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Novel Laparoscopic System for Quality Improvement and Increased Efficiency

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Abstract

Background: Starting in the 1970s, the surgical arena has greatly advanced in surgical technologies and techniques. The advent of laparoscopic systems has improved patient care and clinical outcomes and is widely accepted as standard of care throughout many parts of the world. Although laparoscopic surgical systems and techniques have advanced, they have not completely mitigated surgical complications, such as cross contamination resulting in infection, technology failures and procedure delays that can lead to conversion to open surgery, and excessive capital equipment costs. Additional improvements are necessary to mitigate complications and excessive upfront costs.

Methods: We reviewed the literature to determine the current laparoscopic systems available today, and surveyed three different institutions in the United States to collect data on reusable laparoscopic procedures and costs to gain an understanding of the acquisition and ongoing costs of the reusable laparoscopic systems. Institutions included ambulatory surgery center, a medium sized rural hospital, and a large suburban hospital.

Results: Our literature search revealed that infection rates from laparoscopic surgery range from 3.9 to 7.6 percent and the survey results showed that procedure delays occur due to inadequate sterile processing and poor inter-operative visualization. The average laparoscopic system cost for one surgical procedure for the reusable laparoscopic system was approximately $1,020.00 US dollars.

Conclusion: There are improvements that need to be made to reusable laparoscopic systems and to the sterile reprocessing process. Single-use laparoscopes today eliminate large up-front capital expenditures, which can be cost prohibitive for certain institutions. Additionally, reprocessing delays, and the potential for cross contamination, leading to complications and increased healthcare costs, are not a factor with single-use laparoscopes. Assuming the cost per procedure for both single-use and re-usable laparoscopes are equivalent, not having the upfront costs and the increased potential for complications, the single-use laparoscopes greatly contribute to continuous quality improvement and reduction in healthcare costs.

Keywords: Laparoscopic System, Cross Contamination, Laparoscope

Background

Quality improvement (QI) in healthcare consists of measurable processes and procedurea followed on an ongoing basis with the goal; for continuous improvement in in healthcare services and the health status of certain populations. The Institute of Medicine (IOM), a recognized leader and advisor on improving the United States' healthcare, defines quality in healthcare as a direct correlation between the improvement in health services and the improvement in health outcomes of population health.[1] The World Health Organization (WHO) identified six dimensions of quality: These dimensions require that health care be: (1) effective, which means evidence based medicine that results in improved health outcomes for various individuals and populations, based on need; (2) efficient, which means health care that maximizes resources and avoids waste; (3) accessible, which means health care delivery in a timely and geographically reasonable where skills and resources are appropriate to the medical needs; (4) acceptable/patient-centric, which individualizes care to the patient, cultures, and communities; (5) equitable, which is health care quality that is the same regardless of gender, race, ethnicity, geographical location, or socioeconomic status; (6) safe, which means benefit (efficacy) outweighs the risk [2]. Dimensions one, two, and six are directly applicable to the medical device industry.

Bataldi and Davidoff define quality improvement in healthcare requiring change to become an intrinsic part of everyone's job everyday as the combined and unceasing efforts of healthcare professionals, patients and their families, researchers, payers, planners, and educators make the changes that will lead to better patient health outcomes, better system performance (care) and better professional development (learning [3] Changes that improve patient outcomes can be directly applied to the medical device industry and is the main reason for medical device research and development.

Medical devices developed to diagnose and/or treat patients are tested for effectiveness and they must meet very strict safety standards to mitigate risk and potential harm to the patients and the end users. In addition to safely delivering a therapy or providing a safe diagnostic use, efficiency and ease of use are also important to help the end user be more efficient in his or her practice. If a device is difficult to use or extends the procedure time, then it is not helpful to the patient nor the end user.

