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Journal
BackBone, 2(0)

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Publication Date
2019

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Abstract

Surgical procedures are costly due to staffing, medication use and processing and maintenance of surgical equipment. Surgical procedures involve a varying quantity of instrumentation depending on several factors including the degree of difficulty of the procedure and the individual surgeon's needs and preferences. Most facilities process unused surgical tools wasting labor and costs. Trimming costs while maintaining quality of care is a constant challenge in healthcare. This review discusses utilizing lean methodology to discover waste with surgical tools, implementing changes to common surgical tools and the feasibility of incorporating disposable tools.

Key Words: Single use [zb3] instrument, Transforaminal Lumbar Interbody Fusion, Lean Methodology

INTRODUCTION

The Centers for Medicare and Medicaid (CMS) project a spending of $6.0 trillion dollars on healthcare in 2027[1]. Of this, $912 billion is expected to be spent on surgical procedures alone by 2025[2]. A contributing factor to this rise in spending is due to the growth of the aging population. Medicare has over 50 million beneficiaries to date utilizing healthcare services. Estimates are wide ranging however low back pain is one of the most common symptoms patients seek medical attention for in the aging population. A survey in 2014 found over 28% of adults surveyed experienced lower back pain in the past 3 months[3]. There are many procedures that are done to alleviate symptoms and pathological changes for the lower back/spine. For example, spinal fusions are just one method to pathologies causing severe spinal pain symptoms. This procedure exemplifies the growing trends of healthcare expenditures. The average age of patients getting spinal fusions rose by 5 years and the number of procedures has more than doubled from 174,223 to 413,171 discharges during 1998-2008 time span[4].

With the climbing costs of healthcare in the United States, it is often an area under constant scrutiny for its large contribution to the national gross domestic product. For example, in 2015 the U.S. spent 18% of its total expenditures on healthcare alone compared to the 7.0% in 1970. This demonstrates the large percentage the US spends on the ever-rising cost of medicine. The operating room (OR) is a highly orchestrated environment requiring a lot of preparation and moving parts all while maintaining the highest level of quality. Given thus, it is often regarded a major contributor to significant cost and waste in the healthcare system.

Cost reduction efforts are underway for surgical procedures. Discussion of OR cost and waste reduction is well documented[5,6,7] (Hubbard, RM et al. , Stonemetz, J et al., Lunardini, D et al.,). Amongst OR expenditures, instrumentation costs are of importance to investigate for optimization. For example, Farrokhi et al. at Virginia Mason Medical Center compiled

data from 2 neurosurgical procedures (minimally invasive spinal surgery and deep brain stimulators) to estimate potential institutional savings up to $2.8 million a year through a 70% reduction in instrument processing through sterile supply[8,9]. Because of its clear cost contributions to medical spending and the rise of spinal procedures in the aging population, it is fair to consider a thorough investigation utilizing lean management to eliminate waste and consider the implementation single use instruments.

Figure 1:

DISCUSSION

Before implementing surgical instrumentation changes in the OR setting, there are a lot of factors to take into consideration: surgeon preferences/training, storage-space availability, and the type of procedures being conducted at the institution. One of the major challenges is that all procedures require a basic set as well as their own unique set of requirements and instrumentation. For example, a single level kyphoplasty requires less time, anesthesia, man power, and usually about 5-8 instruments[10] compared to a three level transforaminal lumbar interbody fusion (TLIF), which ususally requires over 40 instrumentaions[11]. With this, equipment storage and staffing are often a limiting factor thus making centralizing cost-effective strategies a challenge.

When looking to make modifiable changes, one must recognize that there are commonalities within the diversity of spinal procedures. This partially stems from the fact that spinal procedure are performed by both Orthopedic surgeons as well as neurosurgeons. In addition, many surgeons are trained somewhat differently to perform the procedure, thus contributing to increased labor costs and surgical instrument use. To begin investigation in the cost savings process in the operating room setting (OR), we recommend considering a whole system analysis of the current process in place for each procedure. An effective approach is by lean methodology. Lean methodology is a principle to find and eliminate inefficiencies while maintaining or improving overall[12]. Industries in other sectors such as manufacturing, financial or aerospace have implemented similar processes with repeated success in eliminating waste and reducing

