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Assessing the Relation between Quality and Sustainability in the Operating Room

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ASSESSING THE RELATION BETWEEN QUALITY AND SUSTAINABILITY IN THE OPERATING ROOM

A Thesis

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Abstract

Maintaining quality at an affordable cost has been a major challenge for many healthcare organizations. Healthcare providers are trying to address this issue while protecting the environment, meeting social responsibilities and contributing to sustainable development of systems. Instead of linking quality with just clinical outcomes, healthcare services are trying to view quality and safety as part of professional ethics or "the right thing to do." In order to provide a framework for quality assessment in healthcare systems, the Institute of Medicine (IOM) pointed out that the system should have the following six aims: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.

Sustainability in healthcare can be defined as a balance of the needs of patients, economic concerns, and environmental costs. The concept of sustainability is defined by three main pillars: economic development, social development and environmental protection. This thesis provides an understanding regarding the causal relations between variables that lead to overall long-term sustainability of operating rooms (ORs), which will in turn help hospitals establish a framework to evaluate sustainable development.

The objective of this thesis is to discuss how the variables that occur during a total knee arthroplasty (TKA) procedure can affect quality dimensions: efficiency, effectiveness, safety, patient-centeredness, timeliness and equitability, and illustrate their association with the economic, social, and environmental components of sustainability. This thesis is divided into two major chapters. The second chapter lists variables observed in an OR during the time of surgery and portrays the cause-effect relationship between the variables and the six quality aims for each component of sustainability by using causal loop diagrams (CLDs). Using the results obtained at the end of second chapter, all the variables were made into a checklist, which is discussed in the

third chapter. It was validated by an expert panel consisting of a surgeon, lean and six sigma expert, and supply chain expert. Therefore, this study identified variables that affect the quality dimensions and thereby, OR sustainability. The checklist can be used to evaluate sustainability of the practices in OR.

Chapter 1. Introduction

Maintaining quality at an affordable cost has been a major challenge for many healthcare organizations. Healthcare providers are trying to address this challenge along with protecting the environment and meeting social responsibilities towards the community, patients and staff (Marimuthu & Paulose, 2016; Hampton, 2007). Jameton & McGuire (2002) defined sustainability in healthcare as a balance of the needs of patients, economic concerns, and environmental costs. Sustainability in healthcare gave the definition of "Triple Bottom Line" in order to provide better patient care, improve population health and reduce per capita cost (Wolff, 2013). In order to address the quality challenges while simultaneously improving cost efficiencies and patient safety, healthcare systems are adopting the concept of "Triple Bottom Line," with an objective to extend the goal of sustainability to the organization, people, and the planet itself (Slaper & Hall, 2011).

1.1. Sustaining Quality

Healthcare services, instead of linking quality with just clinical outcomes, are trying to view quality and safety as part of professional ethics or "the right thing to do" (Keroack et al., 2007). In order to provide a framework for quality assessment in healthcare systems, the Institute of Medicine (IOM) pointed out that the system should have the following six aims: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (Institute of Medicine (US) Committee on Quality of Health Care in America, 2001). Many care organizations have already implemented different techniques, like six-sigma, lean or total quality management, in order to achieve a cost or quality gain, but there is a whole new challenge that is evolving: sustaining that gain (VanEtten, 2013).

The concept of sustainability was generated due to awareness of the possible ecological crisis around the end of the 20th century to address concerns for preserving natural resources for the future (Du Pisani, 2006). The International Survey of Corporate Sustainability Reporting defined sustainability as including “quantitative and qualitative information on their financial/economic, social/ethical and environmental performance in a balanced way” (p. 7) (KPMG BV (Amsterdam), 2002). The concept of sustainability is defined by three main pillars: economic development, social development and environmental protection (World Commission on Environment and Development, 1987). The understanding of sustainability and sustainable development is the same in this study and can be used interchangeably, as done by previous researchers (Faezipour & Ferreira, 2011; Fischer, 2014).

This study considers quality and sustainability as equally important and inter-dependent factors in healthcare. Neglecting quality eventually leads to a reduced timely, efficient, safe, equal, effective and patient-centered delivery of the services and thereby drop in patients’ satisfaction (Prakash, 2010). However, even if the quality is monitored and maintained for years, when the sustainability is not prioritized, quality improvement of the system will eventually lose the ability for the integration and acknowledgement of economic, environmental, and social concerns throughout the decision-making process (Slaper & Hall, 2011). Figure 1 describes the scope of the components of sustainability with considering quality as equivalent to sustainability variables. The outer circle of the diagram represents the six dimensions of quality and the three components of the inner circle represent the components of sustainability. The study asserts that the changes in any of the variables (either quality or sustainability) will ultimately affect both sustainability and quality gains in the system, by studying the sustainability challenges with respect to the quality problems.

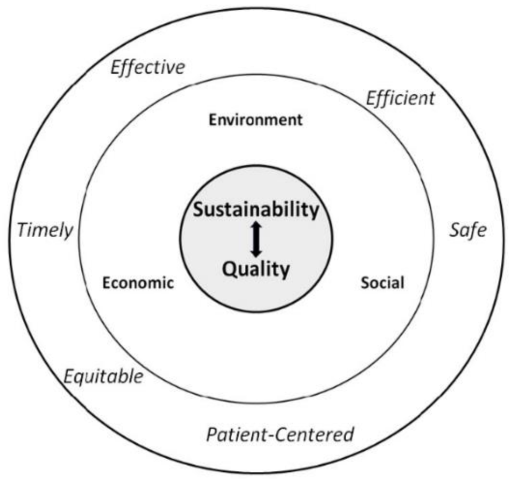

Figure 1. Interrelations between Quality Dimensions and Sustainability Components

1.2. Motivation: Sustainability Challenges

A healthcare system has a complicated structure which puts it through continuous constraints: technological, economic or political (Capolongo et al., 2016). Challenges a healthcare system face includes increasing quality standards and higher patient expectations, increasing costs of medical technologies and medication and restricted resources (Coiera & Hovenga, 2007).

Another major challenge in healthcare is the ineffective utilization of resources. According to the 2009 report by the Institute of Medicine, roughly 30% of the money spent on healthcare, around $750 billion, was wasted on unnecessary or inefficient services ("IOM: 30% of health spending was waste," 2012). The Institute of Medicine's (IOM) National Roundtable on Healthcare Quality reported three kinds of quality problems: overuse, underuse, and misuse (Institute of Medicine (US) Committee on Quality of Health Care in America, 2001). Overuse is the provision of a healthcare service where the potential for harm exceeds the possible benefits, while underuse is the inability to provide a proper service to a patient, and misuse can be an appropriate service provided, but due to the occurrence of some unexpected complication, which

could be preventable, the patient does not receive the full potential benefit of the service (Chassin, Galvin, & the National Roundtable on Health Care Quality, 1998).

Overuse and unnecessary care account up to 50% of all healthcare costs, in addition to the half-a-trillion dollars per year that experts attribute to lost productivity and disability (Binder, 2013). In a study conducted by McGlynn et al., 2003, participants received only about half of the recommended processes involved in care. According to the latest survey, 75% of patients were unable to identify the clinician responsible for their care, about 66% of patients do not know how much their care costs until the point that they get a bill, and less than half were receiving clear information on the benefits and trade-offs before undergoing treatments (“Opinion | Waste in the Health Care System,” 2012). Healthcare misuse is another term for committing medical errors. *To Err is Human* estimated that from 44,000 to 98,000 people die in U.S. hospitals due to preventable medical errors (2000).

The motivation behind this study is to explore the interrelations between the six quality aims and the three components of sustainability, in total knee arthroplasty (TKA). This study specifically assesses the sustainable development of an operating room (OR) by finding the variables that affect the efficiency, effectiveness, equitability, safety, patient-centeredness, and timeliness of the process.

1.3. Scope and Objective

This thesis explores how the economic, social, and ecological factors of healthcare sustainability are related to quality using a system dynamics approach, with a case study in TKA. TKA is a safe and effective procedure to relieve pain and correct leg deformity when nonsurgical treatments like medications and using walking supports are no longer helpful (“Total Knee Replacement,” 2015). The objective of this study is to address how the variables that occur during

a TKA procedure can affect quality dimensions- efficiency, effectiveness, safety, patient-centeredness, timeliness and equitability, and illustrate their association with the economic, social, and environmental components of sustainability by using causal loop diagrams (CLDs). CLD is a basic form of representation in system dynamics modeling, visualizes cause-effect relation between different variables in a system. These interrelations will in turn help hospitals establish a framework to evaluate sustainable development. This thesis is divided into two major chapters. Second chapter lists variables observed in an OR during the time of surgery and portrays the cause-effect relationship between the variables and the six quality aims for each component of sustainability by using causal loop diagrams (CLDs). Using the results obtained from the chapter 2, all the variables were made into a checklist, which is discussed in the third chapter. The checklist was validated by an expert panel consisting of a surgeon, lean and six sigma expert, and supply chain expert. This thesis will answer the following research questions:

1. What are the economic, social, and ecological barriers faced during TKA?
2. Can a system dynamic approach model the relationship between quality and sustainability in healthcare?
3. What does the outcome of the causal loop diagram modeling quality and sustainability during TKA look like?

Chapter 2. Assessing the Relationship Between Quality and Sustainability in the Operating Rooms through Causal Loop Diagrams

2.1. Introduction

Maintaining quality at an affordable cost has been a major challenge for many healthcare organizations. Quality in healthcare systems is not just restricted to the clinical outcomes but is viewed as part of professional ethics or "the right thing to do," (Keroack et al., 2007). In order to provide a framework for a better quality assessment in healthcare systems, the Institute of Medicine (IOM) proposed six aims: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (Institute of Medicine (US) Committee on Quality of Health Care in America, 2001). Care organizations have already been implementing different types of techniques, like six-sigma, lean or total quality management, in order to achieve a cost or quality gain, but the next challenge is sustaining that gain (VanEtten, 2013). Therefore, healthcare organizations are shifting towards sustaining quality.

A sustainable healthcare organization is defined to "have a clear purpose and consistently find ways to maintain that purpose despite significant changes to the world around them" (p. 11) (Coiera & Hovenga, 2007). The concept of sustainability is defined by three main pillars: economic development, social development and environmental protection (World Commission on Environment and Development, 1987). A study from the Commonwealth Fund found that hospital sustainability efforts could save the healthcare industry up to $5.4 billion over five years and $15 billion over 10 years (Brimmer, 2012). The assurance of sustainability in healthcare operations would result in both financial and quality improvements for healthcare (Tudor, 2007). The understanding of sustainability and sustainable development is the same in this study and the terms can be used interchangeably, as done by previous researchers (Faezipour & Ferreira, 2011; Fischer, 2014).

Healthcare systems have a complicated structure with continuous technological, economic and political constraints (Capolongo et al., 2016). Challenges the healthcare system face include increasing complexity, increasing demands, increasing costs of medical technologies and medication, higher patient expectations, and restricted resources (Coiera & Hovenga, 2007). Apart from these, another major challenge in healthcare is the ineffective utilization of resources. Roughly 30% of the money spent on healthcare, almost around $750 billion, is wasted on unnecessary or inefficient services (IOM: 30% of health spending was waste, 2012).