In addition to quality improvement, a requirement for the entire healthcare industry is to follow strict quality standards. Medical device manufacturers must have robust quality systems in place per the regulations and standards. They must strictly adhere to the United States (US) Food and Drug Administration's (FDA) requirements in the Code of Federal Regulations (CFR) [4], International Standards Organization (ISO) Standards, and the European Medical Device Regulations (MDR) requirements for medical devices marketed outside of the United States [5,6]. The FDA also acknowledges certain ISO standards and other standards for medical devices to be marketed in the US called Recognized Consensus Standards [7]. Both healthcare systems and the medical device manufacturers must demonstrate ongoing quality improvement.

One major area significantly improving the quality of healthcare that has progressed over the years is the improvement of surgical techniques and surgical devices to improve patient outcomes. The Harvard Business Review (HBR) (Brighton, MA), a publication from Harvard Business Publishing and a wholly owned subsidiary of Harvard University that publishes on management, reported in 2016 that the greatest advancement in surgery technology has been the advent of laparoscopic surgery, which allows surgeons to perform complex operations through small incisions in the skin [8].

Minimally invasive surgery has transformed surgery after decades of technique and medical device development. The introduction of endoscopy into surgical practice is one of the most disruptive technologies in the medical device industry. Endoscopy originated in the 19th century, was developed at that time by urologists and internists. Historically, the surgical community thought that large medical problems required large incisions to the point that the advancement of endoscopic and laparoscopic surgical techniques were not appreciated. Laparoscopes, which are endoscopes used for abdominal surgeries, involve the use of a thin tube-like fiberoptic instrument to view internal organs and guide minimally invasive surgeries by inserting the laparoscope through a trocar to view the organs in the abdomen and permit less invasive surgical procedures [9]. To help with the advancement of less invasive techniques, in 1976 the Surgical Study Group on Endoscopy and Ultrasound was formed in Hamburg. Five years later, the Society of American Gastrointestinal Endoscopic Surgeons was formed. In 1987 the first issue of the journal Surgical Endoscopy was published, and the following year the First World Congress on Surgical Endoscopy took place in Berlin. The sweeping success of the "laparoscopic

revolution" (1989–1990) in many parts of the world marked the beginning of less invasive techniques and encouraged surgeons to consider new perspectives. Early on laparoscopy was primarily used for diagnostic purposes until the middle to late 1980s. In the 1980s surgeons began perfecting minimally invasive laparoscopic surgical techniques, where instruments can be inserted through much smaller incisions. Lukichev in 1983 and Muhe in 1985 developed the first techniques for laparoscopic surgery. The techniques were finally recognized in 1987 when the French gynecologist, Mouret performed the first acknowledged laparoscopic cholecystectomy with four trocars [8,10]. Finally, by the 1990s laparoscopic techniques had become widely accepted in the world of surgery and endoscopy was incorporated into mainstream surgical procedures [11].

It is well documented that the laparoscopic approach allows for shorter procedure times, and has proven to be safe compared to open procedures. Laparoscopic techniques provide clinically beneficial advantages over open methods and have significantly contributed to quality improvement in patient care over the years by demonstrating improved patient outcomes. Laparoscopic surgery results in a decreased need for pain medication, allows for the patient to tolerate food and drink sooner, shorter recovery time, lower rate of surgical site infections (SSIs), shortening postoperative and total hospital stay, reducing overall complications without compromising patients' safety, reduced mortality, and reduced costs reported by some are important advantages of less invasive techniques over open surgical techniques [12-16].

Surgeons can now perform nearly every abdominal operation using a high-resolution camera and specialized instruments through incisions ranging from 3mm to 15mm. These smaller incisions typically lower the risk of infection and reduce recovery times thereby enhancing patient safety. There are multiple manufacturers of the reusable laparoscopic systems. Multiple manufacturers have developed and market reusable laparoscopes and supportive equipment for procedures such as cholecystectomies, hernia repairs, colectomies, hysterectomies, and other gynecological uses. Examples of reusable laparoscopic equipment manufacturers include Karl Storz Endoscopy-America (El Segundo, California, USA), Stryker® (Kalamazoo, MI, USA), Olympus® (Tokyo, Japan), and Richard Wolf (Vernon Hills, IL, USA), and Boston Scientific (Marlborough, MA, USA) [17-21].

