular type of product in order to obtain the price that was favorable to the hospital. Because of vendor influence, many hospitals around the country limited the access that vendor representatives had in the cath lab as to avoid any influence vendor representatives may have had on the choice of products the physician may have used. OHI has valued the input and knowledge that the vendor representatives provide and thus have not been as restrictive to vendor representatives as most facilities have.

**Scope of the Problem**

This study was designed to see the influence of vendor representatives on the cardiologists at OHI. The results of this study were not intended to be indicative of other hospitals. The study only uses data obtained from the cath lab at OHI. The data obtained used information from the utilization of coronary stents. Not considered were the effect of vendor representatives on other products that they also represented and were utilized by the cardiologists at OHI. This study was not intended to determine if the time that was spent each and every day and the amount of time per visit that a vendor representative had spent in the cath lab had a relative effectiveness on the selection decision of each cardiologist. Also not studied was the effect that vendor representatives had on the cath lab staff that worked with the cardiologist, and how that may have influenced directly or indirectly the selection decision of the cardiologists.

**Significance of the Problem**

Hospitals, Hillcrest Medical Center and OHI included, have wanted to give the best care to their patients. In today’s
medical environment, hospitals have become more conscious about cost. They have to stay in budget if they want to stay viable. If the presence of vendor representatives does affect the product selection that physicians choose, with no affect to patient care, then that could affect the compliancy of the contract that the hospital has with a vendor and thus increase supply costs for the hospital. If this study showed that the physicians or some of the physicians have been influenced, whether they were cognitive of it or not, then it may be worth looking at restricting the access the vendor representatives have in the cath lab at OHI. It would be beneficial to bring the results to the cardiologists just to help remind them of the potential influence the vendor representatives may have on the overall budget of the department. It may have been speculated that the presence of vendor representatives had an influence on the physicians but no study has been documented nor done at OHI to prove or disprove that notion.

Definition of Terms

**Angioplasty Balloon Catheter**: Medical device used during cardiac catheterization procedures to open blocked coronary arteries.

**Automatic Implantable Cardiac Defibrillator**: An implanted medical device that can detect a life-threatening irregular heart rhythm and produce an electrical jolt from its battery to correct the irregular rhythm.

**Bare Metal Stent (BMS)**: Type of coronary stent that has no drug coating.

**Cardiac Catheterization Laboratory (Cath Lab)**: Department in the hospital that performs the procedures that involve the insertion of a catheter inside the heart or a vessel of the heart for investigation of disease or for treatment of disease.

**Coronary Intervention Equipment**: Medical devices used to open blockages in coronary arteries and restore vascular flow to the heart muscle.

**Coronary Interventional Guidewires**: Medical device used during cardiac catheterization procedures to traverse coronary arteries for the deliverance of angioplasty balloons and coronary stents.

**Coronary Stents**: A flexible scaffold tube-shaped medical device usually made of stainless steel or a chromium alloy implanted in a coronary artery to keep a blocked artery open.

**Drug Eluting Stent (DES)**: Type of coronary stent that is coated with a drug that slowly releases the drug to block the growth of tissue inside the stent.

**Medical Industry**: A sector in the economic system that provides products and services to treat patients.

**Percutaneous Coronary Intervention**: A nonsurgical procedure to treat the narrowing of coronary arteries by accessing the arterial system through a puncture through the skin, usually in femoral artery near the groin.

**Reptrax Logs**: Third party medical vendor tracking system which can give information about each vendor representative and each representative’s visit to the cardiac cath lab including time in and time out.

**Standardization**: Limiting the number of similar products to be able to negotiate a
better price by increasing the volume of the remaining products.

**Vendor Representative:** An individual who represents a medical device company and promotes a device in the cardiac catheterization lab and has expertise in the device’s implementation.

**Xper Inventory Management Coordinator:** Computer system and software produced by Philips that allows for the reporting of inventory usage during cardiovascular procedures done in the cath lab.

### Review of Literature

Does the presence of a medical industry representative or vendor rep, as it is known in the hospital environment, influence the decision making of a cardiologist while working in the cardiac catheterization lab? There have been studies that have shown that marketing by pharmaceutical companies affected physicians’ prescribing choices. Studies have also shown that physicians were unaware that the promotional tactics of pharmaceutical companies affected their own prescribing habits (Ryan, 2010). Medical device vendor reps promoted their products but they also had a secondary role which was one of clinical support and on-site technical knowledge for the usage and deployment of their respective devices. Hospitals found that they needed to work collaboratively with their physicians and have had to show a united front when dealing with vendor reps (Montgomery & Schneller, 2007).

**Physician and Industry Relationships**

Physicians and the medical industry have had a long-standing working relationship in the United States. Since the 1970s, the medical industry-physician relationship has given the world an overwhelming array of life-saving medicines and medical devices (Nakayama, 2010). Entrepreneurial physicians have translated their innovative ideas into life-improving and life-saving devices by working with biotechnology companies and academic researchers (Stossel and Stell, 2011). Industry has needed physicians to enroll patients in clinical trials and to test prototype inventions. Research physicians have worked collaboratively with the industry and were deserving of appropriate compensation for their part in research and development (Nakayama, 2010).

Compensation for physician collaboration has been scrutinized in the past ten years. Academic medical centers and professional organizations have enacted policies and restrictions that have governed the relationship between physicians and the industry representatives to avoid any potential conflict of interest. Since the turn of the last century, many academic medical centers and professional organizations have enacted self-imposed conflict of interest policies between their institutions and its physicians with the pharmaceutical and medical device companies. These conflict of interest policies were created to avoid any perception of misconduct, fraud, or dishonesty (Nakayama, 2010).

For many years ethical issues have become a major concern for health care institutions. The issues have been written and talked about these days extensively as
the pharmaceutical industry’s marketing strategies have possibly influenced physicians’ drug prescribing practices. It has been shown by several studies that even the smallest of gifts, such as pens, paper tablets, and cups can influence a physician’s drug prescribing habit even without his or her own awareness of the influence (Ryan, 2010). In order to get the most expensive and the most promoted drugs to the most patients possible, pharmaceutical companies spent billions of dollars every year on the physicians who were the most susceptible to marketing (Fugh-Berman and Ahari, 2007). Pharmaceutical representatives have been highly trained on how to approach physicians. These drug reps used finely titrated doses of friendship to influence physicians to increase drug sales according to Shahram Ahari, a former drug rep. Ahari went on to say:

While it’s the doctors’ job to treat patients and not to justify their actions, it’s my job to constantly sway the doctors. It’s a job I’m paid and trained to do. Doctors are neither trained nor paid to negotiate. Most of the time they don’t even realize that’s what they’re doing... (Fugh-Berman and Ahari, 2007, p624).