The motivation behind this study is to understand causal relations between variables related to the commitment towards quality improvement and overall long-term sustainability of the operating rooms (ORs), which will in turn help hospitals establish a framework to evaluate sustainable development. This chapter explores the interrelations between the six quality aims and the three components of sustainability, in total knee arthroplasty (TKA), using a system dynamics approach. System dynamics is a modeling and simulation methodology used for understanding nonlinear behavior of complex systems by involving the interaction between the variables through feedback loops, where a change in one variable influences the changes in other variables over time, which in turn is related to the original variable, and so on (Forrester, 1961). Causal Loop Diagram (CLD) is a basic form of representation in system dynamics modeling that can visualize cause-effect relations between variables in a system.

2.2. Literature Review

2.2.1. Quality and Lean Wastes

The Institute of Medicine's (IOM) National Roundtable on Healthcare Quality reported three kinds of quality problems: overuse, underuse, and misuse (Institute of Medicine (US) Committee on Quality of Health Care in America, 2001). Overuse is the provision of a healthcare

service where the potential for harm exceeds the possible benefits, while underuse is the inability to provide a proper service to a patient, and misuse can be an appropriate service provided, but due to the occurrence of some unexpected complication, which could be preventable, the patient does not receive the full potential benefit of the service (Chassin et al., 1998).

Overuse and unnecessary care account for up to 50% of all healthcare costs, in addition to the half-a-trillion dollars per year experts, attribute to lost productivity and disability (Binder, 2013). In a study conducted by McGlynn et al., (2003), the participants received only about half of the recommended processes involved in care. According to a survey, 75% of patients were unable to identify the clinician responsible for their care, about 66% of patients don’t know how much their care costs until the point that they get a bill, and less than half were receiving clear information on the benefits and trade-offs before undergoing treatments (“Opinion | Waste in the Health Care System,” 2012). Healthcare misuse is another term for committing medical errors. *To Err is Human* estimated that from 44,000 to 98,000 people die in U.S. hospitals due to preventable medical errors (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000).

Quality problems, even when detected quickly, might slow down the process, waste time and require correction. This impacts the overall efficiency and leads to increased costs. In order to eliminate such quality defects, the most essential step is to identify them. Implementation of lean techniques emphasizes on eliminating waste in all forms. Hospitals are seeing the need to improve the quality of delivery methods and processes by reducing waste (non-value-added components). Therefore, by adopting lean techniques, hospital management can start seeing quality improvement as a way reduce costs. One of the core principles of lean is to eliminate waste, which is defined as activities that do not add value to the customer or the process. Table 1 illustrates possible wastes

that can incur in the OR through a lean perspective with examples of variables that will be used in the current study.

Table 1. Various Possible Wastes that can Incur in the OR

Waste	Examples	Related Variable
Defects	Instrument defects Broken parts (instruments that need servicing) Contamination of instruments or holes in blue wraps	Total time delay due to instrument Number of instrument defects
Waiting (time on hand)	Time delays due to waiting on instruments	Total time delay due to instrument
	Turnover time between the surgeries	Turnover Time
Transportation	Overcrowding of the OR	Unnecessary traffic in OR
Over processing	Over usage of disposable materials	Segregation of wastes into trash bags
	Allocation of staff (unnecessary presence of an employee)	Number of staff present
	Unnecessary usage of supplies per surgery (drugs, instruments, linens, rags, sponges, needles, etc.)	Percentage of unused instruments per surgery
Non-Utilized Talent	Non-value-added time of each personnel during their stay in OR	Percentage of non-value-added time
	Employees not fully trained	Experience of the staff
Unnecessary/ Excess Motion	Walking in and out of the "blue-zone" area	Unnecessary traffic in OR
Inventory	Extra stocking of instruments, implants prior to surgeries	Unnecessary usage of instruments per surgery

2.2.2. Quality and Sustainability

Maintaining quality involves establishing the connections between all the components of sustainability and thereby helping in achieving better patient outcomes, better system performance and better professional development (Batalden & Davidoff, 2007). This study considers quality and sustainability as equally important and inter-dependent factors in healthcare. Neglecting quality eventually leads to a reduced timely, efficient, safe, equal, effective and patient-centered delivery of the services and thereby drop in patients' satisfaction (Prakash, 2010). However, even

if the quality is monitored and maintained for years, when the sustainability is not prioritized, quality improvement of the system will eventually lose the ability for the integration and acknowledgement of economic, environmental, and social concerns throughout the decision-making process (Slaper & Hall, 2011).

Figure 2 describes the interrelation between quality and sustainability components by assuming that changes in the quality factors affect sustainability factors and vice versa. The outer circle of the diagram represents the six dimensions of quality and the three components of the inner circle represent the components of sustainability. Changes in any of the variables (either quality or sustainability) will ultimately affect both sustainability and quality gains in the system.

Figure 2. Relation between Quality and Sustainability

2.2.3. Causal Loop Diagrams

A causal loop diagram (CLD) is an important system dynamics tool that captures the feedback structure of the system. It is a qualitative method for visualizing how different variables in a system are interrelated and how they influence each other to create system thinking. (Causal Loop Diagram-Tool/Concept/Definition, n.d.). They bring out the systematic feedback in processes by showing how variable X affects variable Y and, in turn, how variable Y affects

variable Z through a chain of causes and effects. With the help of CLDs, behavior of the problem can be predicted by drawing a mental model (Haraldsson, 2004).

A CLD is used to map the cause-effect relationship between different variables within the system. The two variables are linked with an arrow with one of the two states of polarity, positive (+) or negative (-). The arrow starts from the "cause" variable and goes into the "effect" variable. The positive polarity of the linkage denotes that the increase (decrease) in the cause variable will lead to an increase (decrease) in the effect variable, all else being equal. Thus, both variables move in the same direction. On the other hand, the negative polarity designates that the increase (decrease) in the cause variable will lead to a decrease (increase) in the effect variable, all else being equal (Sterman, 2000). Thus, the variables move in the opposite direction. Although, CLDs cannot represent the fact that the current levels of variables influence other variables' behavior; neither can they help represent how these influences work.

2.2.4. Research Gaps

A study done by Faezipour & Ferreira (2011), explained the complexity of the healthcare system and addressed sustainability challenges by using CLDs. The authors described healthcare as a complex system of systems and framed the objective to effectively represent the complexity. The study tried to bring a better understanding towards the categories (quality, patient, provider, financial, environmental/energy, resources) that could be used as a basis to build a sustainable healthcare framework. Their study was based on an extensive literature search done on healthcare sustainability. Each category included variables that were used in building the causal models for sustainable healthcare system. The quality included patients' safety, effectiveness of services, staff efficiency, accessibility to services and resources, staff morale and ethical behaviour, and provision of equal services to the patients. The authors proposed additional approaches and

considerations like performing “what-if” analysis or considering the significance of emerging technologies and markets from the results obtained from the CLDs to address sustainability challenges.

Although the study identified key factors and provided a strong internal validity, the major drawback of this study is the factors identified by the authors to affect the healthcare sustainability were vague and cannot be measured. The authors developed various sustainability indicators to provide a starting point to measure and important engineering metrics in understanding healthcare sustainability. But the authors provided an example for each of the six sustainability categories they initially defined. Another research gap of this study is that it excluded studying factors influencing the OR sustainability which contributes majorly to any hospitals’ sustainability. In any healthcare organization, ORs constitute a major portion of earnings, and that is where a majority of the payers’ money is going. Variables such as value-added/non-value-added time of the staff, staff communication, total surgery time, segregation of trash, etc. would have been obtained only through direct observation of a surgery.

Another research which used CLDs was done by Kiani, Gholamian, Hamzehei, & Hosseini (2009). The main objective of this chapter was to use CLD as a useful tool to capture the structure of e-Business systems in order to achieve a better understanding of an e-Business model. The authors divided the entire business model into four areas: product, customer interface, infrastructure management and financial aspects, which were considered as four pillars for the model. These factors were further divided into components which acted like “building blocks” for the study. Each building block had a loop with the variables related to each other. These factors were not included in the CLD as variables but just acted as the framework to the final causal loop diagram. So, the entire CLD is divided into 4 different sections without creating any kind of

clustering of variables and avoiding confusion. While not specifically related to healthcare, this study demonstrates the use of CLDs in industry.

Despite a few studies available regarding the sustainability of a healthcare organization, there is a dearth of research concerned about the sustainability of ORs specifically, especially using a system dynamics approach. With an objective of addressing this gap in the literature, this chapter discusses how the variables that occur during a TKA procedure can affect quality dimensions: efficiency, effectiveness, safety, patient-centeredness, timeliness and equitability, and illustrate their association to the economic, social, and environmental components of sustainability by using CLDs. These variables set metrics and indicators in order to assess the sustainability. Therefore, by investigating the relation between the variables for each component of sustainability, their effect on sustainability can be measured and assessed. This leads to three main research questions for the current study:

1. What are the economic, social, and ecological barriers faced during TKA?
2. Can a system dynamic approach model the relationship between quality and sustainability in healthcare?
3. What does the outcome of the CLD modeling quality and sustainability during TKA look like?

2.3. Methods

In this study, the cause-effect relationship between the variables that affect the quality and thereby sustainability of an OR were illustrated using CLDs. The initial process involved defining variables influencing quality and sustainability through direct observation of the surgeries and through an extensive review of similar studies. The end diagram was segmented into three separate CLDs for economic, social and environment components of sustainability. Therefore, each CLD

had cause-effect relationships between the variables that were contributing towards that particular component. A table, corresponding to each diagram, included the source of each variable. The validity of the variables was evaluated by a follow-up interview with an expert panel consisting of a surgeon, supply chain administrator, and lean and quality control professional. Final CLDs show the relation between the essential variables that can affect quality and sustainable development.

The three diagrams explain the variables contributing towards economic, social and environmental sustainability respectively and are categorized through the six quality dimensions of efficiency, effectiveness, equitability, timeliness, safety, and patient-centeredness. While some variables contribute positively towards OR quality improvement, some cause delay in the process and are not beneficial to the customers. Such variables were considered as “barriers” or “wastes” or “non-value-added.” Table 1 describes the examples and definitions of such wastes that can occur in an OR.

2.3.1. Causal Modeling

The purpose of using CLDs was to improve understanding of the relationships between significant quality variables in an OR and illustrate how they were related to the three components of sustainability. All the variables collected through direct observation of the surgeries, extensive literature review, and expert panel input (causes) were categorized into three diagrams. In each diagram, variables leading to certain quality dimensions are connected by arrows. The variables collected through observing TKA surgeries were labelled as the case-study variables and the remaining variables obtained through literature review and expert panel input were labelled as ideal variables.