However, as the surgical community continues to innovate and refine safe surgical practices, HBR stated the benefits of continued technical improvements may be much more incremental, thereby having less impact on improving safety. In other words, HBR stated the largest gains in patient safety may have already been realized now that these minimally invasive techniques are in wide use [8].

Although the opinion of the HBR is a valid point, there is ample opportunity for laparoscopic systems to continue to improve to mitigate complications that occur from these systems and improve patient outcomes. Although infrequent, laparoscopic equipment malfunctions or failures can produce unacceptable delays in critical situations that involve potentially life-threatening injury. Examples of potentially correctable equipment-related problems may include inadequate supply of insufflation gas, damaged laparoscopic light source/fiberoptic conduit, faulty camera, other instrument malfunction or break in insulation, and possibly software-related issues, and inadequately cleaned laparoscopes necessitating the need for a second scope. If the problem occurs during the setup phase or at the beginning of the case, and can be resolved quickly and definitively, the procedure should continue laparoscopically. Kindel et al (2015) published that if the malfunction cannot be readily corrected, then one should consider converting to an open procedure without undue delays [22]. Changing the treatment plan from a laparoscopic procedure to an open procedure will then be an increased risk to the patient [12-16].

Some of the issues with existing technologies include poor visualization due to fogging and smoke, which can add time to the procedure; infections due to inadequate sterile reprocessing of reusable devices, which increases risk and cost of care to the patient; burn injuries due to the temperature of the scope, bowel injuries due to poor visibility leading to sepsis, light source related fires, and complications leading to death [13,23-26].

When there is poor visualization due to laparoscopic lens fogging (LLF), LLF hampers vision and impedes operative efficiency and may impact accuracy. Infections rates are still an issue due to inadequate reprocessing leading to cross contamination [12-14,26,27].

Novel Single-use Laparoscopic System

A novel single-use laparoscopic system (Xenocor, Inc., Salt Lake City, UT) has been FDA cleared and CE marked for single use and is intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs [6].

The first component is the Xenobox™ image processing unit (Figure 2, FDA cleared 2016 and CE marked 2016) converts the digital signal from the camera to high definition multi-media interface (HDMI) signal for display onto the HD monitor for the surgeon to view. The Xenobox is then used with any one of the three single-use, sterile Articulating Xenoscope Laparoscope Devices [27]. The 5mm Xenoscope, which was FDA cleared in early 2020, includes a 0° camera on a rigid shaft with a ± 90° articulating tip, in a 36cm long shaft, and a 1080P high-definition video image. The 30°10mm Xenoscope, FDA cleared, and CE marked in 2017, includes a 30° camera on a rigid 36cm shaft. Lastly, there is a 0°10mm Xenoscope, FDA cleared, and CE marked in 2016, which includes a 0° camera on a rigid 36cm shaft [28].

Figure 1: Xenocor™ Xenoscope Laparoscope

Figure 2: Xenocor™ Xenobox

The following are significant features that differentiate the single-use Xenoscope Articulating Laparoscopic System from reusable laparoscopic systems [6,27]: The Xenoscope System is a disposable Single-use Device that arrives at the facility pre-sterilized and ready for single-use. The laparoscope Shaft Materials are non-conducting to minimize electrosurgical arcing and the LED (liquid emitting diode) light source does not heat up like a standard xenon light source; the LED light source heats up to a maximum of 104°F (40°C). The imaging system consists of proprietary high definition (HD) Clear-View Imaging. This proprietary imaging allows for clearer HD imaging, does not fog, and is able to visualize through smoke. Lastly, the Xenobox is compact and it replaces the image processor, camera heads, light source and cords, and recording device of the large capital equipment required for the reusable devices. It has 1080P HD clarity, a small physical footprint, plug and play compatibility, and it is compatible with all existing laparoscopic towers and monitors.