Relationships between health care professionals and vendors could have been detrimental to the health care mission if an employee’s decision making appears to be influenced. Many hospitals and the healthcare industry as a whole have come to realize since 2000 that some steps have been needed to eliminate any business practices that have resulted or could have resulted in improper influences (George, 2007). This has also been recognized by the American Medical Association (AMA), the Advanced Medical Technology Association (AdvaMed), and the Pharmaceutical Research and Manufacturers of America (PhRMA). The AMA has an extensive code of ethics regarding physicians’ dealings with conflict of interest including both biomedical research and clinical trials (Cader-Thompson, 2003). PhRMA has also enacted its own set of ethical standards with its code on interactions with healthcare professionals that were set up in 2002. These voluntary codes were updated in 2009 to further address interactions with regard to marketed products and prelaunch activities to clinical investigators and other individuals and entities as they relate to the clinical process ("Code on Interactions with Healthcare Professionals," 2008). Like PhRMA, AdvaMed also updated its code of ethics in 2009 to further clarify the appropriate relationship between medical device companies and the health care professional to which they interacted with ("Code of Ethics on Interactions with Healthcare Professional," 2009). Congress also has taken action in overseeing the ethical behaviors between physicians and the medical industry with several pieces of legislation. One that has gathered a lot of attention was The Physician Payment Sunshine Act of 2007, more commonly called the Sunshine Act. Its purpose was to make public any and all dealings between physicians and medical industries transparent and in the public’s eye. Payments and transfers of value to physicians have always been a normal part
of business. The Sunshine Act’s intention was to keep those transactions ethical and eliminate any questionable behavior. Any transfer that was valued over $25 must have been recorded by the industry company. Included in the report would have been who the physician was, a description of the nature of the transfer and its value, when and where the transfer occurred (Devine, 2012).

**Medical Supply Costs**

Every year medical costs increase in the United States. The cost of healthcare as a percentage of the Gross Domestic Product (GDP) in 1960 was five percent. In 2008, it was seventeen percent and it is projected to be twenty percent by the year 2018. There have been many factors that have contributed to the increase in medical cost and some are more significant than others. New technology, which included new procedures, drugs, and devices, has been estimated to account for between 38% and 65% of the health care cost growth (Social Security Advisory Board, 2009). From 2003 to 2005, the average hospital’s medical supply cost increased by 40 percent, going from $36 million to $50.5 million during that two year span. These supply costs represented as much as 31 percent of the total cost per case for hospitals. Physician preference items (PPIs), such as orthopedic implants, mechanical devices used for surgery, and implantable devices such as pacemakers, defibrillators, and cardiac stents, accounted for up to 61 percent of the cost of medical supplies for hospitals (Montgomery and Schneller, 2007).

Physicians decided what PPIs they wanted to use based on their own experience with the devices, the particular need for the patient, and comfort level that they had with the companies and their representatives (Montgomery and Schneller, 2007). The cost of the PPI has been taken on by the hospital in its treatment of the patient. The price of the device may not have been known by the physician as many manufacturers have demanded a secrecy clause in their contracts with the hospitals. The secrecy in those contracts affected nearly 60 percent of the $112 billion cost of all medical devices used in 2007 and the device industry’s returns to shareholders doubled that of the pharmaceutical industry in that same year. This lack of transparency has compounded the problems of cost for hospitals. Hospitals had no idea what the average market price was for some devices and thus prevented them from making better informed judgments when they negotiated for the cost of those devices. This has led to a wide range of prices paid across the country for any one of many PPIs. A survey conducted by the Integrated Healthcare Association (IHA) showed a particular hip implant device used by different hospitals ranged in price from $2,300 to $7,300 (Lerner et al., 2008).

This lack of transparency has contributed to the physicians and the hospitals having different goals. The vendors of these PPIs targeted their sales not to the hospital but to the physicians. The physicians then told their hospitals which device they wanted. Because the physicians were unaware that there was such significant price dispersion between similar products, the physicians appeared to be insensitive to the cost of the device.
selected (Lerner, Fox, Nelson, and Reiss, 2008).

What a hospital billed their payers does not reflect what they received in payment. Most insurance carriers follow the lead of Medicare. Medicare’s reimbursement to a hospital has been based on the diagnosis-related group (DRG). This per-case payment was designed to cover all the services, including devices, provided by the hospital in its treatment of a patient. Generally device prices have gone up while the DRGs by Medicare have decreased in many instances (Montgomery and Schneller, 2007). Physicians, historically, have had the ability to bill separately from the hospital for their services so they were unaffected by narrowing margins. The physicians were not directly challenged like the hospitals were to perform the same procedures as before but to utilize less hospital supplies. Hospitals and Physicians Working Together To Contain Costs

Hospitals have been dependent upon the physicians to admit their patients to them. Not only did physicians control admissions but they were the major decision makers as to what treatments and what devices were to be used. Now because of cost controls pressure, hospitals were trying to change the nature and degree of the physicians’ autonomy and at the same time not reduce the physicians’ commitment to the organization (Montgomery and Schneller, 2007). Physicians have needed hospitals too. The hospitals have provided the resources, the facilities, and the highly trained staff. If hospitals were to make any gains in controlling their supply costs, most specifically the cost of PPIs, then they needed to work with their physicians. Hospitals have started to rethink the purchase of PPIs and have taken a hard look at standardizing medical devices when possible (Ferenc, 2009).

There have been many challenges or barriers hospitals have faced in their goal to standardize the purchasing of PPIs. Industry vendors for a long time have had influence on product selection of physicians. Standardization proponents have found the power relationship between the vendor and the physician disruptive to the system (Montgomery and Schneller, 2007). A survey was conducted by Materials Management in Health Care and the Association for Healthcare Resource and Materials Management to find the challenges hospitals face trying to standardize the purchase of PPIs and steps hospitals have taken to reduce the cost of PPIs (Ferenc, 2009). The results are displayed in figures 1 and 2.
Figure 1. Major challenges or barriers to standardizing the purchase of physician preference items (PPI).