After determining the influential variables in the study, the next step was to draw the causal relationships between the variables and their effects on each other. Vensim™, the Ventana ® Simulation Environment, was used to create the CLDs. Vensim is an interactive software that allows the development, exploration, analysis, and optimization of simulation models (Eberlein & Peterson, 1992).

2.3.2. Data Collection

For the purpose of the case study, the variables were observed during 13 TKA surgeries. This study followed IRB-approved data collection procedures (Appendix II). The data was obtained in 2015 and 2017 at two sites and three surgeons. The patients requiring primary unilateral TKA, generally 60 years of age or older were considered as the participants for the study. Two researchers attended each surgery to collect data and stayed in the OR for the entire time of surgery. The researchers were only allowed to take photos of the instruments, tables, and stands; but not allowed to take pictures of any individuals. To follow the safety rules, the researchers were not allowed to touch any instruments or enter the sterile sections of the OR.

Prior to the data observation, the team made time study and work sampling sheets for collecting the data in the ORs (Appendix I). Variables such as total surgery time, time for the entire surgical episode, weights/ number of the trash bags, and number of staff in the OR were derived from the time study data collection sheet for the OR. Staff resource utilization was obtained from the work sampling sheets. Accessibility to equipment was obtained from the design layout of the OR. Time delayed for the surgeon due to the instruments had been noted either on the work sampling sheet or time study sheet. The presence of the computer-assisted navigation system was noted in the time study sheet. These observations inspired the list of variables that might affect sustainability and quality outcomes.

2.3.3. Literature Review

A few variables during the surgery are important for assessing the sustainability in the OR but were outside the scope of data collection. These variables were obtained from an extensive literature review. Platforms for electronic database of literature such as Google Scholar, PubMed and Web of Science were used for the search of previous studies linked to sustainability and quality in healthcare systems. There was limited work done in sustainability of TKA procedures or even linking quality and sustainability. Therefore, similar studies or relevant studies have been considered and benchmarked to suit this current study. Although some of the references did not directly point out influences on OR sustainability, they studied the relation to a corresponding quality factor which would thereby affect a sustainability component. The list of sources for the study of economic sustainability, social sustainability, and environmental sustainability are included in tables 2, 3 and 4 respectively.

2.3.4. Follow-up Interview Sessions

After defining potential variables through observations and literature review, a panel of 3 experts; a surgeon, a supply chain administrator, and a lean and quality control professional; were interviewed to validate the variables in this study. All the variables were categorized into three different lists: Economic, Social, Environment. Each list was sub-categorized into six quality dimensions: effectiveness, efficiency, timeliness, patient-centeredness, equitability, and safety. The lists were given to experts during the interview. An abstract was made to summarize the study (and their role in validating the variables collected as a part of the study) and given along with the sheets (Appendix III). The panel provided their specialized input and opinion regarding the variables. All the interviews were documented in writing. Each member expressed their opinion for variables and mentioned difficulties that might be present in measuring some variables in the

list. At the end of the interview, a few variables were added as they proved to be necessary for overall sustainability of the OR.

2.3.5. Creating the Final CLDs with the Variables Obtained

All the variables were divided into three categories: economic sustainability, social sustainability and environment sustainability. Accordingly, three CLDs corresponding to each category of sustainability were drawn to relate the variables towards each quality component (efficiency, effectiveness, safety, equitability, timeliness, patient-centeredness). All the diagrams were made in Vensim® software. Each variable was connected to one or more variables depending on the relationship between the variables. The relation between the variables was shown by the +/- sign present at the end of each arrowhead.

2.4. Results

The purpose of this study is to determine the possible variables that could affect quality improvement and sustainable development in an OR. A myriad of factors arose during data collection that contribute towards reduced costs, wastes and improved quality. Tables 2, 3 and 4 summarize the list of variables contributing towards the economic, social and environmental sustainability in ORs. The models were derived from the data collected by observing the TKA surgeries, the literature review, and the expert panel input.

2.4.1. Economic Sustainability

CLDs portray the relation between the variables and their connection to the quality dimensions. The OR economic sustainability is affected by changes in the economic efficiency, effectiveness, safety, timeliness and equitability. During the direct observation, the team found variables such as total OR time, total surgery time, patient prep time, total delay time caused due

to instruments, total weight and segregation of the trash affect the OR quality. Total OR time contributed toward both efficiency and timeliness of the OR staff. Reduced pre-operative patient prep time, adopting safe surgical procedures and timely finished turnaround time contributed to an efficient OR.

The CLD for economic sustainability did not include patient-centeredness. Although there were patient-centeredness related variables that can affect the economic sustainability in a healthcare system such as adopting alternative payment methods or cost containment strategies of companies, this study is restricted to OR, so patient-centered variables were outside of the scope of the economic sustainability CLD.

Variables such as turnaround time, paycheck satisfaction, loss of revenue due to over-usage of the ORs, cost of trash disposal, and cost incurred in sterile processing of the instrument were added into the study during the literature review. Satisfaction over pay may impact the attitudes and behaviors of the employees in an organization (Singh & Loncar, 2010), which may in turn affect effectiveness and equitability. Previous studies suggested that if the staff goes over the allotted time, there will be a loss in revenue due to over usage of the OR, which could affect the OR efficiency both in time and money (Madni et al., 2018). In some cases, surgeries were cancelled within the 24 hours of the scheduled day of the surgery, which negatively impacts OR efficiency.

The quality of an OR is also judged by timeliness of the staff. Variables such as total OR time and turnaround time are important in deciding the timeliness of OR staff. The interview process added variables like time gap between scheduled and actual time for first surgery and wait time before the surgery. During these interviews, the supply chain expert stated that the time gap between the scheduled and the actual time of the beginning of first surgery of the day leaves a huge impact on the staff timeliness for the rest of the day.

Another important dimension of OR quality is safety and how it affects the economic sustainability of the OR. Variables influencing safety during a surgery were instrument quality, readmission rate and the total time of the surgery. Instrument quality was recorded in terms of the total time delays due to defects per surgery. These defects include: 1) Instruments dropped during the surgery; 2) Instruments not available during the time of surgery; 3) Instruments failed the quality check (holes in the blue wraps). Apart from the defects, instrument delays obtained from the Surgeon's/ Resident's work sampling sheet were recorded during the surgery in order to calculate the time wasted due to the lack of efficiency in handling the instruments in the OR. The instrument defects not only could affect the total surgery time (therefore the OR time) due to prolongation of surgery, but also jeopardizes the safety of the patient, and lead to increased costs. Figure 3 portrays the causal relationship between economic sustainability and efficiency, effectiveness, equitability, safety, and timeliness of the OR and Table 2 summarizes all the variables used to link economic sustainability with quality factors.

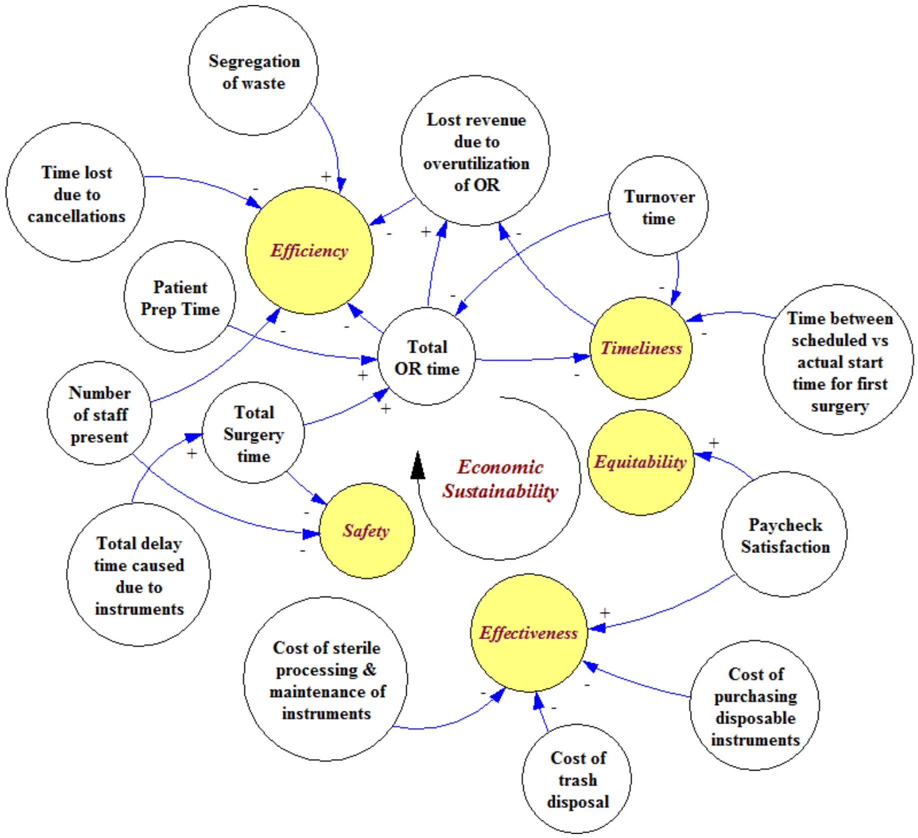

Figure 3. Economic Sustainability

Table 2. List of Variables used in the CLDs-Economic Sustainability

Variable	Description	Quality Factor	Source
Variables from Case Study			
Total Surgery Time	Time elapsed from the time-out until the patient is wheeled out	Efficiency, Timeliness, Safety	Data Collection: Time Study Lit Review: (Hariharan & Chen, 2015)
Total OR Time	Time elapsed from first tray is brought into OR until patient is wheeled out	Efficiency, Timeliness	Data Collection: Time Study
Patient Prep Time	Time elapsed from patient wheeled-in until time-out is called	Efficiency	Data Collection: Time Study
Number of staff present	Number of personnel present during the time of the surgery	Efficiency, Safety	Data Collection: Time Study

(Table cont'd.)

Variable	Description	Quality Factor	Source
Total time delay due to instrument	Total surgeon's time delayed due to delays in instruments	Efficiency	Data Collection: Work Sampling Lit Review: (Thomasson et al., 2016) Interview: Expert Panel Analysis
Segregation of wastes into trash bags	Segregation of trash generated into different colored bags	Efficiency	Interview: Expert Panel Analysis Lit Review: (Stall et al., 2013)
	Additional Variables		
Time lost due to cancellation	Cases cancelled by the patients within 24 hours of the scheduled surgery time	Efficiency	Interview: Expert Panel Analysis Lit Review: (Foster, 2012)
Lost Revenue due to overutilization of OR	Revenue lost when staff went over the scheduled time of surgery	Efficiency, Timeliness	Lit Review: (Madni et al., 2018)
Cost of Trash Disposal	Cost incurred in disposing the trash	Effectiveness	Lit Review: (Dias et al., 2017); (Shinn et al., 2017)
Cost of sterile processing and maintenance of the instruments	Costs incurred in cleaning, sterile processing, storage, repair and maintenance of instruments	Effectiveness	Lit Review: (Stockert & Langerman, 2014)
Paycheck Satisfaction	Effect of employees' satisfaction over the pay on their performance	Effectiveness, Equitability	Lit Review: (Weaver et al., 2015); (Singh & Loncar, 2010)
Turnover time	Time elapsed between the prior patient leaving the OR until another patient is wheeled in for surgery.	Timeliness	Lit Review: (Divatia & Ranganathan, 2015); (Foster, 2012)
Time gap between scheduled vs actual time for first surgery	Difference in the time between scheduled and actual start time of the first surgery	Timeliness	Interview: Expert Panel Analysis
Cost of purchasing disposable instruments	Cost incurred in purchase of single use instruments	Effectiveness	Interview: Expert Panel Analysis
Number of Equipment Defects	Equipment defects include instruments dropped during the surgery, instruments failing the quality checks	Safety	Lit Review: (Thomasson et al., 2016)

2.4.2. Social Sustainability

The scope of social sustainability in this study focuses on the people (staff, patients) present during the surgery. The social sustainability of an OR is affected by changes in efficiency, effectiveness, safety, timeliness and equitability.