Novel Single Use Device Features Mitigate Issues Seen with Reusable Laparoscopes

The features listed previously address many issues not addressed with other technologies. Xenoscope arrives sterile at the institution. This eliminates the need for sterile processing in order to use for the first time like most other reusable scopes thus having immediate availability for use [27-30]. Disposable equipment also eliminates infection and cross-contamination caused by inadequate sterile processing. This eliminates one of the root causes of SSIs, particulate on the scope, since it is not reusable [13,25,26,31]. Some laparoscopes go through re-reprocessing, which is defined as after the initial cleaning, an additional cleaning was required due to particulate noted on the scope at the time of opening the packaging in the surgical suite or earlier in the central cleaning, inspection, and sterilization process [32].

The proprietary shaft materials prevent risk for arcing when electrocautery is in use. This prevents inadvertent tissue to burn that results in patient injury. In addition, one of the known causes of operating room fires is fiber optic light sources [24]. The integrated tuned LED light source does not cause risk for burn injury or operating room supplies to potentially ignite since the light source only rises to a maximum of 104°F (40°C). Reusable laparoscopes contain warnings about the large amounts of thermal energy emitted and high temperature of the light source and to not touch tissue or the operator as insufficient space between the light source and the tissue may cause tissue destruction [29,30,33].

One of the fundamental principles of safe and successful endoscopic procedures is an ability to maintain a clear operating field. LLF, splatter of irrigation fluids and body fluids all impact a surgeon's ability to maintain a clear operating field [34]. In effort to reduce LLF, manufacturers developed various anti-fogging fluids and warming devices. Various anti-fogging techniques are used including scope warmers, FRED™ (Medtronic, Dublin, Ireland), Resoclear™ (Resorba Medical, GmbH), chlorhexidine, povidone-iodine (Betadine®, Avrio Health LP, Stamford, CT USA), and immersion in heated saline [35]. Fogging due to temperature changes and debris covering the lens are the main reasons to inadequate views in surgeries. The reason for lens fogging is that the temperature of the lens is lower than that of the internal viscera. In order to minimize the temperature difference to prevent fogging, some surgeons soak the lens in warm saline for 30 to 60 minutes before use [36]. The Xenoscope produces clearer images in smoke and/or steam filled operative fields due to its proprietary HD Clear-View Imaging. This reduces the need to remove the scope and clean it to maintain the ability to image and it eliminates the need for a spare scope in a warm bath to exchange out the device that has poor image quality. Removal of the scope to maintain a clear lens increases procedure time. Reducing extra steps and delays increases efficiency before and during the procedure. Another way to reduce set-up time is to eliminate a step called white balancing. White balance is synonymous with color balance and it is a function that gives the camera a reference to "true white". It tells the camera what the color white looks like, so the camera will record it correctly [36]. Before surgery, the reusable laparoscopes are tested, including white balance, focus, adjusting the brightness, aperture, and wiping lens are some of the tests. The Xenoscope does not require "white balancing" upon set-up. Different reusable systems perform this differently. This process is not required for the Xenoscope System, which saves set-up and preparation time.

The Xenocor Xenobox allows for smaller operating room (OR) and storage room footprints than that required of capital equipment and the numerous sterile scope and camera sets for reusable systems. The only equipment required to be supplied by the facility is an HD monitor with an HDMI or USB-C input and an insufflator. Optional equipment includes a video recorder and a printer, whatever is standard for the treatment facility. The compact Xenobox not only occupies very minimal space, most importantly, it prevents the facility from incurring up front expensive capital equipment costs [27].

The benefits of a disposable laparoscopic system have been identified. When we think of single-use disposable laparoscopes, we tend to think that reusable equipment costs less than single-use devices. We wanted to look further into the costs of the reusable systems to further understand if the reusable system shows a cost benefit that potentially outweighs the advantages of the disposable system.

Rationale

Cost is an important factor when considering the value of acquiring a new technology into a hospital system. We conducted a three-center survey to assess the costs of reusable laparoscopic systems. The objective of this survey was to collect all cost data points for laparoscopes to assess the costs of reusable laparoscopes.