- No plans to standardize PPI due to the belief that it will cause the physicians to take their business to a competing hospital
- Implement patient-demand matching (e.g. appropriateness for implant for patient functionality)
- Centralize equipment and instrumentation for procedures in facility
- Impose price ceilings for particular item categories (payment-cap method)
- Limit number of manufacturers physicians can choose to order PPI devices from (formulary model)

Figure 2. Steps hospitals and health systems are taking to reduce the cost of PPI.
Many hospitals around the country have been able to get their physicians to come to an agreement with them in their attempts at standardization of medical devices. They have found that working with physicians to reduce cost of PPIs was the most effective way to reduce supply costs as PPIs significantly contributed to the overall cost per case. The Medical Center of Central Georgia, working with a consultant, realized it could save $1.7 million dollars working collaboratively with its physicians by standardizing its most expensive supplies such as drug-eluting stents, bare metal stents, coronary angioplasty balloons, and coronary interventional guidewires. By working collaboratively with its physicians, MCCG could put up a united front to the vendors and not worry about the vendors leveraging the physicians against them. The overall cost savings are reinvested in equipment for the heart center and other areas of the hospital which benefits the physicians as well as the hospital. St. Tammany Parish Hospital in Covington, Louisiana, set a goal to reduce supply cost per case without affecting the quality of patient care provided. By working with the physicians that implant the pacemakers and the automatic implantable cardiac defibrillators (AICDs), they were able to negotiate and settle on one vendor with the physicians’ full approval for one year. Their one year savings for this alone was $623,000 in 2006. Based on this success they expanded their negotiations to stents, catheters, balloons, and guidewires and saved an additional $364,000 (Williams, 2007).

Five tactics for engaging physicians in supply-cost savings initiatives that hospital administrators can use are: “build a compelling case; help physicians understand the cost profiles of the products they are using and how they contribute to the total cost of care; give physicians a voice in supply-cost negotiations; stick to your guns; share the rewards” (Williams, 2007, p.67).

By giving physicians a voice in supply cost negotiations, St. Tammany saved nearly $1 million in supply cost in its cardiac catheterization lab in 2006. In the past when St. Tammany tried to standardize cost without the physicians’ input, they failed as vendors were able to leverage the physicians and get the physicians to take the vendors’ side.

There have been two main approaches to the standardization of supply costs, the formulary model and the payment-cap model. The formulary model would have limited the number of choices of vendors from which PPIs are purchased. Formulary model could have also limited the range of products that are purchased for a particular procedure. Hospitals have used a similar model for pharmaceuticals and this model has been in line with other industries and their supply-source reduction efforts. It was assumed that the hospitals commitment to a vendor for higher volumes will result in lower prices. It was also assumed that the vendor would have a range of products that would suffice the needs of the physicians for the various needs of the patients. Other assumptions were that the wide range of products on the market was not needed as there were products that were effectively equivalent,
and the patient safety was improved by the proficiency of the operating staff from using a familiar product (Montgomery and Schneller, 2007).

Because the formulary model limited the choices that a physician had, it put the burden on the physician to adapt to the limited products available. This could have altered the physician’s practice decision or made for frequent requests for exceptions. The hospital having had to make sure that the limited choices available did not impact the patient’s outcome, thereby scrutinizing product evaluation to insure product equivalency. Hospitals needed to be careful not to upset their physicians, who could have taken their services and patients to nearby facilities (Montgomery and Schneller, 2007).

The payment-cap model did not explicitly limit particular vendors but instead standardized costs setting the price paid for any product in a particular category. Any vendor was allowed to compete for business but they offered an equivalent product at the price ceiling that was established. This could have subsequently restricted the availability of products for physicians if the vendors were unwilling or unable to come in under the set ceiling price. A variation of this was the ‘reverse auction’. This entailed multiple pre-qualified vendors the opportunity to bid on a carefully defined product, with the low bidders guaranteed committed volumes (Montgomery and Schneller, 2007). In the payment-cap model it was the product vendors that were burdened with the task of keeping the pricing strategy in order. Hospitals, to be effective with this model, first persuaded the physicians to agree that the products were equivalent. The hospitals needed to convince the vendors that the physicians were in agreement with them about the product equivalency and that few product exceptions would have been made before negotiations were made (Montgomery and Schneller, 2007).

Many hospitals recognized the importance of encouraging physicians to be engaged with them in setting the guidelines and goals of standardization. Tangible incentives such as investing in capital equipment, dedicated, trained specialty surgical staff, and providing staff for pre- and postoperative patient education, facilitated physician cooperation. Hospitals that had high level of cooperation among physicians and administrators had better success in standardizing costs (Montgomery and Schneller, 2007).

Vendors and Hospitals

The medical device industry and their representatives commanded the making, supplying, and distributing of PPIs. These suppliers also provided the knowledge about their products, the training of the usage of their products, and gave on-site technical help in the hospital setting. Vendor companies have also spent millions of dollars per year supporting their representatives so that they can have some influence in the cardiac catheterization lab (Kern, 2009). Most hospitals have utilized third-party services that helped them monitor when they had vendor reps in their buildings. Some of the major monitoring services have been Vendormate and Reptrax to name a few. Vendor reps had to sign into these monitoring services’ kiosks when they visited a hospital. They were then issued a temporary name tag that
identified their department destination. These systems also tracked their departure time. Systems like these made it easier and more effective for hospitals to enact their own existing policies on vendors (Traynor, 2009).

A study conducted by the Stanford doctors from October 2008 to April 2009 looked at the effect that the presence of a stent representative had on implantation rate of that representative’s stent. The representatives were self-scheduled. The study demonstrated that the presence of a stent company representative had a significant positive impact on the implantation rate of that company’s stent. The two companies with the lowest volume of business had the greatest influence by their respective representatives during visits (Kern, 2009). These results were not a big surprise to those working in the cardiac catheterization lab. Most vendor representatives are very personable and well-liked by the cath lab staff and physicians (Kern, 2009). That would be more of a concern ethically if the cath lab only chose a particular device because they liked the vendor rep rather than going with the product that had the clinical advantage for that situation (Ryan, 2010).

**Physicians New Responsibility**

The role physicians have today in healthcare has evolved such that they have had to become more than just a health care provider. According to the Bain & Company survey, a majority of physicians, regardless of their demographics, believe that they have a responsibility to help contain healthcare costs. Physicians are ready to adjust their clinical practices and more than ever are likely to align their interests with the hospitals with which they work. In the past, physicians felt that it was solely the payer’s responsibility to worry about cost, but at present physicians are beginning to consider cost along with efficacy in treatment.