During the data collection, non-value-added activities of each personnel was recorded. Any of the OR staff involved in non-value-added activities (activities that do not contribute towards benefitting the patient) can affect OR efficiency. For example, although the nurse spends a significant amount of time on the computer during the surgery, since it doesn't benefit the patient (customer) in any way, it is therefore, treated as non-value-added activity in this study. The staff communication and reliance were observed many times. Staff members relying on each other for some information or help during the surgery contributes positively towards OR efficiency, but unnecessary discussion wastes time.

Through literature review, variables like staff safety assessments, paycheck satisfaction and surgical safety checklists were included. Irrespective of the changes in the healthcare industry, previous studies stated that disparities such as a distinguishable gender gap in pay leads to growing dissatisfaction and a high prevalence of burnout among employees (Weaver et al., 2015). Therefore, paycheck satisfaction not only is an answer to the equal treatment of the employees, but also helps with motivation towards effective services. Though the experience of staff was not included in the data collection, previous studies and the interviews revealed that it does matter in deciding the time of the surgery, surgical safety, and thereby the OR efficiency. The surgeons had varying perceptions towards using new equipment and other technological interventions during the surgery. During the data collection, the team observed that only 1 out of 3 surgeons was ready to use the computer-assisted navigation system during surgery.

Another major factor of social sustainability is safety. Many hospitals use a surgical checklist before the beginning of the surgery to reduce possible errors and improve surgical safety. Along with patient safety, staff safety is also an important factor, and therefore, regular staff safety assessments are essential. There is an assessment test by OSHA (Hospital Safety and Health Management System Self-Assessment Questionnaire), which should be implemented in hospitals (Occupational Safety and Health Administration & U.S Department of Labor, n.d.). Although it is important to include more details about the patient, the scope of this study is restricted to the OR and therefore, various factors related to patients (such as readmission rate, patient satisfaction) have been excluded. Figure 4 portrays the causal relationship between the variables leading towards social sustainability and table 3 provides the list of all variables used in the study of social sustainability.

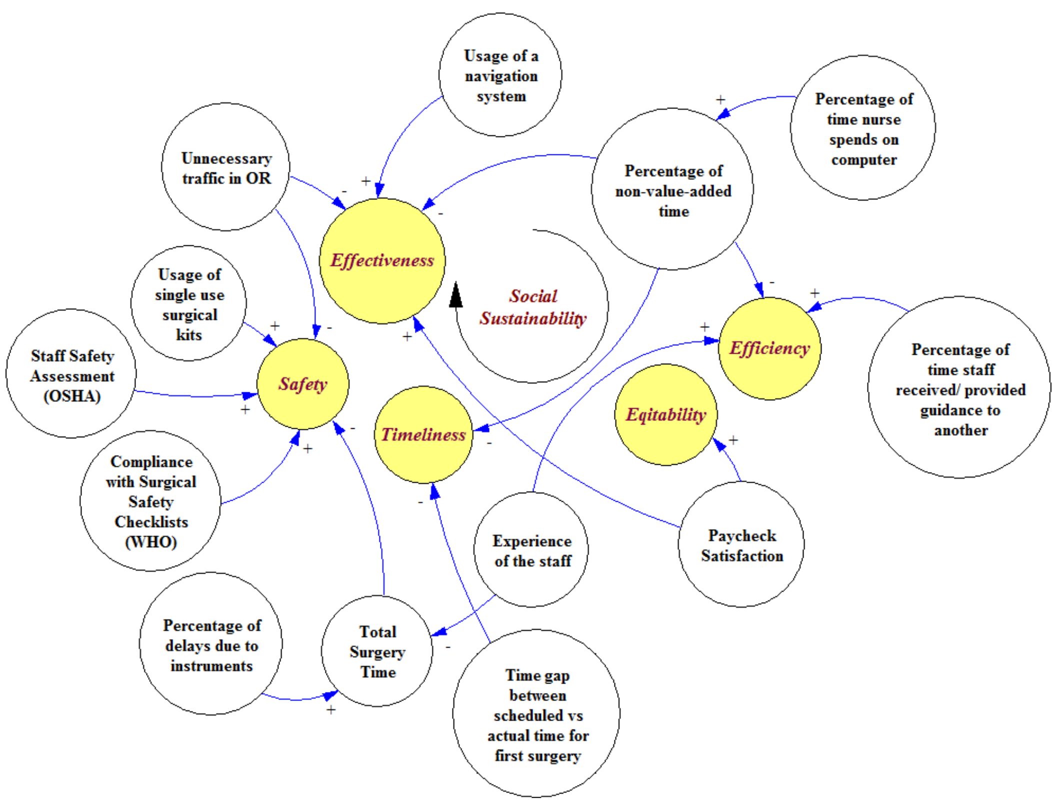

Figure 4. Social Sustainability

Table 3. List of Variables used in the CLDs-Social Sustainability

Variable	**Description**	**Quality Factor**	**Source**
		Variables from Case Study	
Percentage of non-value-added time	Time spent by personnel that wouldn't eventually benefit the patient	Efficiency, Effectiveness, Timeliness	Data Collection: Work Sampling
Usage of a navigation system during a surgery	Usage of a navigation system during a surgery (Y/N)	Efficiency	Data Collection: Work Sampling; Time Study Lit Review: (Bolognesi & Hofmann, 2005); (Seon et al., 2009)
Percentage of time nurse spends on computer	Time a nurse spends on computer during the surgery	Efficiency	Data Collection: Work Sampling From Lit Review: (Carayon, 2012)
Percentage of time staff received/ provided guidance to another during the surgery	Communication flow during the surgery	Efficiency	Data Collection: Work Sampling Lit Review: (Lingard et al., 2002)
Total surgery time	Time elapsed from the time-out until the patient is wheeled out	Timeliness	Data Collection: Time Study Lit Review: (Lingard et al., 2002)
Total time delay due to instrument	Total surgeon's time delayed due to delays in instruments	Safety	Data Collection: Work Sampling From Lit Review: (Thomasson et al., 2016); (Wong et al., 2010)
		Additional Variables	
Experience of the staff	Experience of staff in terms of years in current position	Efficiency	Lit Review: (Tucker et al., 2008)
Unnecessary traffic in OR	Number of times staff walked in and out of the blue-zone area or left OR during surgery	Effectiveness, Safety	Lit Review: (Panahi et al., 2012)

(Table cont'd.)

Variable	Description	Quality Factor	Source
Paycheck Satisfaction	Effect of employees' satisfaction over the pay on their performance	Effectiveness, Equitability	Lit Review: (Weaver et al., 2015); (Singh & Loncar, 2010); (Ogrod, 1997)
Usage of WHO Surgical Safety Checklist	(Yes/No) Usage of a WHO checklist in a surgery	Safety	Lit Review: (Thomasson et al., 2016); (Molina et al., 2016)
Staff Safety (OSHA Checklist)	(Yes/No) Did all the staff present in OR go through the staff safety assessment and is aware of guidelines?	Safety	Lit Review: (Lynch et al., 2009); (Occupational Safety and Health Administration & U.S Department of Labor, n.d.)
Usage of single use surgical kits	(Yes/No) Usage of a single-use kit in a surgery	Safety	Lit Review: (Siegel et al., 2015)
Time gap between scheduled vs actual time for first surgery	Difference in the time between scheduled and actual start time of the first surgery	Timeliness	Interview: Expert Panel Analysis

2.4.3. Environmental Sustainability

This study did not include equitability, timeliness, and patient-centeredness since the scope of the study only covers what happens inside an OR. Variables such as segregation of trash and number and weight of the trash produced per surgery have been collected during the direct observation of the surgeries. During the post-study interview, the supply chain expert emphasized that segregation of trash contributes towards both economic and environmental sustainability. Therefore, it was included in both the tables.

There is a vast literature done in environmental sustainability, but since this is related to OR, the scope of the variables is restricted to suit the purpose of the study. For example, this study assumes the trash generated from the OR is segregated from the trash generated from rest of the hospital. There was unnecessary extra usage of supplies observed. Although there is no certain standard regarding the usage, the fewer supplies used, the more effective the OR will be. During

the data collection, the team noticed that at the end of every surgery the OR staff takes out the trash into three different bags, red white and yellow. Red is used for bio-hazard trash, white is for disposable trash and yellow is for used linens. Along with the number of bags (of each color) and weight of each bag generated per surgery, segregation of the trash into different bags and identifying the bio-hazard trash at the end of each surgery is an important factor that counts to both effectiveness and safety of the ORs. Similarly, implementing single-use kits during the surgery decreases the effectiveness as cleaning and sterilization of these instruments may turn out to be more challenging than sterilizing instruments manufactured for several uses and re-sterilizing would just alter its original features, making it non-compliant with the manufacturer's specifications (Cancel, 2016).

Table 4 summarizes the list of all the important variables constituting towards environmentally sustainable healthcare. Figure 5 portrays the causal relation between the variables leading towards environmental efficiency, effectiveness and safety in the OR.