Methods

A three-page survey was created, with consultation of medical professionals in the field, for collecting data about laparoscope-related practices and costs. The survey was completed by three different institutions. Participating sites were diverse in type, location, and size (Table 1). One site was an ambulatory surgery center (ASC), one was a rural hospital (RH) and one was a suburban hospital (SH). All three sites were located in the Western United States. The survey did not collect any human subject data, nor did it identify any personnel who provided the data. All sites were JCAHO-accredited facilities which demonstrates that the institution has a commitment to continuous improvement in patient care [37]. Sites followed central reprocessing standards published by national organizations, instructions from the device manufacturers, and the site's standard operating procedures [38,39].

Table 1: Site Characteristics

Characteristic	Site 1	Site 2	Site 3
Description	Ambulatory Surgical Center (ASC)	Rural Hospital (RH)	Suburban Hospital (SH)
Number of procedures per year	230	998	1500

Surgery managers were polled, and they completed the survey that included questions in the following categories: Initial acquisition cost of scopes, consumable reprocessing materials, rental fees, reprocessing fees including labor and equipment, delay costs, and re-reprocessing costs.

Results

The first calculation to determine the average cost per use included using the monthly rental cost of the type of scope, multiplied by the number of scopes in inventory then divided by the number of procedures to obtain the initial cost per use for the laparoscopes. Sites provided the capital equipment cost required at the time of purchase at their facility. This ranged from 837,184.00 to 2,786,348 US dollars (Table 2). All equipment was estimated to have a life span use of seven years. Using the number of procedures per year and amortizing capital equipment over seven years, the capital equipment cost per use was calculated by adding the cost of all capital equipment divided by seven then divided by the number of procedures. The laparoscopic system rental costs and the capital equipment costs were added together to obtain the initial total cost per use.

Table 2: Capital Equipment Costs for Reusable Scopes

Equipment	Site 1 ASC	Site 2 RH	Site 3 SH
Towers	837,184	837,184	1,674,368
Back-Up Towers	--	--	837,184
Back-Up Monitors	33,000	--	44,000
Boom	--	--	230,796
Total Costs	870,184	837,184	2,786,348

For maintenance and repairs, all sites negotiated service agreements with manufacturers; service was provided monthly to maintain and replace reusable laparoscopes. This provides the sites with a consistent cost each month and scopes are replaced immediately when needed. Sites reported that there was very little cost to maintain and repair the capital equipment. At two sites, a biomedical engineer was employed by the site to maintain the equipment. Employee cost data was requested but it was not provided due to the complexity of the cost structure and the sites were hesitant to provide salary or hourly rate information that they considered confidential.

All sites reported procedure delays. Scopes were reprocessed upon initial purchase because they are provided non-sterile. Scopes are then reprocessed through sterile processing after each use (Table 3). Sites reported time spent waiting for a scope to be available to proceed with the procedure. The reasons for delays included scopes not ready for use due to need to soak in a warm bath for 30 to 60 minutes; upon visual inspection, gross particulate was visible; or scope was contaminated by the surgical team during the procedure requiring a second scope to be provided to the surgical suite.

Table 3: Reprocessing fee per use

Reprocessing Fees (USD)	Site 1 ASC	Site 2 RH	Site 3 SH
Cleaning Costs	0.48	2.68	0.58
Pre-Cleaning Labor	2.50	1.46	2.00
Leak Testing	-	2.92	2.20
Manual Cleaning	2.50	2.92	2.20
Visual Inspection	2.50	0.58	0.43
Cleaning Verification	0.50	0.88	1.08
High Level Disinfected	0.50	1.46	2.20
Sterilization - Autoclaving	10.00	12.25	8.23
Sterilization - Other	-	7.30	13.00
Drying	5.00	5.83	3.25
Storage	2.50	4.38	3.25
Total	26.48	42.66	38.42

Another issue identified is that laparoscopes needed to be re-reprocessed due to the above-mentioned reasons for delay and due to expiration of the sterilization date. Sites were asked for the total number of re-reprocessing events each year. This number was then multiplied by the reprocessing fee to obtain the total cost per year at the site. This total was then divided by the procedures per year to obtain a cost that was amortized over all procedures (Table 4).