The Bain survey showed that 80 percent of physicians felt that they had a responsibility in controlling healthcare costs as a part of their jobs. Physicians who are already cost conscious believe that they will be even more cost conscious in the future and physicians who are the least cost conscious believe that within the next two years costs will become more influential in their decision making for patient care. Unlike the past when physicians equated new product innovation with improvement, today physicians are more skeptical believing that the burden of proof from medical companies is higher than ever. There must be a substantial difference in performance and medical outcomes to convince physicians. At present, physicians have a high satisfaction for existing products and believe the biggest unmet need in medical devices is cost-effectiveness (Farkas, 2011).

For decades physicians and the medical industries have worked together to provide new and innovative products and procedures. This joint venture has benefited both parties in addition to the health and standard of living to all of mankind. In the past there have been moments when the ethics of both parties have been in question. This has led to a need of a set of standards of practice and code of ethics for the AMA, PhARMA, and...
AdvaMed. Congress has also enacted legislation known as the Sunshine Act to help keep an eye on the ethical relationship of physicians and industry. Substantial increases in hospital medical supply costs, in a large part due to the high cost of PPIs, without a matching increase in Medicare reimbursements, have necessitated hospitals to join with physicians in finding new strategies to rein in costs.

Two methods of standardization of medical costs are the formulary model and the payment-cap model, both of which work more effectively for hospitals with the support and collaboration of physicians. Hospitals still see value in having vendor representatives in the building but have taken steps to oversee the representatives’ visits. Physicians have found that their profession has now added the additional responsibility of helping keeping healthcare costs down not only by working collaboratively with hospitals but also by the way they practice.

Methods

Hypotheses

The purpose of this study was to see if the presence of a vendor representative from a medical company would affect the product selection of the cardiologist who was performing an interventional procedure in the cardiac catheterization laboratory at Oklahoma Heart Institute on the Hillcrest Medical Center campus. The study was intended to show if there was a difference in the product selection by the cardiologists when a vendor representative had made an appearance in the cath lab versus when a vendor representative had not made an appearance in the cath lab. This information can then be used to assess whether the presence of a vendor representative affected the cath lab’s overall usage of coronary stents and see if the usage by the physicians stayed in accordance with the agreements that were set up with the different medical device companies. The hypotheses are first, that the presence of the medical device vendor representatives in the cardiac cath lab would have affected the product selection of the cardiologists in that the physician would be more likely to use a company’s stent if that company’s representative was present that day in the cath lab department; second, the overall usage of DES stents by the physicians would not be similar to the usage that is required in the stent company contracts for the negotiated prices that were agreed upon by the hospital with the stent companies; and third, the overall usage of BMS stents by the physicians would not be similar to the usage that is required in the stent company contract for the negotiated prices that were agreed upon by the hospital with the stent company.

Design

To test the first hypothesis, a quasi-experimental design was utilized. The dependent variable was the product choice made by the physicians for each procedural day during the length of the study. The independent variable was whether there was a medical vendor representative present or not present in the cath lab for each day of the study. The study timeline consisted of twelve months during the period of January 2012 through December 2012. The coronary stent usage was pulled
for every cardiac interventional procedure during the study timeline to give a large and unbiased accounting of all the study devices. The physicians and the company vendor representatives were not aware that the usage of each physician and the product of each company were being tabulated.

The second hypothesis and the third hypothesis were tested using a quasi-experimental design. There were two dependent variables that were similar for each test. The first dependent variable was the actual product usage for the physician group as a whole. The second dependent variable was the product usage that was expected by following the contract agreements.

Participants

The participants in this study were the eight practicing Interventional Cardiologists at the study hospital. All procedures that were done by these eight cardiologists during the entirety of the study from January 1, 2012 to December 31, 2012 were analyzed. The participants were distinguished from each other by the reference of Physician 1, Physician 2, Physician 3, Physician 4, Physician 5, Physician 6, Physician 7, and Physician 8. The product usage of all the physicians was then collectively grouped and labeled as All Physicians. The products tracked for the study were all the coronary stents, categorized by DES and BMS, which were used in this cardiac cath lab. These products were supplied by three different medical device companies. The three companies were distinguished from each other by being labeled Company A, Company B, and Company C. Each company had a least one type of DES stent and one type of BMS stent. Company B and Company C had contract agreements for set amounts of usage by the cath lab in order for the cath lab to receive the discounts.

Sources of Data

Data were retrieved from two different computer tracking systems. The first system was from Reptrax, which is a web-driven software service that has assisted in the credentialing and tracking of medical vendor representatives for hospitals all across the United States. By using Reptrax, all visits by all the vendor representatives of each of the companies whose product usage was being tracked for the study were downloaded and recorded. Each visit by each vendor’s representative was then entered into a spreadsheet separating each visit by company and by date. The visits were tracked from January 1, 2012 through December 31, 2012. Any visit by one of the three companies being tracked was considered a presence in the cath lab.

The second tracking system was the Xper Inventory Coordinator. This system recorded all data including supplies used for every procedure performed in the cath lab that was studied. A report was run for each month of calendar year 2012 that displayed every coronary intervention procedure for each day of the month. The report showed which physician performed the procedure and which coronary stents were utilized. The report was then analyzed and each product was recorded into an Excel
spreadsheet which was sorted by company, device, and date.

The data obtained from the Reptrax system were considered valid and reliable in that all representative visits are required to be initiated by registering in on the Reptrax system. The Reptrax system prints out a temporary one day identification sticker with the representative’s name, face, company, and date of visit. No representative is allowed to enter the cath lab without this temporary identification. All visits are logged and can be retrieved at any time.

The data in the Xper Inventory System were considered accurate, valid, and reliable. All products that were used for any procedure were scanned into the procedure report with the Xper Inventory System. The physician then dictated his procedure by using the information that was placed in the procedure report. Any missing device that the physician utilized during the procedure would have been made known during this dictation process and the missing data would have been placed into the procedure report. This was further scrutinized during the billing process to ensure no products were missing from the procedure report. This set of data was then cross referenced with the data that identified which of the three companies’ representatives were present respectively. From this information it was then tabulated by each physician for each product for days that a company representative was present and for days that a company representative was not present. For example, Physician 1’s product usage was sorted and tallied to show the number of DES stents from Company A, and then the number of BMS stents from Company A. This was then further sorted by the days Company A’s representative was present and by the days that Company A’s representative was not present. This was then repeated for Physician 1 with Company B, and then Company C. This process was then repeated for the remaining seven physicians.

