Research proposal

The factors that influence the application of the Lean Six Sigma Process methodology in the Central Sterilize Supply Department at a Specialized Medical Centre to reduce the amount of surgical instruments reported missing

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## Contents

1. Introduction .................................................................................................................. 4  
2. Background, rational and literature review ................................................................. 5  
   2.1 Introduction to Surgical Sets .................................................................................... 5  
   2.2 Introduction to Sterile Processing Standards .......................................................... 5  
   2.2.1 Decontamination process ................................................................................... 5  
   2.2.2 Inspection and preparation ................................................................................ 6  
   2.2.3 Sterilization process .......................................................................................... 6  
   2.2.4 Sterile storage area ............................................................................................ 7  
   2.3 The Association for the Advancement of Medical Instrumentation (AAMI) Standards .... 8  
   2.5 Sterile Processing Developments .......................................................................... 8  
   Lean Improvement ....................................................................................................... 8  
   Introduction to Lean ..................................................................................................... 8  
3. Problem statement ......................................................................................................... 9  
4. Research question ......................................................................................................... 9  
5. Research hypothesis ..................................................................................................... 9  
6. Aim ................................................................................................................................ 10  
7. Objectives ................................................................................................................... 10  
8. Conceptual Framework ............................................................................................... 10  
   8.1. Figure 1. Conceptual framework of effective management of surgical instruments ....... 11  
   8.2. Figure 2. A Systematic explanation framework of the reprocessing procedure of surgical instruments ................................................................. 12  
9. Research Methodology ............................................................................................... 13  
9.1 Research design ....................................................................................................... 13  
9.2. Study setting .......................................................................................................... 13  
9.3. Population and sampling ....................................................................................... 13  
   9.3.1. Inclusion criteria .............................................................................................. 14  
   9.3.2. Exclusion criteria ............................................................................................ 14  
9.4. Instrumentation ....................................................................................................... 14  
9.5. Data collection ....................................................................................................... 14  
9.6. Pilot study ............................................................................................................... 15  
9.7. Reliability and validity ........................................................................................... 15
9.8. Data analysis ......................................................................................................................... 16
10. Ethical consideration ............................................................................................................. 16
11. Time Frame .......................................................................................................................... 17
12. Budget .................................................................................................................................. 18
13. Summary ............................................................................................................................... 18
14. Conclusion ............................................................................................................................. 18
15. References ............................................................................................................................. 19
1. Introduction

Health care is a vital component of modern society, presenting an enormous display of social, political, technological and economic challenges. Despite these challenges health care professionals strive to deliver the highest quality care possible. The primary indicator of a health care establishment’s success is its patient outcomes (Seavey, 2010: 462). The ability to provide impeccable preventative care consistently is of great importance to achieving the goal of reducing the overall cost of health care for patients and providers alike. Despite a growing emphasis on preventative care in the health care system, 51.4 million surgical procedures were performed in America in 2010 alone (Centers for Disease Control and Prevention [CDC], 2010), demonstrating the continued prominence of surgery in American health care. It is therefore of utmost importance that health care facilities improve the delivery of care for those undergoing surgery, who often represent the most vulnerable of patients. In order for a surgeon to have the best chance of performing a successful operation, he or she requires a proper set of sterile instruments. The Central Sterile Supply Department (CSSD) is responsible for this chain of tasks referred to as instrument reprocessing. It is a complex process driven by the needs of the operating rooms they support. Therefore, hospitals all over the world are working to improve their CSSDs to ensure safety and effectiveness. The Specialized Medical Centres is one of the largest healthcare systems in Saudi Arabia that delivers a wide variety of care to both National Guard children and adults. This study focused on one of these hospitals in Eastern region of Saudi Arabia. The researcher will study the causes of the missing instruments that occur in the CSSD of this hospital while utilizing an A-3 problem solving approach as recommended by The Specialized Medical Centres. Lean process improvement and a 5S methodology to drive change were implemented and the researcher will study the factors that influence the implementation. Lean is a method of increasing process efficiency by reducing non-value-added time. 5S is a Lean tool that increases efficiency and is characterized in the five steps of Sort, Set in Order, Standardize, Shine and Sustain. A3 is a problem solving process that can use Lean methods to bring improvements in the CSSD (Jacobs, Robert & Richard, 2013:100)
2. Background, rational and literature review