Figure 2: The 5's of lean management

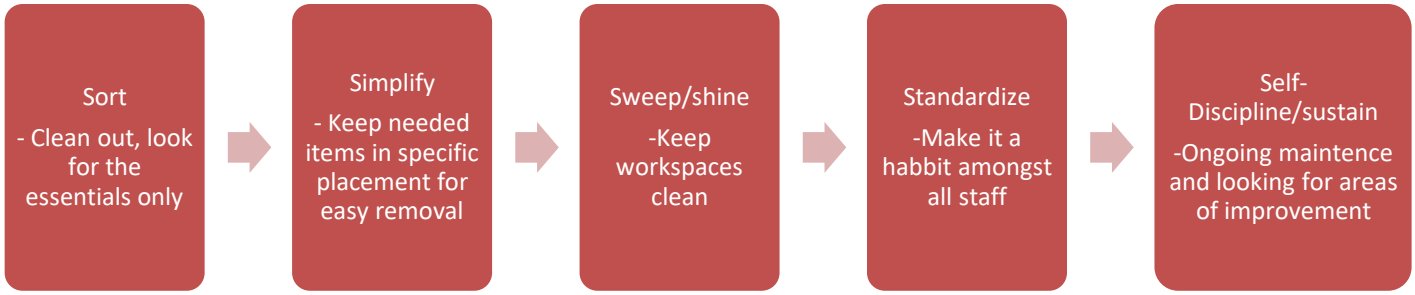

Figure 2 shows the 5 s principle of lean management. Focusing on the 5 steps has been shown to minimize waste and optimize performance [12.21]

expenditures[13]. The diversity of industries utilizing this method can also be applicable to the healthcare industry. Lean methodology focuses on the "five S's" principles - sort, simplify, sweep, standardize, and self-discipline[14] (see figure 2).

In order to sort and simplify the surgical setting, a consistent and or quantifiable area is best served. An area that is quantifiable in the OR is waste and redundancy as seen with surgical instrument use. Surgical instrumentation requires a several step process to meet high quality of standards. In general, instruments are first manually scrubbed then washed in a dishwasher. The piles of tools are then sorted by hand and assessed for functionality. The tools are next organized into trays based on the surgeons' preference and procedure. The trays are autoclaved and stored in rooms to cool down. This process can take around 2-3 hours to execute. When the procedure is scheduled to take place, one of these prepped trays is taken into the OR where a surgical technician will open, organize the instruments, and conduct a formal instrument count. After the surgery is completed, this whole process is repeated.

We recommend starting with analysis of surgical instrumentation usage. First observe and document instrument usage during all procedures. Several reports published findings demonstrating unused surgical instruments are routinely placed in surgical trays. For example, an observational study found that of the 10 cases observed in a plastic surgery setting over 50% of the surgical instruments in the trays remain unused[15].

Next, we recommend the surgeon and team members discuss findings and "sweep" or allow for members to have ability to pardon less or unused

instrumentation prior to implementing removal of the unused tools. Virginia Mason Medical Center performed lean methodology and reported a 70% reduction of instrument trays for minimally invasive spine (MIS) surgeries with equivalent effectiveness of the surgeries performed[8]. In this study, they compared of over 430 MIS spine cases both prior and post implementation of lean methodology and found these measures to reduce the time spent for both patient in the OR and overall surgical time.

Once the sweep of all process is completed, it can be standardized and simplified. For example, spine surgical teams in a group can collectively review their lean method results and standardize the all tools used at an institution with respect to similar procedures. Reduction of even a single instrument can impact labor time and costs as well. A large medical center in Chicago reviewed four surgical specialties including neurosurgery, and quantified cost of processing surgical instrumentation. This study found it takes 4.02 seconds to decontaminate and 12.51 seconds or pack an instrument prior to sterilization costing about $0.10 in labor per instrument[8]. When considering cost of maintaining autoclaves and washers as well as the needed energy and also depreciation of the instrument, all cost rises to over $0.50 per instrument[9]. Accounting for labor costs and processing the tools, the group suggest elimination of 80 unused surgical instruments from a tray that is used around 10 times a week for a year would save around $4,000 to $20,400 a year for a single tray[9].

Considerations of the Single Use Device System

When lean methodologies have been implemented for surgical instrumentation with established validity and reproducibility, we recommend the consideration of a single use surgical instrument system for spinal surgeries. Single use kits are already being used effectively for suture removals, OBGYN procedures, and tonsillectomies. There are many debates across hospital networks discussing the pros and cons of implementing these systems in other fields. When considering if these devices can be effectively employed, we suggest considering the cost, patient outcomes, the organizational impact, and sterility.