There were multiple reasons why coronary stents, both DES and BMS, were chosen for this study. First, these devices’ usages were easy to quantify and were precisely tracked. Secondly, both categories, DES stents and BMS stents, were under contract with a certain percentage of usage per company for each category. Company A was guaranteed 70% of the usage by the cath lab per quarter for the DES stents. Company B was guaranteed 25% market share, and Company C was not promised any usage but was allowed to compete for the remaining 5%. For BMS stents, Company B was guaranteed 75% usage, Company A and Company C were allowed to be in combination not to exceed the remaining 30%. Lastly, the reason why these products were tracked was that these products tended to have frequent cath lab site visits by their respective representatives.

Data Analysis

The raw data were then analyzed to find each physician’s usage for each company’s DES stent as a percentage of the total number of DES stents used by each physician. These data were then separated into two groups. The first group consisted of the days that a company representative
was present the day that his or her product was used. The second group consisted of the days that a company representative was not present the day that his or her product was used. Then the totals of each physician were added together to give the total for all physicians showing the usage of each company’s stent with each respective representative present and/or not present. This same process was done for the BMS stents. Then the total usage of a company’s stents both for DES and BMS were established with both the presence of a company representative in the lab and when that respective company’s representative was not present. Once the total number of stents both DES and BMS used were calculated for all companies by all of the physicians when there was not a company representative present, then the expected frequency of usage for each stent was computed by using a proportionality method. The proportion of each stent type, for example DES, Company A, was calculated from the total number of stents, both DES and BMS used from all companies. The data were entered into Microsoft Excel (Microsoft Office Professional Plus, 2010) for the purpose of calculating and creating graphs to illustrate the results.

The first null hypothesis was that the physicians would have used the different companies’ stents in the same proportion whether a company’s representative had made a presence in the cath lab that day or not had made a presence in the cath lab that day. \( H_0: f_0 = f_e \). The first alternate hypothesis was that the physicians’ proportions of stent usage for the different stent companies would be different when a company’s representative had made a presence in the cath lab that day than it would be if a company’s representative had not made a presence in the cath lab that day. \( H_a: f_0 \neq f_e \). The Chi-Square test was performed to find if there were a statistical significance between the two groups and the initial level of significance was 0.01.

The second null hypothesis was that the product proportional usage of DES stents of the group of physicians as a whole would be similar to the product proportional usage of the contracts’ agreements \( H_0: f_0 = f_e \). A Chi-Square test was performed to find if there was a statistical difference between the proportional usages of the physicians as a group compared to the expected usages in accordance with the contracts’ agreements. The second alternative hypothesis stated that the product proportional usages of DES stents of the physicians as a group would not be similar to the expected amount of usages following the contracts’ agreements \( H_a: f_0 \neq f_e \).

The third null hypothesis was that the product proportional usage of BMS stents of the group of physicians as a whole would be similar to the product proportional usage of the contracts’ agreements \( H_0: f_0 = f_e \). A Chi-Square test was performed to find if there was a statistical difference between the proportional usages of the physicians as a group compared to the expected usages in accordance with the contracts’ agreements. The third alternative hypothesis stated that the product proportional usages of BMS stents of the physicians as a group would not be similar to the expected amount of usages.
following the contracts’ agreements \( (H_0: f_0 \neq f_a) \).

**Limitations of the Study**

The study was designed to see if there was a difference in the product selection choice of physicians if a medical device representative was present. It did not try to see if different representatives were more effective in influencing the decision making. It also did not take into consideration different patient factors that might have affected the choice of the physicians when they chose one particular stent over another for example.

The study only included coronary stents that were actually deployed and coronary stents that were opened for the case but not utilized for whatever reason. Not considered was the scenario where one company’s stent was attempted but did not cross the lesion so was not deployed but was removed and replaced by a stent from a different company in which that second company’s stent did cross the lesion and was deployed so was counted on the survey where the first stent was not.

It was assumed that all the medical device representatives did indeed check in with the Reptrex system. If a representative did forego the proper check-in policy then that representative’s presence would not be recognized in the study data. This study only considered that the company representative made an official visit to the cath lab; it did not take in consideration how long the representative was present, nor which physicians the representative interacted with, nor did it exclude emergencies that may have occurred late at night, long after the representative had left the cath lab.

Another unaccounted for variable could have been that a certain product size from one company may have been requested by a physician and it was out of stock that day, forcing the physician to choose a similar-sized product from a different company. All of these variables would have affected the total percentage of usage for the physicians and whether those usages were done in the presence of a medical device representative or not.

**Summary of Results**

**Descriptive Data Analysis**

One thousand, two hundred and ninety-one stents were used by the physicians during the twelve-month period of the study. The stents were separated by each company and further separated by whether a company representative was present that day in the cath lab when that representative’s stent was used or whether the stent was used on a day that company’s representative was not present. The expected stent usage was calculated by using the same proportion that the physician had with his stent usage when there was not a company representative in the cath lab and using that proportion on the usage of stents that were used when a company representative was present.

The data collected demonstrated that Company C’s DES stent’s usage was approximately 24 percent of the total volume of stents used in the cath lab. It was then expected that when a Company C
A representative made a presence in the cath lab, then 24 percent of the stent usage in the cath lab that day would be Company C’s DES stent which would be a quantity of 31. The observed number of stents used with a representative present and no representative present along with the percentage that each stent group is out of the total number of stents used is presented in Table 1. In addition, the expected number of stents used with a representative present and then without a representative present is presented below in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Company and Type of Stent</th>
<th>Observed Stents Used</th>
<th>Expected Stents Used</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A DES</strong></td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td><strong>B DES</strong></td>
<td>64</td>
<td>995</td>
</tr>
<tr>
<td><strong>C DES</strong></td>
<td>10</td>
<td>209</td>
</tr>
<tr>
<td><strong>A BMS</strong></td>
<td>12</td>
<td>91</td>
</tr>
<tr>
<td><strong>B BMS</strong></td>
<td>4</td>
<td>24</td>
</tr>
<tr>
<td><strong>C BMS</strong></td>
<td>10</td>
<td>347</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>129</td>
<td>1182</td>
</tr>
</tbody>
</table>

A bar graph comparing the expected usage versus the observed usage of stents grouped by company and type of stent used when a company representative is present may be seen in Figure 3.