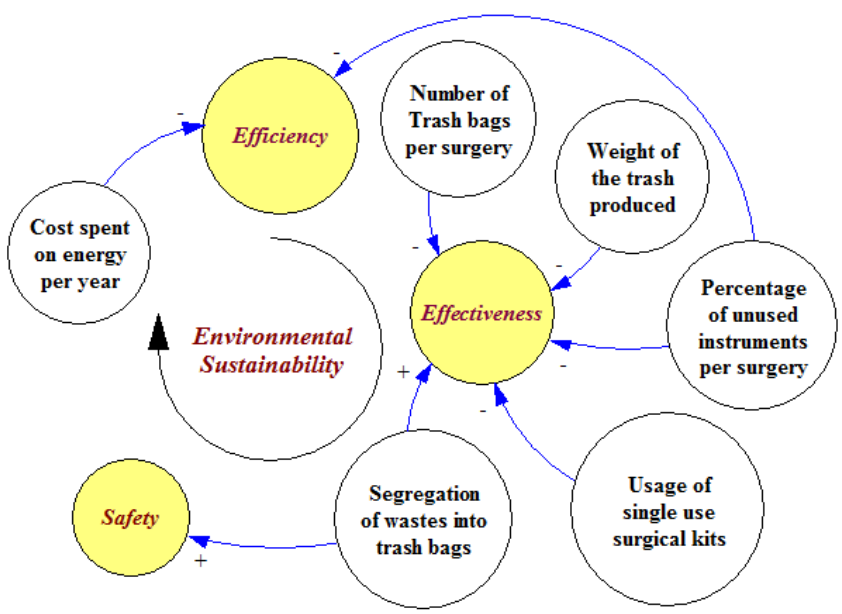

Figure 5. Environmental Sustainability

Table 4. List of Variables used in the CLDs-Environmental Sustainability

Variable	**Description**	**Quality Factor**	**Source**
Variables from Case Study			
Segregation of wastes into trash bags	Segregation of trash generated into different colored bags	Effectiveness, Safety	Data Collection: Time Study Lit Review: (Shinn et al., 2017); (Dias et al., 2017) Interview: Expert Panel Analysis
Number of trash bags per surgery	Number of trash bags (of each color) generated in an OR	Effectiveness	Data Collection: Time Study Lit Review:(Conrardy, et al., 2010); (Chaerul et al., 2008);
Weight of the trash produced per surgery	Weight of each trash bag (of each color) in lbs. in an OR	Effectiveness	Data Collection: Time Study Lit Review: (Conrardy et al., 2010); (Chaerul et al., 2008)
Additional Variables			
Percentage of unused instruments per surgery	Percentage of instruments left out on the instruments table per surgery	Efficiency	Lit Review: (Conrardy et al., 2010)
Cost spent on energy per year	Cost spent on electricity used per year	Efficiency	Lit Review: (McGain & Naylor, 2014)
Usage of single use surgical kits	(Yes/No) Usage of a single-use kit in a surgery	Effectiveness	Lit Review: (Siegel et al., 2015)

2.4.4. Data Obtained from Case Study

Variables collected through direct observation during the data collection were: total surgery time, total OR time, patient prep time, total time delay due to instruments, percentage of non-value-added activities in OR, usage of navigation system, percentage of time a staff received/ provided guidance, segregation of trash into bags, number of trash bags per surgery, weight of the

trash per surgery. This section summarizes all the data obtained from the case study and difficulties involved in obtained a few variables.

Table 5 summarizes the data collected during the direct observation of the surgery. The total OR time was not available for a few surgeries due to the research team missing the time at which the first instrument or the first staff entered the OR. The time taken for patient prep, surgery time, total OR time from each surgical case was collected in terms of minutes.

Table 5. Time Study Data Collected from Direct Observation

Activity	Number of Cases Observed	Mean (min)	Std. Deviation (min)
Patient Prep Time	13	43.38	11.75
Surgery	13	102.15	16.11
Total OR Time	7	191.43	58.61

Out of the 13 surgeries observed, on an average 6.18% of the surgeon's time during the surgery was delayed due to instruments. It could be because of the lack of training of the staff, or lack of coordination between the staff, or any of the equipment defects.

The surgeries with navigation systems lasted significantly longer than the ones without it. In the 13 surgeries observed (6 with navigation and 7 without navigation), the total surgery time was observed as:75.00min (6.76min) versus 52.14min (14.33min), p=0.007) (Gudipudi et al., 2018). The p-value from a two-tailed t-test performed assuming unequal variances (alpha level of 0.05) to determine any statistical differences between surgeries using navigation systems and traditional surgeries. The non-value-added activities increased for the company representative (rep) by 18% (p=0.005) and by 17% for the scrub tech (p=0.025) while using the computer-assisted navigation system. Since the p-values are less than the alpha level (0.05), a significant difference does exist for both personnel. However, the non-value-added time decreased by 7% (p=0.1) for the surgeon despite not being statistically significant (Gudipudi et al., 2018).

Table 6 summarizes the mean and standard deviation of the percentage value-added time for activities of each OR staff. All the data have been obtained through recording the activities of each personnel in the OR every two minutes during the 13 surgeries observed. During observation, the nurse spent 36.99% (6.99%) of their total time in front of a computer. This activity was considered as non-value-added to the patient and the process, but nevertheless it is the duty of a nurse to record the important details of the surgery such as the type and amounts of drugs administered to the patient.

Another important variable observed was communication flow between the staff. Communication in the OR was also necessary, but in some cases, it was simply lengthening the process. Table 7 summarizes the mean of the percentage of activities in OR that involved communication between the staff.

Table 6. Descriptive Statistics of the Value-Added Activities of the OR Staff

Staff	Mean	Std. Deviation
Nurse	34.58%	9.10%
Surgeon	70.19%	7.51%
Scrub Tech	54.38%	13.26%
Rep	34.89%	12.84%

Table 7. Percentage of Activities in OR that Involved Communication between the Staff

Staff	Activity	Mean	Std. Deviation
Rep	Providing guidance to scrub-tech	11.02%	5.17%
	Interacting with surgeon during surgery	8.04%	5.50%
Scrub Tech	Guidance from rep	9.16%	6.86%
	Interacting with doctor during surgery	18.79%	11.56%

2.5. Discussion

In this study, the causes of each sustainability component have been modelled through the CLDs. The final models consist of a subsequent cause-effect relation between the variables that

affect each of the quality dimension that lead a sustainable development in an OR. Variables from each diagram were collected through the data observation of the TKA procedures, an extensive review of previous studies in similar areas and interviews conducted at the end of the study. Sources for the variables were included in the tables 2, 3, 4. Each sustainability component was illustrated by an individual diagram (figures 3, 4, and 5).

The data from the direct observation methods (case study) was analyzed to review the time study variables such as total OR time, total surgery time, patient prep time etc., and work sampling variables such as percentage of non-value, percentage of time the nurse spent at the computer, unnecessary traffic in OR etc. These variables provide insight on the wastes occurring in the process such as non-value-added activities, unnecessary traffic, time delays, unnecessary usage of instruments etc. in the OR and possibilities of reducing these wastes.

The team was able to conveniently measure all these variables. However, a few times, the time at which the first instrument tray/ first staff entered the OR was missed. The team developed a time study sheet to collect the time related data from the OR. This had been made prior to the data collection, definitions of total OR time, time taken for prepping the patient, and the total surgery were provided in table 2. Although not included in the data collection, turnaround time also counts towards the OR staff timeliness and affects economic sustainability. Foster (2012) found a 28.5 min median time was utilized by the staff from prior patient exiting room until next patient enters room.

Another factor the team had difficulty measuring was instrument defects that occurred during the surgery. Although the OR staff are mostly careful to avoid mistakes with instruments, a few times during a surgery, there were delays that were caused by the instruments. For example, an average of an 6.18% of the surgeon’s time in the OR was wasted due to instrument delays.

According to a very recent study, 33% of the orthopedic cases observed did not have the required equipment or began with a certain defined instrumental defect in the operating rooms (Thomasson et al., 2016).

Segregation of trash is another variable that the OR staff majorly paid attention to. During the interviews conducted post study, the surgeon and supply chain expert agreed that properly segregating trash not only benefits the environment but also helps save money for the hospitals. The cost of disposing the trash varies with each type. For example, the trash produced from the red colored bag is bio-hazardous and disposing the wastes from these bags is costlier compared to the recyclable trash. Stall et al., (2013) revealed that an average of 14kg trash is produced from each TKA procedure of which 19.2% is bio-hazardous waste and only 2.2% can be recycled. The authors suggested to encourage the use of the environmentally-friendly surgical products for efficient waste management. During the time of observations, the current study found that on an average 45% (21.15kg in the total trash of 46.65 kg) of the trash generated went into red bags (bio-hazardous trash), and 54% of it was regular trash.

There were also high rates of cancellation of the surgery on the day or a day before the scheduled surgery time. This often leads to waste of the staff time and hospital resources. A study done by Kumar & Gandhi (2012) found that lack of operating time (63%), caused due to delay in the beginning of the surgery, delay in preparation and cleaning of the ORs (before and after surgery), and delayed transportation of the patients, was the most important factor of cancellation. The total surgery time is another important factor that affects OR economic efficiency and OR safety. For this study, the total surgery time was defined as the time elapsed between the time-out and the time at which the patient is wheeled-out from the OR. This includes time during which surgery is performed, closing, dressing the wound, and wheeling the patient out of the OR. In case

of back-to-back surgeries, delay in the time at which the first surgery of the day starts affects rest of the cases.

Along with the economic and environmental sustainability, this study also focused on the social sustainability of the OR. Variables such as introducing new technology/ equipment and IT involvement have been observed to affect the OR staff. The team found that each surgeon had a different perception towards the new equipment in the OR. For example, the surgery time was prolonged with the usage of a computer assisted navigation system (as stated in the results), but one surgeon preferred to use the navigation system, while the other two did not.

2.5.1. Limitations

This study focuses on the efficiency immediately associated with the surgical procedure and does not follow patients during their recovery to determine if surgery quality affects health outcomes. Since this study is limited to activities within the OR, most of the safety factors involved in the preoperative and post-operative stages are ignored. This includes factors such as patient satisfaction and readmission rate of the patients, since they required a follow-up from the patient and feedback regarding the stay at the hospital. Faezipour & Ferreira (2013) treated patient satisfaction as one of the key factors in the healthcare sustainability social pillar and explained that it can be used as a key sustainability indicator in healthcare. Another safety parameter most of the studies included was the readmission rate. During the follow-up interview, two of the three panel members mentioned that most of the hospitals define readmission rate as a follow-up visit to the clinic within a 30-day period after surgery, which includes inquiries regarding proper usage of medicines, physiotherapy and rehabilitation. However, readmissions also cover if the patient is back to the hospital and readmitted for any reason within the next 90 days after surgery. Therefore,

although the readmission rate is considered as an important safety factor, it is a difficult variable to measure and is outside the scope of the current study.

2.6. Future Work

Future work for these models can be extended to simulate variables leading to sustainability throughout for an entire hospital. New variables such as management issues, culture, gender, type of insurance (Medicare/ Medicaid/ management care insurance), patient satisfaction, post-surgery surveys etc. can be added to make the model more accurate. Results can be validated by collecting data either through direct observations or through sufficient number of data records available from surgeries.

The variables obtained from this study can be used to form a checklist which is to be used assess the sustainability of the ORs. The checklist can standardize all the variables that the staff need to measure in order to evaluate their sustainable development.

2.7. Conclusion

Quality in healthcare can be defined as the degree to which any healthcare service is consistent with current professional knowledge and increases the likelihood of desired outcomes. Whereas, sustainability is a balance of the needs of patients, economic concerns, and environmental costs. Quality and sustainability are assumed as equally important and inter-dependent factors in healthcare. This provided a base for defining the variables that affect each component of sustainability through the perspective of the six quality aims.