One of the arguments that most hospitals are quick to consider is the cost effectiveness of implementing a single-use system vs the already established multi-use spinal surgery devices. In considering the cost, it is important to consider both the cost of surgical delays due to instrumentation problems and the cost of maintaining the devices themselves. According to a cost analysis study conducted at the University of Rochester Medical Center there was a loss of $3600 per hour due to OR start delays overall[17]. When considering this average cost per hour at your institution, one must inquire to see what percentage of cases are delayed either due to instrumentation causes. This may range anywhere from missing devices from prepared trays, instrumentation failure, or ineffective sterilization of the equipment. According to a study published by Radcliff, 44.4% of 9259 spinal surgeries experience ≥1 hour of preoperative delay[18,19] If it is found that a significant fraction of case delays are due to instrumentation errors, the stated $3600 per hour can be costly. Considering this, the implementing of single use devices can help reduce these delays due to their ready availability. Instead of waiting the hours required for re-sterilization of equipment or absorbing the cost of opening a second kit for a single missing device as discussed previously, the use of single use devices will eliminate this waste. If there is an issue with a single use device, it becomes possible to retrieve another device at a moment's notice without impact on time or processing costs.

In addition to the institutional cost of delayed start times, the cost of using single use devices for neurosurgery is less than that of reusable instruments. As stated above, a study investigating single-use neurosurgical device system in minimally invasive spinal surgery and deep brain stimulators has shown large savings over multi-use device systems of up to $2.8 million per year[8,9]. This can be attributed to the decrease costs of labor needed for sterile processing, the cost of maintaining and using machinery for processing, and the cost of processing unused instruments within the prepared trays.

Another large consideration in implementing new instruments is the patient outcome. It has often been regarded that the reusable instruments would

provide better outcomes due to their high-quality materials and durability. Thus, it can be inferred that instruments that hold up against time would provide better patient outcomes. However, a yearlong prospective study was conducted by Ottardi et al. to compare a disposable instrument kit for lumbar arthrodesis with the standard reusable instrument[25]. The study showed that the disposable kits allowed for innovative technology to be implemented thus leading to better performance and patient safety. This is further explained by the fact that disposable instruments can reduce the incidence of surgical site infections due to decreased air exposure.

This study by Ottardi also found that the instruments have an organizational impact as well. The study analyzed the organizational impact both short term and long term (12 vs 36 months) by implementing a qualitative scoring index (1-5) taking into account staff training, support staff, impact of internal processing, equipment purchasing systems, equipment updating, additional equipment, etc.. Based on this scoring index, it was found that the disposable equipment had a significant impact in reducing organizational strain. Since these single-use instruments take up less space than the reusable instruments, it can be deemed easier for the hospital to manage and store. In addition, when considering the changing technology in spinal surgeries, the disposable instruments can be updated more readily to meet new standards. It can be argued that updating requires frequent meetings and new training which can be costly. However, Ottardi explains that due to the frequent meetings and training, there is a positive impact not only on patient outcomes, but also purchasing processing and internal processing[25].

One final consideration in the sterility of single-use neurosurgical devices. It has been argued that institutional protocols requiring autoclave tape/sheets are important to prove sterility of the device, something that is not seen in single-use instruments. However, according to study quoted by Agarwal, about 3% of the 2050 devices studied amongst low income or middle-income countries had visual evidence of attached organic debris even after the completion of a European based sterile protocol[19]. Thus, eluding to the only true way to ensure 100%

sterilization without cross-contamination of blood pathogens and debris is to implement a single use devices protocol. According to another study conducted by Alfa et al, screws that were reprocessed showed increased endotoxin levels demonstrating that water can be a source of infection[26]. The use of a single-use systems virtually eliminates any of these contamination risks[25].

CONCLUSION

The health care industry continues to be a significant expenditure to the federal budget due to several factors including increase in the aging population and in the number of surgical procedures. Efforts are continuously made both at the federal level and hospital level to decrease expenditures while maintaining the quality of care. In the OR setting, main expenditures include labor costs, usage of machinery and processing of surgical instruments. We recommend implementing lean methodology to identify and eliminate waste which will improve costs and decrease labor time. The OR in hospitals are implementing lean methodology enjoying positive effects[21]. With lean management, we do highlight many of the pros of implementing a single-use device system in spinal surgeries. Surgical tool kits can be developed in order to decrease the cost of cleaning machinery, staff wages, and also reduce the risk of cross contamination of diseases such as the transfer of prions that are difficult to remove[18]. However, it is important to note that there is limited thorough research investigations in the spine surgical setting regarding the implementation of single-use instruments and believe that this must be considered on a case-by-case basis per institution.

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