Table 4: Re-reprocessing Costs

Re-reprocessing Costs	Site 1 ASC	Site 2 RH	Site 3 SH
# Re-reprocessings per year	250	100	300
Reprocessing fee	$26.48	$42.66	$38.42
Cost Per Year	$6,620	$4,266	$11,526
Procedures per year	230	998	1500
Re-reprocessing Costs Per Use	$28.78	$4.27	$7.68

Total cost per use for reusable laparoscopic systems was calculated by adding the initial device cost per use defined previously, initial reprocessing cost required upon receiving the reusable systems, consumable equipment, re-reprocessing costs per use, and delay costs per use (Table 5). The average cost per use for one surgical procedure was $1,019.24.

Table 5: Total Costs for Reusable Laparoscopes

	Site 1 ASC	Site 2 RH	Site 3 SH
Device cost per use	1,107.45	982.05	610.26
Reprocessing fee	26.48	42.66	38.42
Consumable equipment	4.99	49.05	26.56
Re-reprocessing costs per use	28.78	4.27	7.68
Delay costs per use	N/A	93.98	35.10
Overall Cost Per Use	1,167.70	1,172.01	718.02
Average Cost Per Use	1,019.24		

Discussion

Managers and supervisors and their staff spend abundant hours on administrative tasks and responsibilities related to managing and maintaining reusable laparoscopes [41]. In addition to regulatory requirements and ISO standards, an additional standards organization, Association for the Advancement of Medical Instrumentation® (AAMI), develops standards and other technical documents for the purpose of enhancing the safety and efficacy of the use and management of medical devices and health technologies. One of the three groups that AAMI serves is the group of sterilization professionals, the Facility Guidelines Institute (FGI) [42]. FGI, an independent, not-for-profit organization, is dedicated to developing guidance for the planning, design, and construction of healthcare facilities [43]. These guidelines include sterile processing departments. Within the department there are decontamination requirements, assembly and packaging requirements, and sterilization requirements, water quality, and storage requirements. Administration must provide proof of documentation of supervision of the work practices to ensure quality assurance [44]. Central processing has many requirements to protect patients, and these requirements are very time consuming, labor intensive, and testing intensive for re-usable equipment that ultimately is very costly. These costs were not provided by the survey sites but do contribute to overall costs. In addition, there are costs related to hospital space for capital equipment, preparing for inspections, water, and electricity. As a result, this cost analysis greatly underestimates the true cost per laparoscopic procedure.

Delays cost the site money due to operating room personnel not working during this time. The sites were not able to provide data on the costs of delay as they were not able to quantify the multiple costs involved with surgical procedure delays due to wait time, staffing costs during the delay, decrease in number of surgeries per operating room suite due to delays, increase in medications administered due to prolonging the time for the patient under anesthesia or sedation, plus changes in central processing staff's routine to rush a laparoscope to the operating room due to a scope that is not usable.

Laparoscopic equipment allows for minimally invasive surgeries to be performed, which has demonstrated a reduction in surgical site infections (SSI) compared to open techniques. SSI rates range from 5.8 percent to 7.6 percent. This varies depending on the type of surgery and whether the surgery is open or a minimally invasive laparoscopic technique. Caroff et al (2019) reported an overall infection rate of 4.1% for laparoscopic surgery, with a range of 3.9 to 5.1 percent depending on the type of laparoscopic surgery [25]. Alkaaki et al (2019) reported a SSI rate of 4.0%. [13]. There are multiple brands of laparoscopes available today throughout the world. The current standard-of-care includes the use of re-usable laparoscopes. While infection rates are reduced with the use of laparoscopes, vs. open techniques they are not completely mitigated. The re-usable laparoscopes are at risk for introducing pathogens into patients (cross contamination) resulting in infection. Medical devices for single use are of interest because they do not require reprocessing for multi-use, which decreases the risk for infection [13,26]. Infections can be mitigated by strictly abiding by the requirements for sterilization techniques of the laparoscopic instruments with appropriate sterilizing agent, but contaminated devices that may be the root cause of infections can only be completely mitigated with single-use devices [31]. Only one brand of laparoscopes is FDA cleared and CE marked for disposable single use, the Xenoscope™ Laparoscopic System (Xenocor, Inc., Salt Lake City, UT, USA) [41]. The single use laparoscope (like Xenoscope™ Laparoscopic System, Xenocor, Inc., Salt Lake City, UT, USA) [27] is shipped to the facilities in a single use package that maintains their sterilization for up to four years, compared to only 14 days to six months to one year for reusable devices depending on the method of sterilization, packaging, and hospital policies [45]. Siu et al (2016) published a systematic review on the costs and safety of reusable compared to disposable laparoscopic instruments. The