By using the system dynamic approach, a cause-effect relationship was developed between the variables and the quality aims for each sustainability component in an OR. Economic sustainability is affected by cost efficiency, cost effectiveness, staffs' timeliness, equitable

treatment of the staff and the safety measures in the OR. Similarly, social sustainability is affected by efficiency, equitability and timeliness of the staff, effectiveness of the process and safety of the process and the staff in OR. In case of environmental sustainability, the quality (efficiency, effectiveness, safety) of the trash management is considered important.

This study aims to determine the variables that could affect quality and sustainability in an OR. The CLDs help in understanding the causal relations between the variables and the quality dimensions for each sustainability component. This in turn helps in establishing a framework for assessing the sustainable development of the operating rooms (ORs). These variables provide an insight to address the quality issues and improve them while addressing to sustainability challenges in OR.

Chapter 3. Surgical Checklist to Assess the Sustainability of Operating Rooms

3.1. Introduction

Quality in healthcare is defined as "the degree to which healthcare services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge" (p. 21) (Institute of Medicine (U.S.), 1990). The Institute of Medicine introduced a framework to distinguish an ideal healthcare system from the health care that people actually receive. This report stated that healthcare should follow six quality aims: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (2001). To improve the quality of patient outcomes and delivery methods, hospitals need to take initiatives such as investing in new technology, medicines, encouraging better facilities and reducing wastes (non-value-added variables). While improving quality is important, it is equally important to sustain those quality improvements for the healthcare systems in order to keep up with the plethora of challenges and demands. Therefore, healthcare organizations are shifting towards sustaining quality long-term.

The World Commission on Environment and Development defined sustainable development as the "process of change in which the exploitation of resources, the direction of investments, the orientation of technological development, and institutional change are all in harmony and enhance both current and future potential to meet human needs and aspirations" (p. 43, 1987). The commission recognized three interdependent and mutually reinforcing pillars of sustainability: economic, social and environment. Coiera & Hovenga (2007) defined sustainable healthcare as a system that "has a clear purpose and consistently find ways to maintain that purpose despite significant changes to the world around them" (p. 11). For a sustainable healthcare organization, the economic pillar ensures the economic security of the system. The social pillar

highlights equity, empowerment, accessibility, and organizational stability. The environmental pillar considers efficient and cost-effective ways for consumption and protection of current resources (Mackay & Wolbring, 2013). The motivation of this study is to develop a framework to assess the relation between variables that affect quality and sustainable development of an OR.

The assurance of sustainability in healthcare operations may result in both financial and quality improvement for healthcare (Tudor, 2007). Sustainability in healthcare is linked to the definition of “Triple Aim” to include balancing the individual experience of care, improving the health of populations and reducing the per capita costs of care for populations (Berwick, Nolan, & Whittington, 2008).

3.1.1. Scope and Objective

This chapter explores how the six aims of quality are related to the economic, social, and environmental factors of healthcare sustainability by considering a case study of total knee arthroplasty (TKA). TKA is a safe and effective procedure to relieve pain and correct leg deformity when nonsurgical treatments like medications and using walking supports are no longer helpful (“Total Knee Replacement,” 2015).

The six quality aims (safety, efficiency, effectiveness, equitability, timeliness, patient-centeredness) help identify the variables needed to achieve sustainable development in an OR. In this study, efficiency evaluates the performance of the staff, whereas effectiveness studies the process and the degree to which objectives are achieved, safety involves adopting safe procedures and following safety guidelines, equity involves unbiased treatment of staff and patients, patient-centered care includes customer-based care, and timeliness of the process is following the time standards and finishing the procedure within a set time.

3.1.2. Motivation: Sustainability Challenges in TKA

The motivation behind this study is to establish a framework with the variables to evaluate quality and thereby, the sustainable development of the operating rooms (ORs). Sustainability is defined by three main pillars: economic, social and environmental development. There are a few specific challenges that arise in the sustainable development of TKA procedures: cost of the procedure, non-value-added activities and delays in the OR, and improper disposal of the trash generated post-surgery.

TKA is one of the most expensive procedures in the US, with the hospital, implant, and physician charges averaging nearly $40,000 per case, and constituting to a sum $15–18 billion per year (Ilfeld, Mariano, Williams, Woodard, & Macario, 2007; Weinstein, 2000). In spite of the high costs, many people opt for the TKA procedures every year. This brings a major need to economically sustain the process.

A major challenge in TKA procedure is to improve the processes without compromising the patient care. In a healthcare setting, a process or activity is considered value-added if it coincides with the patients' interests, and this is something that the patient is willing to pay. Non-value-added activities are those which do not add any value to the process or the service but may be an inherent part of the process. A best way for reducing the costs, without jeopardizing patient care, is to focus on reducing non-value-added activities. This helps healthcare organizations to achieve significant cost savings and sustain those gains while improving patient care (Langer & Renaud, 2010).

Environmental sustainability has become a major issue in many healthcare organizations. The procedure and cost of disposal of trash generated is different for each type of trash. While

disposal of the biohazardous waste is costlier, higher amounts of solid waste affects the environment. A case study conducted in 2013, based on the waste audit of 5 primary TKA performed by a single surgeon, reported that per TKA, an average of 64.5% of waste per weight was normal solid waste, which required transport and dumping in a landfill, and 19.2% was biohazard waste requiring high-energy treatment processes, and only 14.3% of waste by weight was recycled (Siegel et al., 2015).

3.2. Methods

This study resulted in a checklist that can be used to evaluate the sustainability of the OR through the variables that affect the quality. The checklist helps in assessing the relation between the six quality aims and the economic, social and environmental sustainability of the OR. The variables in the checklist were obtained through a direct observation of the TKA surgeries and through an extensive literature review. The variables responsible for different quality aims were categorized through economic, social and environmental sustainability. After all variables were collected and defined, an expert panel validated the final checklist.

3.2.1. Variables through Direct Observation

The observed data was obtained in 2015 and 2017 at two sites with three surgeons. The patients requiring primary unilateral TKA, usually 65 years of age or older were participants for the study. Prior to all the observations, the team created the data collection sheets for time study in the OR and the sterile processing department, and work sampling for all the personnel in the OR. Two researchers were allowed to stay in the OR for the entire time of the surgery for collecting the data. For this study, the utilization of the staff is determined by recording and evaluating the value-added and non-value-added activities in the OR.

3.2.2. Variables through Literature Review

Various platforms of electronic database such as Google Scholar, PubMed and Web of Science were used as the platforms for searching the previous studies in this area of research. Keywords such as “healthcare sustainability”, “sustainability in ORs” etc., were used to obtain the variables affecting the quality of the OR. Although there were only a small number of studies that discussed the quality or sustainability of an OR, it helped in collecting some variables for this study.

3.2.3. Variables through Expert Panel: Validity of the Checklist

An expert panel consisting of a surgeon, supply chain administrator, and a lean & quality control professional validated the checklists. Each panel member was given one sheet for each component of sustainability: economic, social, environment. Each sheet consists a table of variables classified according to the six quality aims: efficiency, effectiveness, equitability, safety, timeliness, patient-centeredness. In some cases, there weren’t any quality variables that contributed towards a particular sustainability component. For example, no patient-centered variables affected the economic sustainability. Therefore, all six quality aims were not addressed in each checklist. During the process of interviewing, each individual evaluated the importance of the variables included in the checklists. They were also asked to evaluate the quality dimensions for each sustainability component. The panel provided their input and opinion regarding the validity and importance of each variable. By the end of the panel review, a few variables were considered necessary for the study and therefore, added to the list.

3.4. Results

Each table consists of the variables that are responsible for sustainable development of the ORs. These lists are a combination of the variables either positively or negatively affecting quality and sustainability. Variables such as total surgery time, total OR time, patient prep time, total time delay due to instruments, percentage of non-value-added activities in OR, usage of navigation system, percentage of time a staff received/ provided guidance, segregation of trash into bags, number of trash bags per surgery, weight of the trash per surgery were collected through direct observation of the surgeries.

The variables that were included through the literature review were lost revenue due to overutilization of OR, cost of trash disposal, Cost of sterile processing and maintenance of the instruments, paycheck satisfaction, turnover time, time gap between scheduled vs actual time for first surgery, cost of purchasing disposable instruments, number of equipment defects, unnecessary traffic in OR, compliance with WHO surgical safety checklist, percentage of unused instruments per surgery, usage of single use surgical kits.

After conducting the expert panel analysis, the following variables are added to the tables. Variables such as time lost due to cancellation of the surgeries, time gap between scheduled vs actual time for first surgery, cost of purchasing disposable instruments were added during the interviews conducted with the expert panel at the end of the study.

Although the team didn’t have a chance to test the complete checklist, there was a chance to record a few variables. Table 8 summarizes the data collected during the direct observation of the surgery. The team was able to record the total OR time for a few surgeries as the time at which the first instrument or the first staff entered the OR was missed. The patient prep time, total surgery time, total OR time were collected in terms of minutes.

Table 8: Time Study Data Collected

Activity	Number of Cases Observed	Mean (min)	Std. Deviation (min)
Patient Prep Time	13	43.38	11.75
Surgery	13	102.15	16.11
Total OR Time	7	191.43	58.61

Among the 13 surgeries observed, on an average 6.18% of the time accounted to delays in the surgery time due to instruments. Major reasons for delays included lack of training of the staff, or lack of coordination between the staff, or any of the equipment defects.

Table 9 provides the mean and standard deviation of the value-added time for activities of each OR staff (in percentages). All the data was obtained through recording the OR activities for every two minutes during the 13 surgeries observed.

Table 9. Mean and Std. Deviation of the Value-Added Activities of OR Staff

Staff	Mean	Std. Deviation
Nurse	34.58%	9.10%
Surgeon	70.19%	7.51%
Scrub Tech	54.38%	13.26%
Rep	34.89%	12.84%

3.4.1. Sustainability Checklists

The checklists are designed to be used by an IE professional or an OR personnel for auditing mostly inside the OR. The variables for each component of sustainability are divided into two groups based on the frequency with which they are measured. A few variables need to be measured for every surgery, while some can be collected and analyzed once in every 6 months. Variables such as assessing the paycheck satisfaction, cost spent on energy, cost of disposal, cost of purchasing disposable instruments, cost of sterile processing and maintenance of the instruments, lost revenue due to overutilization of OR can done once in a year, therefore, can be

skipped in the checklist during the data collection at the time of surgery. The auditing of these variables can be done for every 6 months or once in a year. Figures 6, 7 and 8 are the checklists of the variables that need to be used for every surgery.