2.1 Introduction to Surgical Sets

A surgical set is a collection of instruments that can be used to help a surgeon in the performance of a surgery (Swanson, 2008:241). There are thousands of different surgical instruments set available and each set may contain hundreds of different individual instruments. Not every surgery will require every instrument in a particular set, but the goal of having large sets is to ensure that a surgeon will have everything that he or she may need to successfully complete an operation. Instruments are typically divided into three major categories; hand held, endoscopes, and powered tools (Swanson, 2008:241). Hand held instruments typically are divided further into forceps, scissors, retractors and needle holders. Endoscopes are instruments which can be introduced into the body to give a view of its internal parts. Powered instruments can be used for a variety of purpose; the only commonality between these instruments is the fact that they are battery operated. Almost every instrument comes in a variety of sizes that account for the differences in surgical areas of the body as well as the difference in sizes of a patient. Furthermore, a single instrument of one size could have many varieties based on which edges are sharp, what direction the blades curve if at all and how much of the tip of the instrument has ridges (Swanson, 2008:247).

2.2 Introduction to Sterile Processing Standards

The tasks of any CSSD technician begins immediately following the transportation of instrument sets used in an operating room procedures. The instruments are typically sorted and placed into closed containers and cart by the operating room nurses at the completion of an operation and are then to be moved to the CSSD decontamination area (Favero & Bond, 2015:881-917).

2.2.1 Decontamination process

The decontamination area is the location within the healthcare organization that is specified for the cleaning of all contaminated items. The CSSD staff should have the
proper knowledge on how to handle the equipment and choosing the correct cleaning techniques as per manufacturer instructions. It is important that health care facilities follow a good work practice and safety procedures to minimize the risk of possible exposure to pathogens in the decontamination area (Favero & Bond, 2015:881-917).

Correct size cleaning brushes are vital when cleaning instruments with lumens. The different disinfectant processes in the decontamination area include mechanical, ultrasonic, and manual cleaning. When selecting the type of method, the CSSD staff personnel who are assigned to this area should know the manufacturer's instructions for each instrument handled to avoid damage to the instruments and voiding the instruments' warranty (Hung & Lin, 2015:104, Huber, 2010:319-320).

2.2.2 Inspection and preparation

Clean instruments must be opened and disassembled to insure that all instruments are clean before sterilization. The instruments should be carefully assembled, checked, wrapped, and labelled in preparation for the sterilization process. The CSSD staff must be able to inspect the devices for cleanliness and proper functioning. It is important for the CSSD staff to demonstrate the proper knowledge and skills to maintain instruments in a safe manner (Jabbari, Alikhah, Alamdari, Behzad, Mehrabi, Borzui & Bakhshian, 2012:64-69). Some specialized instruments required certified CSSD staff to select the proper techniques for wrapping and carefully selection of which sterilization cycle to use according to the manufacture instructions (Kaushal, Doke, Shan & Mittal, 2015:282-285).

2.2.3 Sterilization process

The instruments to be sterilized must be properly identified and the correct methods and cycles are to be selected according the manufacture instruction of the instruments. The parameters for each sterilization cycle must be carefully followed for quality assurance. All values of the sterilization process must be understood and implemented by trained CSSD staff. Sterilizers must be operated by trained personnel and the quality assurance measurement must be carefully documented for future tracking and recall purpose (Sukhlecha, Vaya, Parmar & Chavda, 2015:1-6). The staff working in the sterilization areas must wear the appropriated attire according the health organization policy and
procedures, it is important that staff strictly follow the dress code to protect the environment from contamination (Avachat, Zambare & Phalke, 2012:77-79).

2.2.4 Sterile storage area

The CSSD has a dedicated area to store sterile instruments with positive ventilation systems and daily checking of temperature and humidity according to the organization policies and procedures (Swanson, 2008:241). Sterile storage starts as soon as the sterile instruments are unloaded from the sterilizer. According to the Joint Commission International standards (2012:20) to protect the sterile instruments from contamination staff in the OR and CSSD staff should consider the environmental factors. The area should be dry, clear from dust and a low traffic flow. Sterility maintenance covers (dust covers) may be used to protect sterilized devices/items that are use less than one month to maintain sterility. Cover sterile packs with sterility maintenance covers at the CSSD prior to distribution to the operating rooms (Shriyan, 2015:7-16).