results were reported on data from 2000 to 2015 from Medline and EMBASE databases. Due to lack of published evidence, Siu et al theorized that there may be advantages of single-use instruments over reusable by having increased quality, increased safety, ability to always have a sterile device, ease of use, and most importantly patient outcomes, but additional studies are warranted [46].

The FDA has identified endoscopes as a subset of medical devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed. This identification was based on knowledge learned through Medical Device Reports (MDRs), recalls, periodic outbreaks of microbial transmission or patient infections reported in the literature or media, reports provided by the Centers for Disease Control (CDC), the Veterans Administration (VA), and other health care settings; and manufacturer-initiated surveillance studies [47].

Welker (2019) reported, in the orthopedic arena, contamination incidents related to cannulated endoscopes that have caused more scrutiny of re-sterilization and re-use of orthopedic instruments. Sterile, disposable procedure packs are widely used for anesthesia, electrophysiology, and neuromodulation procedures, but reusable instruments and reusable surgical trays continue to be the current standard for most orthopedic procedures. In today's healthcare environment, safety and economic issues are the top priorities. Manufacturing technology has improved enough to make sterile, disposable instruments a safe, economic benefit to hospital ORs. Sterile, single use orthopedic instruments that stand up to the rigors of surgery, will greatly reduce costs by eliminating processing and sterilization costs, can help prevent expensive SSIs, increase efficiency through decreased turnaround time, and by helping to prevent expensive SSIs, and reducing liability risks [48].

Single use eliminates excessive upfront capital expenditures required for laparoscopic imaging and may have an overall lower cost per use than reusable devices. The Xenocor single-use product functions with a universal adapter for any video system as well as the power supply for the integrated light source and high definition (HD) camera. Additional advantages include infection prevention from microbes that may exist on improperly cleaned reusable devices, no delay due to lack of availability or re-reprocessing, ease of use and set up, fog and burn proof, image clarity in smoke, less sterile resources and chemicals used, biomedical engineer time, and administrative time decreases, thus decreasing personnel costs.

Conclusion

There are considerable upfront costs required for capital equipment for reusable laparoscopic systems. They ranged from $837,184.00 to $2,786,348.00 in this survey, which can be quite burdensome and even cost prohibitive for some institutions. This can make a substantial difference for new or expanding operating rooms when adding these costs to the overall costs of the new build or expansion. Single use devices provided sterile from the manufacturer have a very long expiration date compared to reusable devices and do not require reprocessing or re-reprocessing. Single-use laparoscopes today eliminate large up-front capital expenditures, which can be cost prohibitive for certain institutions. Additionally, reprocessing delays, and the potential for cross contamination, leading to complications and increased healthcare costs, are not a factor with single-use laparoscopes. Assuming the cost per procedure for both single-use and re-usable laparoscopes are equivalent, not having the upfront costs and the increased potential for complications, the single-use laparoscopes greatly contribute to continuous quality improvement and reduction in healthcare costs.

More in-depth studies are warranted to better understand all factors that need to be compared between reusable and single-use laparoscopic systems.

Survey Limitations

Limitations to this survey included the inability to collect comprehensive cost data requested due to the complexity of cost structures and surgery managers not wanting to disclose sal-ary information. This also impacted the ability to collect and report all costs for delays. Infection rates were not disclosed as that was considered sensitive information even though the name of the institutions would remain anonymous. Lastly, the survey was small as it took place at only three centers.

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