Date of Observation:

Location:

Time of Observation:

Name of Surgeon:

Variable	Quality Dimensions	Units	Quantity
Total surgery time	Efficiency, Timeliness, Safety	Minutes	
Total OR time	Efficiency, Timeliness	Minutes	
Patient Prep Time	Efficiency	Minutes	
Percentage of time delay due to instrument	Efficiency	%	
Number of staff present	Efficiency, Safety	Number	
Segregation of wastes into trash bags	Efficiency	Yes/No	
Time lost due to cancellation	Efficiency	Minutes	
Number of Equipment Defects	Safety	Number	
Time gap between scheduled vs actual time for first surgery	Timeliness	Minutes	
Turnover time	Timeliness	Minutes	

Figure 6: Checklist for Economic Sustainability

Date of Observation:

Location:

Time of Observation:

Name of Surgeon:

Variable	Quality Dimension	Units	Quantity
Unnecessary traffic in OR	Effectiveness, Safety	Number	
Percentage of non-value-added time	Effectiveness, Efficiency, Timeliness	%	
Usage of a navigation system during a surgery	Efficiency	Yes/No	
Percentage of time nurse spends on computer	Efficiency	%	
Percentage of time staff received/ provided guidance to another during the surgery	Efficiency	%	
Experience of the staff	Efficiency	Number	
Usage WHO Surgical Safety Checklist	Safety	Yes/No	
Staff Safety (OSHA Checklist)	Safety	Yes/No	
Usage of single use surgical kits	Safety	Yes/No	
Percentage of time delay due to instrument	Safety	Minutes	
Total surgery time	Timeliness	Minutes	
Time gap between scheduled vs actual time for first surgery	Timeliness	Minutes	

Figure 7: Checklist for Social Sustainability

Date of Observation:

Location:

Time of Observation:

Name of Surgeon:

Variable	Quality Dimensions	Units	Quantity
Segregation of wastes into trash bags	Effectiveness, Safety	Yes/No	
Weight of the trash produced per surgery	Effectiveness	lb.	
Number of trash bags per surgery	Effectiveness	Number	
Usage of single use surgical kits	Effectiveness	Yes/No	
Percentage of unused instruments per surgery	Efficiency	%	

Figure 8: Checklist for Environmental Sustainability

The checklist has to be filled by an OR personnel by the end of the surgery. During the data collection, the team noticed that the variables were recorded by the staff, therefore this is similar to the current practices and shouldn’t cause any delays. Apart from the regular assessments, there should be another annual sustainability assessment where all the variables are re-evaluated,

and the sustainability of the process is assessed. Similarly, figure 9 is the checklist of the variables for all components of sustainability that need to be measured once in biannual assessments.

Date of Observation:

Location:

Time of Observation:

Name of Surgeon:

Variable	Sustainability Component	Quality Dimensions	Units	Quantity
Cost incurred in purchasing disposable instruments	Economic	Effectiveness	$	
Cost of sterile processing and maintenance of the instruments	Economic	Effectiveness	$	
Cost of Trash Disposal	Economic	Effectiveness	$	
Paycheck satisfaction	Economic, Social	Effectiveness, Timeliness	Scale	
Lost revenue due overutilization of the OR time	Social	Efficiency, Timeliness	$	
Cost spent on energy per year	Environment	Efficiency	$	

Figure 9: Checklist of Variables to be Measured Biannually

The data can be compared each year to analyze and compare the results. Figures 10, 11 and 12 illustrate the checklists filled with the data observed by the team during the time of data collection. These checklists for each component of sustainability include both types of variables in a single table.

Date of Observation: 4/18/2017

Location: Jefferson

Time of Observation: 10:00 AM

Name of Surgeon: Dr. C

Is it applied during surgery? (Yes/ No)	Variable	Quality Dimensions	Units	Quantity
☐	Cost incurred in purchasing disposable instruments	Effectiveness	$	N/A
☐	Cost of sterile processing and maintenance of the instruments	Effectiveness	$	N/A
☐	Cost of Trash Disposal	Effectiveness	$	N/A
☐	Paycheck satisfaction	Effectiveness, Timeliness	Scale	N/A
☐	Total surgery time	Efficiency, Timeliness, Safety	Minutes	42
☐	Lost revenue due overutilization of the OR time	Efficiency, Timeliness	$	N/A
☐	Total OR time	Efficiency, Timeliness	Minutes	121
☐	Patient Prep Time	Efficiency	Minutes	39
☐	Percentage of time delay due to instrument	Efficiency	%	9.09%
☐	Number of staff present	Efficiency, Safety	Number	6
☐	Segregation of wastes into trash bags	Efficiency	Yes/No	Yes
☐	Time lost due to cancellation	Efficiency	Minutes	0
☐	Number of Equipment Defects	Safety	Number	Data not collected
☐	Time gap between scheduled vs actual time for first surgery	Timeliness	Minutes	Data not collected
☐	Turnover time	Timeliness	Minutes	Data not collected

Figure 10: Example of the Economic Sustainability

Date of Observation: 4/18/2017

Location: Jefferson

Time of Observation: 10:00 AM

Name of Surgeon: Dr. C

Is it applied during surgery? (Yes/ No)	Variable	Quality Dimension	Units	Quantity
☐	Unnecessary traffic in OR	Effectiveness, Safety	Number	Data not collected
☐	Paycheck Satisfaction	Effectiveness, Equitability	Scale	N/A
☐	Percentage of non-value-added time	Effectiveness, Efficiency, Timeliness	%	36.36%
☐	Usage of a navigation system during a surgery	Efficiency	Yes/No	No
☐	Percentage of time nurse spends on computer	Efficiency	%	32.79%
☐	Percentage of time staff received/ provided guidance to another during the surgery	Efficiency	%	30.93%
☐	Experience of the staff	Efficiency	Number	Data not collected
☐	Usage WHO Surgical Safety Checklist	Safety	Yes/No	Yes
☐	Staff Safety (OSHA Checklist)	Safety	Yes/No	Yes
☐	Usage of single use surgical kits	Safety	Yes/No	No
☐	Percentage of time delay due to instrument	Safety	Minutes	9.09%
☐	Total surgery time	Timeliness	Minutes	42
☐	Time gap between scheduled vs actual time for first surgery	Timeliness	Minutes	Data not collected

Figure 11: Example of the Social Sustainability

Date of Observation: 4/18/2017

Location: Jefferson

Time of Observation: 10:00 AM

Name of Surgeon: Dr. C

Is it applied during surgery? (Yes/ No)	Variable	Quality Dimensions	Units	Quantity
☐	Segregation of wastes into trash bags	Effectiveness, Safety	Yes/No	Yes
☐	Weight of the trash produced per surgery	Effectiveness	lb.	Data not collected
☐	Number of trash bags per surgery	Effectiveness	Number	2(R), 1(W), 2(Y)
☐	Usage of single use surgical kits	Effectiveness	Yes/No	No
☐	Cost spent on energy per year	Efficiency	$	N/A
☐	Percentage of unused instruments per surgery	Efficiency	%	Data not collected

Figure 12: Example of the Environmental Sustainability

3.5. Discussion

In this study, the variables affecting various quality aims are made into a checklist that can be used to evaluate the three sustainability pillars (economic, social, environment). The variables set an association between quality and any sustainability component and serve as metrics to assess sustainability. But in this study due to the restriction of the scope, not all the quality aims were covered. The economic sustainability checklist consists of variables that affect the economic efficiency, effectiveness, equitability, safety, and timeliness of the OR. There were patient-centeredness related variables such as adopting alternative payment methods or cost containment strategies of companies, but these were outside of the scope of the economic sustainability. The social sustainability of an OR is affected by changes in variables of efficiency, effectiveness, safety, timeliness, patient-centeredness and equitability. In case of environmental sustainability, the variables leading towards environmental efficiency, effectiveness and safety in the OR. This study didn't include equitability, timeliness, and patient-centeredness since the scope of the study only covers what happens inside an OR.

3.6. Future Work

This checklist can be developed and standardized for more surgeries by varying the set of variables with every surgery. The variables in all the checklists can be measured before, during or immediately after the surgery by any staff member or an IE professional with the access to the surgeries. If the hospitals chose to fill entire checklist at a time, a period of time for every six months can be selected, and the staff can collect data for every surgery during that period and this data can be used to assess sustainability. The other way is to separately collect the data for every six and reviewing the data at the end of 6 months.

The surgeon during the interview, brought up the point that encouraging an out-patient surgery centers improve sustainability, as they were already economically sustained. But establishing a surgery center requires more money and the pay of the staff (excluding surgeon) might be affected if they are paid on an hourly basis and they do not work after the patient is discharged. In case of regular hospitals since the patient stays, there might be work for some staff, which is completely avoid in case of out-patient surgery centers.

3.7. Conclusion

This checklist not only helps in assessing the sustainable development in OR, but also helps in understanding the relation between quality and sustainability in an OR. Recording everything in the OR not only helps in removing the non-value-added activities and other wastes, but also in analyzing and eliminating the variation in processes over the years. By implementing such checklists, the OR staff can coordinate with each other, thereby improving quality and sustainability of the ORs and the healthcare organizations.

The direct observation of the surgeries provides the data for the time study variables such as total OR time, total surgery time, patient prep time etc., and work sampling variables like percentage of non-value time of each personnel in the OR, percentage of time the nurse spent at the computer, unnecessary traffic in OR etc. These variables provide insight on the wastes such as non-value-added activities, unnecessary traffic, time delays, unnecessary usage of instruments etc. in the OR and possibilities of reducing these wastes.

Chapter 4. Conclusion

Many healthcare organizations have been working towards a desired goal of sustainability. However, measuring the sustainability has not been an assessable topic. Major hospitals and healthcare systems when talking about sustainability, are only focused on improving the environmental performance. But rather than focusing on the environmental impacts themselves, focus needs to be shifted to evaluate costs and benefits of green practices. Being sustainable helps significantly to reduce unnecessary and unexplained expenditures through better management of resources and waste reduction.

Variables from each diagram were collected through the data observation of the TKA procedures, an extensive review of previous studies in the similar areas and interviews conducted at the end of the study. These diagrams portray the causal relationship between the variables and the quality dimensions for each sustainability component. Based on the CLDs obtains, the variables can either improve the quality or negatively affect the quality. The variables causing a decrease in the quality are termed as “wastes.” These wastes could be categorized as two kinds: the variable represents waste regardless of level; the variable is waste at a high or low level only. The goal is to either eradicate it or reduce/increase the level of the variable to an optimal state. An example of the first type of waste is a variable identifies as non-value-added. A process or activity is considered value-added if it coincides with the patients’ interests, and this is something that the patient is willing to pay. While non-value-added are those which do not add any value to the process or the service but are nevertheless, an inherent part of the process.

By using the system dynamic approach, the cause-effect relationship between variables that can affect each sustainability component in an OR was made clearer. In this study, each sustainability component was divided into each diagram, and each diagram consisted of variables

which were connected the quality dimensions. In the beginning of the study, quality and sustainability were assumed as equally important and inter-dependent factors in healthcare. This provided a base for defining the variables that affect each component of sustainability through the perspective of the six quality aims.

Based on the results obtained from the CLDs, the variables are made into a checklist to assess the sustainability of the ORs. The relation between each variable in the diagram helps in understanding the affect of the variable on each sustainability component. The economic sustainability checklist consists of variables that affect the economic efficiency, effectiveness, equitability, safety, and timeliness of the OR. There were patient-centeredness related variables such as adopting alternative payment methods or cost containment strategies of companies, but these were outside of the scope of the economic sustainability. The social sustainability of an OR is affected by changes in variables of efficiency, effectiveness, safety, timeliness, patient-centeredness and equitability. In case of environmental sustainability, the variables leading towards environmental efficiency, effectiveness and safety in the OR. These variables provide an insight to look for possible ways to improve quality and to address the sustainability challenges in ORs.