Shelf life (expiration date) of patient care items and supplies sterilized by CSSD

Shelf life for surgical instruments processed in CSSD is ‘event-related’ and are delivered with a sterilization processing date (Swanson, 2008:241). Event-related refers to the sterility grounded on the appropriate care and storage of the instruments. If the sterile instruments are exposed to heat, water, or dust then the sterility has been compromised and it cannot be used for a patient procedure. The instruments should be immediately returned to the CSSD for reprocessing procedure (Joint Commission International standards, 2012:20). The reason for the event related should be documented and the infection control officer should be notified about the event (Joint Commission International standards, 2012:20). The OR nurses and CSSD staff should conduct regular audits to ensure that no expired instruments are stored in the sterile storage room; the use of expired sterile instruments can increase the risk for surgical site infection (Shriyan, 2015:7-16).
2.3 The Association for the Advancement of Medical Instrumentation (AAMI) Standards

AAMI is a widely recognized organization that determines standards to be followed by medical device manufacturers, health care technology technicians as well as by operating room nurses and CSSD technicians, (ANSI/AAMI ST79, 2017:200). According to AAMI each surgical instrument set must have a count sheet that promotes accountability and prevent delays in surgery because of missing instruments. Furthermore the Association of perioperative Registered Nurses (AORN) guidelines stated that healthcare organizations should weigh the risks versus the benefits of having a count sheet ready for each surgery and to emphasize to each operating room nurse the accountability of having the count sheet to prevent missing instruments in the perioperative area (Shriyan, 2015:7-16).

2.5 Sterile Processing Developments

CSSD technicians must be able to effectively communicate with those in the operating rooms to ensure the best patient outcomes by providing the appropriate instruments in surgical sets (Douglas, 2013:210). The job of a CSSD technician is complex; they must process large numbers of instruments and manage limited resources. The way that employees respond to these challenges impacts the patient directly (Ridak, 2012:230). Now more than ever, CSSD technicians must be knowledgeable about the different types of instrument and how they can best be used in surgeries to help patients and prevent cost overruns. With advance technology, it is crucial for CSSD technicians and managers to stay up to date on current corporate knowledge and technologies, in order to ensure their successful use that can decrease the number of missing instruments (Douglas, 2013:210).

Lean Improvement

Introduction to Lean

Lean is a systematic approach that impacts an entire business or organizational structure. The most basic elements of the methodology is identifying and eliminating
non-value added time or waste in a process through the utilization of Lean techniques and tools that will result in continuous improvement in the process. When taking a Lean approach to problem solving, it is important to understand the key concept of value-added time (Jacobs et al. 2013:110). Lean adds the “recognize and share achievement” step, an important aspect, especially when working in organizations with cross-functional teams, where some functional groups may not be in roles where they have the ability to witness the achievement in by way of their day-to-day work (Jacobs et al. 2013:110). Which in this study the research focus on the CSSD team whereas instruments are reported lost from the end-user

3. Problem statement
The Specialized Medical Centre reported a 40% missing instrument rate in surgical instruments from January 2014 through July 2014. The problem was identified when surgical procedures had to be cancelled due to lack of surgical instruments. A review of the literature has shown the researcher that each CSSD employee has to follow the workflow on how to handle, inspect, and count each instrument according to the policies and procedures of the organization as well as AAMI and AORN international standards.

4. Research question
The following question guides the proposed research study: What are the factors that influence the implementation of the lean process improvement in CSSD to reduce the rate of missing instruments?

5. Research hypothesis
CSSD teams that adhere to the lean process improvements understand the impact of their task on the patient that undergoes surgical procedures than those who do not adhere or who does not understand the patient care outcomes.
6. Aim
The goal of this project was to reduce the rate of missing instruments within the Central Sterile Supply Department (CSSD) by approximately 100%. The approach of this topic under study overall followed an A3, which is a method of problem solving that involves defining a problem, determining the initial state, determining root causes, developing goals, and countermeasures and implementing change.

7. Objectives
The objectives of the study are to determine whether CSSD technicians and leadership that are knowledgeable about surgical procedures and the patient outcomes are:

- More complaint to the international standards
- More willing to use the lean process to improve the counting of surgical instruments in CSSD.

8. Conceptual Framework
A conceptual framework is the key part of any research that explains the concepts to the study. Furthermore it is also identified as a relationship between the concepts in the propose research study (Grove, Gray & Burn, 2015:163). The conceptual frame work is used to make conceptual differences and to unify ideas. The designed conceptual frame work guides the researcher in reconnoitering the factors that influenced the effective management of surgical instruments in the perioperative rooms and central sterile supply departments. Figure 1 shows the appropriate and inter-related factors that influence effective management of surgical instruments which start at the point of use, cleaning and transportation, decontamination, inspection and preparation for sterilization, sterilization process, sterile storage, and shelf life. Figure 2 explains these factors, and figure 3 illustrates the outcome of effective management of surgical instruments which are patient and organizational outcomes.
Effective management of surgical instruments. At all stages standard policies and procedures should be followed.
8.2. Figure 2. A Systematic explanation framework of the reprocessing procedure of surgical instruments
9. Research Methodology

9.1 Research design

The proposed study will follow a quantitative design. A quantitative approach with a descriptive design will be applied for the purpose of this study. A descriptive design is used to gain more information about the characteristics within a particular field of study (Burns & Grove, 2015:210). A descriptive design is also applied to develop theories and identify problems with current practice and does not entail manipulation of variables (Burns & Grove, 2015:212).