The total number of DES stents from Company B that were required for meeting the contract agreement was calculated by taking the total number of DES used and multiplying that by the percentage that was necessary to meet the contract agreement (70 percent). That amount was approximately 566. The total number of DES stents from Company C that were required for meeting the contract agreement with Company C was calculated by taking the total number of DES stents used and multiplying that by the percentage that was necessary to meet the contract agreement with Company C (25 percent). That amount was 202 stents. The remaining five percent of DES stent usage would go to Company A which amounted to 40 stents. The comparison of the expected number of each company’s DES stents that were expected to be used to stay compliant with the contract agreements is shown with the actual number of DES stents used from each company in Figure 4 below.
The total number of BMS stents from Company C that were required for meeting the contract agreement was calculated by taking the total number of BMS stents used and multiplying that by the percentage that was necessary to meet the contract agreement (75 percent). The remaining 25 percent was to be shared by Company A and Company B for a total of 25 percent. For the contract agreement to have been met, 361 BMS stents from Company C would have had to been used from the total number 483 BMS stents.

Figure 5 displays the number of BMS stents that would have been expected to be used by Company C compared to what was actually used. Company A and Company B’s expected and observed totals are added together as those two companies competed for the remaining 25 percent.

Inferential Data Analysis

The first null hypothesis was that the physicians would have used the different companies’ stents in the same proportion whether a company’s representative had made a presence in the cath lab that day or not had made a presence in the cath lab that day. \( H_0: f_e = f_o \). The first alternative hypothesis was that the physicians’ proportions of stent usage for the different stent companies would be different when a company’s representative had made a presence in the cath lab that day than it would be if a company’s representative had not made a presence in the cath lab that day. \( H_a: f_o \neq f_e \). A Chi-Square test for independence was used to determine whether the presence of a company representative was related to the stent choice of the physicians. The level of significance was adjusted using the Bonferroni correction (Narum, 2005). This correction was deemed necessary as there were eight independent physicians and two different types of stents, DES and BMS. The
level of significance used with the Bonferroni correction was a 0.000526 level of probability. The initial significance level of (0.01) was divided by the number of non-independent tests, 19. This was arrived by doing the test on all stents as one group, then all DES stents as one group, then all BMS stents as one group, and then each physician for each stent (8 physicians X 2 types of stents), this resulted in 19 tests.

The first test was looking at the physicians as a group and their usage of all stents, DES and BMS. The critical value for a Chi-Square test with a level of significance of 0.000526 and five degrees of freedom was 21.9895 and the Chi-Square value was 40.27207. The null was rejected. The Physicians do use a company’s stent at a different proportion to when the company’s representative is not present versus when the company’s representative is present. It can be concluded that it seems that the physician’s stent company choice is affected by the presence of a company representative. Table 2 below shows the observed and expected stent usage with Company A DES combined with Company B BMS.

Table 2

<table>
<thead>
<tr>
<th></th>
<th>Rep</th>
<th>No Rep</th>
<th>Total</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A DES</td>
<td>4</td>
<td>36</td>
<td>40</td>
<td>0.03064</td>
</tr>
<tr>
<td>B DES</td>
<td>64</td>
<td>395</td>
<td>459</td>
<td>0.35538</td>
</tr>
<tr>
<td>C DES</td>
<td>40</td>
<td>269</td>
<td>309</td>
<td>0.20783</td>
</tr>
<tr>
<td>A BMS</td>
<td>12</td>
<td>91</td>
<td>103</td>
<td>0.079783</td>
</tr>
<tr>
<td>B BMS</td>
<td>4</td>
<td>24</td>
<td>28</td>
<td>0.021809</td>
</tr>
<tr>
<td>C BMS</td>
<td>5</td>
<td>372</td>
<td>352</td>
<td>0.272672</td>
</tr>
<tr>
<td>Total</td>
<td>129</td>
<td>1162</td>
<td>1291</td>
<td>1</td>
</tr>
</tbody>
</table>

Looking at the usage of DES stents a level of significance of 0.000526 was used again by utilizing the Bonferroni correction for having the 19 successive Chi-Squares. The critical value with two degrees of freedom was 15.1004. The Chi-Square value calculated was 0.5708004. The null was not rejected. Therefore it would appear that the physicians as a group do not vary their DES stent usage whether a...
company representative made an appearance in the cath lab or not.

This hypothesis was then tested to see whether each individual physician DES stent usage was influenced by a company representative. Based on the data collected and using a level of significance of 0.000526 (Bonferroni correction) with the Chi-Square test, the critical value with two degrees of freedom was 15.1004. All of the physicians, excluding Physicians 7 and 8, individually had Chi-Square values below the critical value of 14.7555 so the null would not have been rejected for all the physicians. This suggested that all the physicians that have enough useful data to test all appear not to have their product choice on DES stents affected by the presence of a company representative in the cath lab. Physician 7 and Physician 8 did not have enough data to perform an accurate Chi-Square test. The actual Chi-Square values are present in Table 4.

### Table 4

<table>
<thead>
<tr>
<th>Critical value</th>
<th>Actual value</th>
<th>Result of Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician 1 (n=117)</td>
<td>15.1004</td>
<td>1.404</td>
</tr>
<tr>
<td>Physician 2 (n=154)</td>
<td>15.1004</td>
<td>2.831</td>
</tr>
<tr>
<td>Physician 3 (n=63)</td>
<td>15.1004</td>
<td>1.148</td>
</tr>
<tr>
<td>Physician 4 (n=129)</td>
<td>15.1004</td>
<td>4.846</td>
</tr>
<tr>
<td>Physician 5 (n=166)</td>
<td>15.1004</td>
<td>1.693</td>
</tr>
<tr>
<td>Physician 6 (n=154)</td>
<td>15.1004</td>
<td>1.415</td>
</tr>
<tr>
<td>Physician 7 (n=11)</td>
<td>15.1004</td>
<td>n/a</td>
</tr>
<tr>
<td>Physician 8 (n=14)</td>
<td>15.1004</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*Note.* Critical values are for $\chi^2_{0.000526 (2)} = 15.1004$. Physicians 7 and 8 did not have enough data to obtain accurate actual values.

Next, the null hypothesis, the physicians would have used the different companies’ stents in the same proportion whether a company’s representative had made a presence in the cath lab that day or not had made a presence in the cath lab that day ($H_0: f_o = f_e$), is tested on just the BMS stent usage. The expected usage of the BMS stents will be adjusted for comparing each company’s expected BMS usage to the overall usage of BMS stents. The observed, percent of total, and the
expected usage of BMS stents can be seen in Table 5.