9.2. Study setting

The study will take place at one of the Specialized Medical Centres in Saudi Arabia. The Specialized Medical Centre have 450 beds are the largest Medical Centres in the eastern region of Saudi Arabia.

9.3. Population and sampling

Burns and Grove (2015:249) define a study population as all individuals that meet certain criteria for inclusion into a specific study. A sample is a subset of the population that is selected for the specific study. Sampling is defined as the process of selecting a group of people that is representative of the population with which to conduct the study (Burns & Grove, 2018:250). For the purpose of this study, the target population (CSSD Staff= 45) includes all CSSD staff that are working in the Operating room, Dental clinics and in the Endoscopic departments.

Table 1.1: Study population

<table>
<thead>
<tr>
<th>Specialized Medical Centre</th>
<th>CSSD staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Central Sterile Supply Department</td>
<td>25</td>
</tr>
<tr>
<td>2. Dental Clinic</td>
<td>3</td>
</tr>
<tr>
<td>3. Endoscopy Department</td>
<td>2</td>
</tr>
<tr>
<td>4. Operating room</td>
<td>5</td>
</tr>
<tr>
<td>Total Population</td>
<td>45</td>
</tr>
</tbody>
</table>
Both day and night staff registered professional nurses will be targeted.

9.3.1. Inclusion criteria

- All CSSD staff
- Both day and night duty staff members will be targeted.

9.3.2. Exclusion criteria

CSSD staff that are on vacation

9.4. Instrumentation

De Vos et al. (2011:186) define a questionnaire as a document containing questions designed to request information appropriate for analysis. A self-administered questionnaire was designed and is based on the objectives of the study, the literature and the researchers’ personal experience. The questionnaire consists of two sections. Section A consists of questions on the respondents’ biographical data. Section B consists of Likert scale and open-ended questions concerning the factors influencing the implementation of the lean process improvement in CSSD.

9.5. Data collection

The researcher will collect the data. The questionnaires will be delivered by hand in a sealed envelope so that the respondents can complete them in their own time. The questionnaires will be collected later the same day. Table 1.2 illustrates the plan for data collection. The researcher will also do observation to observe the workflow of the CSSD and where the surgical instruments get lost.
9.6. Pilot study

De Vos et al. (2011: 237) define a pilot study as a procedure for testing and validating an instrument by administering it to a small group of participants from the intended test population. A pilot study will therefore be done prior to the initiation of the main study to ensure that the questionnaire is suitable and to determine whether the proposed study is feasible. According to Burns and Grove (2015:45-46) the pilot study will also assist in identifying problems that relates to the design of the study and the researcher has the opportunity to gain experience with the subjects, the setting and the methodology. The pilot study will be done at another hospital the same area during which the questionnaire will be issued to five participants in order to ensure the validity and reliability of the instrument. The results of the pilot study will not be included in the actual study.

9.7. Reliability and validity

LoBiondo-Wood and Haber (2010:286) refers to reliability as the ability of an instrument to measure the quality of a concept or construct consistently. Validity refers to the degree to which an instrument measures the attributes of a concept accurately (LoBiondo-Wood & Haber, 2010:286). Content validity represents the universe of content, or the domain of a given construct. Content validity is concerned with whether the measurement instrument and the items it contains are representative of the content domain that the researcher intends to measure (LoBiondo-Wood & Haber, 2010:288). Therefore the questions contained in the questionnaire concern possible factors that could influence the retention of new nurse graduates. Content validity of the instrument was further enhanced by utilising the input of an expert in the field, in this case, the team leader for nursing management at Stellenbosch University and who is also the co-supervisor of this study.

Construct validity on the other hand is based on the extent to which a test measures a theoretical construct, attribute, or trait (LoBiondo-Wood & Haber, 2010:288-290). As mentioned earlier a pilot study will be done to validate the data collection instrument. The instrument was examined by the supervisor and the statistician involved.
9.8. Data analysis

According to De Vos et al. (2011:249) quantitative data analysis is the technique used to convert data to a numerical form and subject it to statistical analysis. Data analysis enables the investigator to draw conclusions from the new found data. The data can be analysed manually or by computer (De Vos et al., 2011:249). For the purpose of this study a qualified statistician employed at Stellenbosch University will assist with data analysis and interpretation.