Table 5

<table>
<thead>
<tr>
<th>Observed</th>
<th>Rep</th>
<th>No Rep</th>
<th>Total</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>12</td>
<td>91</td>
<td>103</td>
<td>0.213251</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>24</td>
<td>28</td>
<td>0.057971</td>
</tr>
<tr>
<td>C</td>
<td>5</td>
<td>347</td>
<td>352</td>
<td>0.728778</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>462</td>
<td>483</td>
<td></td>
</tr>
</tbody>
</table>

Looking at the usage of BMS stents, a level of significance of 0.000526 was used by utilizing the Bonferroni correction for having the 19 successive Chi-Squares. The critical value with two degrees of freedom was 15.1004. The Chi-Square calculated was 27.110434. The null is rejected. The data suggest that the presence of a company representative in the cath lab may affect the BMS stent choice of the physicians.

Next the hypothesis is tested on each individual physician’s BMS usage. Based on the data collected and using a level of significance of 0.000526 (Bonferroni correction) with the Chi-Square test, the critical value with a degree of freedom of 2 was 15.1004. Physician 2 and Physician 5 had Chi-Square values higher (26.081014 and 22.990476, respectively) than the critical value of 15.1004. The null was rejected with those two physicians. They may have their BMS stent choices affected by having a company representative in the cath lab. Physician 1, Physician 3, Physician 4, and Physician 6 all had Chi-Square values below the critical value and so the null was not rejected for each of them. This is suggestive that the presence in the cath lab by company representatives did not affect the BMS stent usage of these physicians. Physician 7 and Physician 8 did not have enough data to make any type of calculations. The actual Chi-Square values on the usage of BMS stents are presented in Table 6 below.

Table 6

Critical values with actual values for each physician BMS stents.

<table>
<thead>
<tr>
<th>Physician</th>
<th>Critical value</th>
<th>Actual value</th>
<th>Result of Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (n=74)</td>
<td>15.100</td>
<td>1.20760</td>
<td>Null Not</td>
</tr>
<tr>
<td>2 (n=155)</td>
<td>15.100</td>
<td>26.0810</td>
<td>Null</td>
</tr>
<tr>
<td>3 (n=63)</td>
<td>15.100</td>
<td>6.51329</td>
<td>Null Not</td>
</tr>
<tr>
<td>4 (n=73)</td>
<td>15.100</td>
<td>9.49751</td>
<td>Null Not</td>
</tr>
<tr>
<td>5 (n=71)</td>
<td>15.100</td>
<td>22.9904</td>
<td>Null</td>
</tr>
<tr>
<td>6 (n=34)</td>
<td>15.100</td>
<td>0.56198</td>
<td>Null Not</td>
</tr>
<tr>
<td>7 (n=12)</td>
<td>15.100</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>8 (n=1)</td>
<td>15.100</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Note. Critical values are for $\chi^2 \text{ 0.000526 (2)} = 15.1004$. Physicians 7 and 8 did not have enough data to obtain accurate actual values.

The second null hypothesis was that product proportional usage of the DES
stents of the group of physicians as a whole would be similar to the product proportional usages of the contracts’ agreements with the companies for DES stents (H₀: f₀ = fₑ). The second alternative hypothesis stated the product usages of the DES stents of the physicians as a group would not be similar to the expected amount of usages following the contracts’ agreements with the companies for DES stents (fₑ ≠ f₀). The initial level of significance was 0.01 and the Bonferroni correction was utilized to account for the nine successive tests, one for the group of physicians and then eight physicians, to produce a level of significance of 0.001111 (0.01 divided by 9). A Chi-Square test was utilized for testing the hypothesis. The critical value was 13.6050 with two degrees of freedom. The Chi-Square value was 76.7733. The null was rejected. It can be concluded that the physician’s proportional usage of the DES stents did not coincide with the contracts’ agreement amounts.

The product proportional usage of the DES stents of each physician compared to the product proportional usages of the contracts’ agreements with the companies for DES stents was tested against the second null hypothesis (H₀: f₀ = fₑ). Each individual physician then had a comparison of the usage breakdown of each company and that was compared to what would have been expected to be the breakdown of each company based on the total number of DES stents used by each physician. These comparisons are shown in Figure 6 and 7.

Each physician’s observed and expected usage was tested. The initial level of significance was 0.01 and the Bonferroni correction was utilized to produce a level of significance of 0.001111. A Chi-Square test was utilized for testing the hypothesis. The
critical value was 13.6050 with two degrees of freedom. Physician 1, Physician 2, Physician 5, Physician 6, and Physician 7 had Chi-Square values greater than the critical value. The null was rejected for these five physicians. It appeared that these five physicians’ DES stent usage was not similar to the usage that was stated in the DES stent contracts. Physician 3, Physician 4, and Physician 8 had Chi-Square values below the critical value. The null was not rejected for these three physicians. It appeared that these three physicians’ DES stent usage was similar to the DES stent contracts. The actual Chi-Square values on the usage of DES stents are presented in Table 7 with the results of the test.

<table>
<thead>
<tr>
<th>Physician</th>
<th>Critical value</th>
<th>Actual value</th>
<th>Result of Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician 1 (n=117)</td>
<td>13.605</td>
<td>13.9035</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 2 (n=154)</td>
<td>13.605</td>
<td>47.5046</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 3 (n=63)</td>
<td>13.605</td>
<td>11.3311</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 4 (n=129)</td>
<td>13.605</td>
<td>7.1816</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 5 (n=166)</td>
<td>13.605</td>
<td>338.378</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 6 (n=154)</td>
<td>13.605</td>
<td>74.9332</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 7 (n=11)</td>
<td>13.605</td>
<td>20.4029</td>
<td>Rejected</td>
</tr>
<tr>
<td>Physician 8 (n=14)</td>
<td>13.605</td>
<td>8.2653</td>
<td>Rejected</td>
</tr>
</tbody>
</table>

Note. Critical values are for $\chi^2_{0.00111} (2) = 13.6050$.

The third null hypothesis was that product proportional usage of the BMS stents of the group of physicians as a whole would be similar to the product proportional usages of the contracts’ agreements with the companies for BMS stents ($H_0: f_o = f_e$). The third alternative hypothesis stated the product usages of the BMS stents of the physicians as a group would not be similar to the expected amount of usages following the contracts’ agreements with the companies for BMS stents ($f_e \neq f_o$).

The initial level of significance was 0.01 and the Bonferroni correction was utilized to account for the nine successive tests, one for the group of physicians and
then the eight individual physicians, to produce a level of significance of 0.001111 (0.01 divided by 9). A Chi-Square test was utilized for testing the hypothesis. Since the BMS stents had only two categories, Company A and Company B were combined to be compared against Company C, the Yates correction was applied to the data (McDonald, 2009). The critical value was 10.6328 with one degree of freedom. The Chi-Square value was 14.4888. The null was rejected. It can be concluded that the physician’s proportional usage of the BMS stents did not coincide with the amounts agreed in the contracts.

The product proportional usage of the BMS stents of each physician compared to the product proportional usages of the contracts’ agreements with the companies for BMS stents was tested against the second null hypothesis \(H_0: f_o = f_e\). Each individual physician then had a comparison of the usage breakdown of each company and that was compared to what would have been expected to be the breakdown of each company based on the total number of BMS stents used by each physician. These comparisons are shown in Figure 8 and 9 that follow.

Each physician’s observed usage and expected usage were tested. The initial level of significance was 0.01 and the Bonferroni correction was utilized to produce a level of significance of 0.001111. The Yate’s correction was used and the critical value was 10.6328 with one degree
of freedom. The Chi-Square value for Physician 4 was 16.99087. The null is rejected for Physician 4. It appeared that Physician 4 BMS stent usage was not similar to the contract amount.

The Chi-Square values for all the other physicians, excluding Physician 8, were below the critical value of 10.6328. For these physicians, the null was not rejected. It would appear that these physicians’ usages are all similar to the contracted amount. Physician 8 did not have enough data to test. The actual Chi-Square values on the usage of BMS stents are presented in Table 8 below with the results of the test.

### Table 8

<table>
<thead>
<tr>
<th>Physician</th>
<th>Critical value</th>
<th>Actual value</th>
<th>Result of Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (n=74)</td>
<td>10.632</td>
<td>4.61261</td>
<td>Null Not</td>
</tr>
<tr>
<td>2 (n=164)</td>
<td>10.632</td>
<td>8.85365</td>
<td>Null Not</td>
</tr>
<tr>
<td>3 (n=63)</td>
<td>10.632</td>
<td>0.64021</td>
<td>Null Not</td>
</tr>
<tr>
<td>4 (n=73)</td>
<td>10.632</td>
<td>16.9908</td>
<td>Null</td>
</tr>
<tr>
<td>5 (n=71)</td>
<td>10.632</td>
<td>3.94835</td>
<td>Null Not</td>
</tr>
<tr>
<td>6 (n=34)</td>
<td>10.632</td>
<td>1.41176</td>
<td>Null Not</td>
</tr>
<tr>
<td>7 (n=12)</td>
<td>10.632</td>
<td>1.00000</td>
<td>Null Not</td>
</tr>
<tr>
<td>8 (n=1)</td>
<td>10.632</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Note. Critical values are for $\chi^2_{0.00111}(2) =10.6328$. n= number of BMS used by the physician.

### Exploratory Statistical Analysis

The physicians as a group appeared to be influenced by the presence of a company representative as the difference in the observed usage and the expected usage was statistically significant for the BMS stents. A hypothesis could be made that the presence of the company representative makes a positive influence on the stent usage by the physicians. This represents a positive relationship for the stent company in that a physician is more likely to use a company’s stent if that company’s representative made an appearance in the cath lab that day. Company A had a higher number of stents used when Company A’s representative was present in the cath lab than was expected to be used, so it could mean that Company A’s representative had a positive influence on the physicians for his company. The same could be said about Company B’s representative. Company C actually had its stent’s usage decrease when a Company C representative was present in the cath lab. This could mean that the presence of Company C’s representative had a negative influence on the physicians for his company.

### Discussion and Conclusions

#### General Discussions and Conclusions

The research previously discussed earlier in this paper showed that there is a very close relationship between medical device companies and physicians. One study did lead the reader to believe that the presence of a company representative of coronary stents did affect the general
practice of the physicians in that cath lab. This author wanted to see if there was any influence by the company representatives when they came to the cardiac catheterization laboratory at Oklahoma Heart Institute on the Hillcrest Medical Center campus on the decision making, or stent choice, of the physicians. The overall usage of the stents was included in this study to see if there might be a connection between the hospital not meeting the percentage usage numbers on the purchasing contracts of the stents and the possible influence of the stent company representatives in the cath lab.

This study came to the conclusion that the presence of the stent companies’ representatives may have some affect on the choice the physicians are making when they are selecting which stent to use. It also appears that the influence was less significant if any at all on the choice of which DES stent was chosen as compared to which BMS stent was chosen. The study also showed that none of the physicians seemed to be influenced on their decision making for the usage of the DES stents. Only two physicians seemed to be influenced by the presence of a company representative when they choose which BMS stent to use.

This study also showed that the physicians had not met the required proportion of stent usage that the buying contracts had required for the usage of the DES stents. They were below the required amount for the usage of Company B’s DES stents. It was believed that the presence of stent company representatives had no effect on whether or not the physician group met the contract number or not for DES stents as the data showed that the representatives’ influence in the cath lab did not affect the physicians’ decision making on which DES stent to use.

**Strengths and Weaknesses**

A strength to this study was that it was a blind study. The physicians and the company representatives had no knowledge that this study was being performed. Their decision making had not been influenced by the recording of the data. The numbers collected in the study were accurate and were not based on generalizations. With a total of 1291 stents used, there was a large-sized sample to test.

However, there were several weaknesses to this study. First, the presence of a company representative meant that a representative had been in cath lab during a portion of the day for the day that was recorded in Reptrax. Not taken into consideration was the fact that the representative may not have actively interacted with all the physicians that worked in the cath lab that day or night. Second, some of the physician’s stent usages were extremely low on the days that a company representative was in the cath lab. Third, there was no indication that a particular company’s stent was used because the physician’s first choice of a company’s stent was not in stock when requested.

**Recommendations**

This study’s results can be given to the physicians and the hospital to show that companies’ representatives appear to have
little influence on the decision making of the physicians. This should be considered a positive conclusion. The study can also show the hospital and the physician group areas of opportunities to reduce cost by being more attentive to the stent usage needed to meet contract rebates. This study can also show the company getting the contract for the biggest stent usage share might need to be changed.

Suggestions for Future Research

This hospital can look at keeping track of the presence of a company representative during a procedure. Examining tracking should be possible by the use of the Xper procedural charting software. Such tracking would give a more accurate measure of the influence of a representative on the physician on a case by case study. This study should also be repeated each year to check for any changes in the decision making of stent usage by physicians and compare that to the standard of care practice versus the increasing presence of company representatives.

It may be appropriate to also study the selection of other interventional products used in the cath lab. Products, such as coronary wires and coronary balloons that might not be under contract for a certain amount of usage. It would be interesting to compare physician decision making with a representative present when the physician does not have to try to stay within the contracted amount.

References


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