10. Ethical consideration

Ethical approval to conduct the study will be obtained from the Health Research Ethical Committee at Stellenbosch University. The researcher will abide by the ethic statement once my proposal has been approved by the ethics committee. Furthermore permission to conduct the study at the specific hospitals will be obtained from the chairperson of Specialized Medical Centre and the CSSD nurse managers and directors.

The respondents will be informed that participation is completely voluntary and no one will be forced to participate in the study. The respondents will not be harmed in any physical or emotional manner. The respondents will also be informed that they are allowed to withdraw from the study at any time without penalty.

Personal privacy, confidentiality of all information obtained and anonymity will be ensured at all times. Privacy can be defined as the ability to keep to oneself that which is normally not intended for others to observe or analyse (De Vos et al., 2011:119). Confidentiality indicates the handling of all information in a confidential manner (De Vos et al., 2011:119). Confidentiality will be ensured by non-disclosure of the names of all the nurses participating in the study. Anonymity will be ensured by providing the data collection instrument to the respondent in a sealed envelope and the participant will be advised to return the instrument, nameless, in the sealed envelope. Anonymity of respondents will also ensure privacy. Deception of respondents will be avoided by providing the respondent correct information regarding the study for example the aim of the study. The researcher will therefore not mislead the subject in any manner.
Furthermore only the researcher, the statistician, supervisor and co-supervisor will have access to the collected data. All questionnaires will be kept in a locked cabinet for at least 5 years once analysis is completed.

Publications of the findings after completion of the research will be done as accurately and objectively as possible. Findings should be communicated to the respondent as a form of recognition as advised by De Vos et al. (2011:136).

11. Time Frame
The time frame for the study is illustrated in the table below:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature review</td>
<td>Continuously</td>
</tr>
<tr>
<td>Data collection instrument</td>
<td>August-September 2018</td>
</tr>
<tr>
<td>Research Proposal</td>
<td>September 2018</td>
</tr>
<tr>
<td>Submit for ethical approval</td>
<td>January 2019</td>
</tr>
<tr>
<td>Pilot study</td>
<td>March 2019</td>
</tr>
<tr>
<td>Data collection</td>
<td>April-May 2019</td>
</tr>
<tr>
<td>Data analyses and interpretation of data</td>
<td>May –June 2019</td>
</tr>
<tr>
<td>Research Thesis</td>
<td>July – August 2019</td>
</tr>
<tr>
<td>Technical and grammar editing</td>
<td>September 2019</td>
</tr>
<tr>
<td>Submission of Thesis</td>
<td>October 2019</td>
</tr>
<tr>
<td>Graduation</td>
<td>December 2019</td>
</tr>
</tbody>
</table>
12. Budget
Table 2: Study budget

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone and Internet</td>
<td>1000</td>
</tr>
<tr>
<td>Stationery</td>
<td>1500</td>
</tr>
<tr>
<td>Travel Expenses</td>
<td>3800</td>
</tr>
<tr>
<td>Language and Technical Editing</td>
<td>6000</td>
</tr>
<tr>
<td>Binding of Thesis</td>
<td>3500</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>2000</td>
</tr>
<tr>
<td>Total expenditure</td>
<td>Zar 17800</td>
</tr>
</tbody>
</table>

13. Summary
Implementing the lean process improvement can help in the CSSD can go a long way towards reducing the missing of the instruments. With everyone on the team working together to ensure that all instruments are adequately cleaned, decontaminated, inspected, repaired, packaged, and sterilized, the patients will receive the quality of surgical care they expect and deserve. The research methodology clearly outlines the steps when the research is initiated, during the research and how finding will be used.

14. Conclusion
Proper instrument management requires good collaboration to help teams in the OR and CSSD to protect the health facilities surgical instruments to increase patient safety and
decrease the enormous amount of missing instruments. The lean process improvement was already implemented in the Specialized Medical Centers, but there are factors that influenced the proper implementation of the improvement process in the CSSD to reduce the amount of missing instruments. The researcher aims to study the reasons that instruments are getting lost during the workflow of CSSD technicians and why the lean process improvements are not implemented in the CSSD.

15. References


Joint Commission identifies top standards compliance issues for 2011. *Joint Commission Perspectives* 2012 Apr; 32(4):1, 6-11


Shriyan, A. A study on the efficiency of CSSD at a health care center, *TJPRC: Journal of Nursing and Patient Safety & Care (TJPRC: JNPSC), 1(2),* Dec 2015, 7-16