While the CLDs provide a clear way to understand the inter-relations between the variables and the quality dimensions, the checklists provide a framework to assess the sustainability in an OR. This study is a foundation for the future models to simulate variables leading to sustainability throughout for an entire hospital. New variables such as management issues, culture, gender, type of insurance (Medicare/ Medicaid/ management care insurance), patient satisfaction, post-surgery surveys etc. can be added to make the model more accurate. Results can be validated by collecting

data either through direct observations or through sufficient number of data records available from surgeries.

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Appendix A. Data Collection Sheets

Time Study sheet for OR

Time Study for OR								
Procedure Category Interval	Category Description (Start and End Points)		Clock time (HH:MM) Obs: Date: Time: Location: Nav No Nav Trad Disp		Notes			
Room & Instrument Prep	First tray unwrapped							
	"Time-Out" is called							
Patient Prep	Patient wheeled in							
	"Time-Out" is called							
Surgery	"Time-Out" is called							
	First closing stetch is made							
Closure	First closing stetch is made							
	Patient is wheeled out							
Instrument Clean up/ Wrap up	Nurse starts counting used instruments							
	Last United Tray Leaves the room							
Rinsing Instruments in the OR	Rep rinses the first instrument							
	Rep places the last rinsed instrument on the tray							
Total Surgeon Time (in the OR)	Surgeon gets suited-up							
	Surgeon takes off gear							
Total Surgical Episode	The first TKA tray enters the room							
	Last TKA tray leaves the room							
Number of Trash bags	White:		Red:		Yellow:		Rag Trees:	
Weight of each bag	Bag 1	Bag 2	Bag 1	Bag 2	Bag 1:	Bag 2:	Bag 1:	Bag 2:
Number of personnel performing surgery	Surgeon:		Orthopedic tech:		Scrub Tech:		Resident:	
	Nurse Practitioner:		Resident:		Nurse:		Rep:	

Time Study for cleaning instruments

Time study for instruments cleaning (United Trays)					
Procedure Category	Category Description	Clock Time	Clock Time	Clock Time	Notes
		Date:	Date:	Date:	
		Time:	Time:	Time:	
		Jeff hwy Kenner	Jeff hwy Kenner	Jeff hwy Kenner	
		Trad Disp	Trad Disp	Trad Disp	
Manual Rinsing	Tech starts rinsing first tray of instruments				
	Tech places last clean tray in cart				
Mechanical Washers	First tray of instruments is placed in the washer				
	Last tray is moved from washer to cart				
Instruments Inspection	Tech starts inspecting the first tray				
	Tech finishes inspecting the last tray				
Instruments packing	Tech starts packing the first tray				
	Tech finishes packing the last tray				
Sterilization	Trays are placed in autoclave				
	Last tray moved from autoclave to cart				
Storage	Cart of instruments placed in storage room				

Work Sampling Sheets

Surgeon

Obs #:	Surgeon					
Date:	Time	Performing Surgery	Instru/ implant Prep	Instrument delay	Not in the room	Others
Time:						
Location:						

Scrub Tech

Obs #:	Scrub Tech								
Date:	Time (H:M)	Set-up instruments on table	Guidance from rep	Search, select or grab instruments (facing table)	Interacting with doctor during surgery (facing surgeon)	Clean-up	Idle	Not in the room	Others
Time:									
Location:									

Company Representative (Rep)

Obs #:	REP						
Date:	Time (H:M)	Instru/implants set-up	Providing guidence to scrub-tech	Interacting with surgeon during surgery	Cleaning up instrument	Idle	Not in room
Time:							
Location:							

Nurse

Obs #:	Nurse							
Date:	Time (H:M)	Charting/ computer work/ phone	Getting materials ready	Working with doctor or tech	Clean-up	Idle	Not in room	Others
Time:								
Location:								

Appendix B. IRB Approvals

ACTION ON EXEMPTION APPROVAL REQUEST

Institutional Review Board
Dr. Dennis Landin, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
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TO: Laura Ikuma
Mechanical and Industrial Engineering

FROM: Dennis Landin
Chair, Institutional Review Board

DATE: December 22, 2016

RE: **IRB#** E9978

TITLE: U2 Knee TM System with a Disposable Trial: Cost and Efficiency Study

New Protocol/Modification/Continuation: Modification

Brief Modification Description: Changed wording of consent.

Review date: 12/22/2016

Approved X **Disapproved** ____

Approval Date: 12/22/2016 **Approval Expiration Date:** 12/18/2019

Re-review frequency: (three years unless otherwise stated)

LSU Proposal Number (if applicable): 44719

Protocol Matches Scope of Work in Grant proposal: (if applicable)

By: Dennis Landin, Chairman DLandin

PRINCIPAL INVESTIGATOR: PLEASE READ THE FOLLOWING –
Continuing approval is CONDITIONAL on:

1. Adherence to the approved protocol, familiarity with, and adherence to the ethical standards of the Belmont Report, and LSU's Assurance of Compliance with DHHS regulations for the protection of human subjects*
2. Prior approval of a change in protocol, including revision of the consent documents or an increase in the number of subjects over that approved.
3. Obtaining renewed approval (or submittal of a termination report), prior to the approval expiration date, upon request by the IRB office (irrespective of when the project actually begins); notification of project termination.
4. Retention of documentation of informed consent and study records for at least 3 years after the study ends.
5. Continuing attention to the physical and psychological well-being and informed consent of the individual participants including notification of new information that might affect consent.
6. A prompt report to the IRB of any adverse event affecting a participant potentially arising from the study.
7. Notification of the IRB of a serious compliance failure.
8. **SPECIAL NOTE: Make sure you use bcc when emailing more than one recipient. Approvals will automatically be closed by the IRB on the expiration date unless the PI requests a continuation.**

**All investigators and support staff have access to copies of the Belmont Report, LSU's Assurance with DHHS, DHHS (45 CFR 46) and FDA regulations governing use of human subjects, and other relevant documents in print in this office or on our World Wide Web site at http://www.lsu.edu/irb*

IRB

EXEMPT APPROVAL
LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER
(Assurance Number FWA00002762)
IRB Registration Number 00000177

FROM: LSUHSC-NO Institutional Review Board

TO: J. M. Moerschbaecher, Ph.D.
Vice Chancellor for Academic Affairs

RE: IRB Application By: **Laura Ikuma, PhD**
Research Institute

Entitled: **IRB # 9638 Title: U2 KneeTM System with a Disposable Trial: Cost and Efficiency Study**

Federal Regulations as published in the Federal Register of January 26, 1981—Part 46 of 45CFR46.101 (b) lists exemptions to regulations of Department of Health and Human Services governing research on human subjects. It is the opinion of the Chairman that your study is exempt as it falls into one of the categories listed, specifically # 4

THE INVESTIGATOR agrees to report to the Committee any emergent problems, serious adverse reactions, or procedural changes that may affect the status of the investigation, and that no such change will be made without Board approval, except where necessary to eliminate apparent immediate hazards. The investigator also agrees to periodic review of this project by the Board at intervals appropriate to the degree of risk to assure that the project is being conducted in compliance with the Board's understanding and recommendation.

PLEASE NOTE:

1. Any advertisement to recruit subjects for this study must be approved by the IRB prior to posting, publication and/or distribution.
2. Other institutional approvals may be required before the study can be initiated.
3. Written notification (at the time this study is completed/canceled) must be sent to the Office of the Chairman.
4. The Principal Investigator must notify the IRB annually of the study's status.
5. Informed Consent is required from each patient.
6. HIPAA does not apply.

Laura Ikuma, PhD, Principal Investigator DATE: 3/6/17

Kenneth E. Kratz, Ph.D., Chairman
Barry Potter, Ph.D., Vice Chairman DATE: 03/07/2017

LOUISIANA STATE UNIVERSITY – BATON ROUGE (LSU)
LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER – NEW ORLEANS (LSUHSC-NO)
OCHSNER CLINIC FOUNDATION (Ochsner)
RESEARCH INFORMED CONSENT

Study Title: U2 Knee™ System with a Disposable Trial: Cost and Efficiency Study
Sponsor name: United Orthopedic Corporation

Principal Investigators: Laura Ikuma, PhD., likuma@lsu.edu, 225-578-5364
Isabelina Nahmens, PhD., nahmens@lsu.edu, 225-578-0943
George Chimento, M.D., gchimento@ochsner.org 504-842-3970
Vinod Dasa, M.D., vdasa@lsuhsc.edu 504-412-1700
Mark Meyer, M.D., msmeyer@ochsner.org 504-842-3970

Sub-Investigators: Emily Lawrentz, PA, elawrentz@ochsner.org
Shannon Branford, NP, sbranford@ochsner.org
Cara Rowe, MSW, CCRP, cjoh26@lsuhsc.edu
Roberto Champney, PhD., rchampney1@lsu.edu
Amani Ahmad, aahma12@lsu.edu
Yasaswi Gudipudi, ygudip1@lsu.edu

Approved - LSUHSC IRB
Signature
03/07/2017
Date

Are you in any other research studies? Yes __________ No __________
please initial your response

You have been invited to participate in a research study. The doctors and staff at LSUHSC-NO and Ochsner study the nature of disease and attempt to improve methods of diagnosis and treatment. This is called clinical research. Understanding this study's risks and benefits will allow you to make an informed judgment about whether to be part of it. This process is called informed consent.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

PURPOSE

The purpose of this study is to measure the efficiency of using disposable trials versus traditional trials in terms of time, resources, and cost. "Trials" are tools used by the surgeon to determine the correct size for the actual orthopedic implant and are not "left in" you. Both systems are FDA-approved and ***do not change the surgical procedures or the final implant used on you.*** As the name implies, disposable trials are thrown away after surgery versus traditional trials that

must be fully sterilized before the next surgery.

You have been asked to participate in this study because we wish to observe the process of using disposable versus traditional trials during surgery. This means several researchers may be present in the operating room in addition to the surgeon and operating room personnel. The researchers will not collect any personal or medical information about you. The researchers will be recording surgical activity times and operating room activities only. This is not a clinical trial.

LENGTH OF STUDY AND NUMBER OF PARTICIPANTS
Your participation in this research study will be for one day (the day of your surgery). There will be 2 sites nationwide enrolling 60 subjects for participation in this study. These subjects will be patients of Ochsner.

PROCEDURE
If enrolled in the study, your surgery will use either the traditional trials or disposable trials. Researchers will observe all steps of surgery and record times, activities of personnel, and resources used (such as surgical instruments and trays). The researchers will not collect any information about you.

RISKS
General / Unforeseeable Risks
This study does not alter your medical care or surgical procedures. The risks associated with participating in this study are no greater than the risks assumed by undergoing this type of surgery. However, participation in the study does not guarantee improved outcomes. Please consult your healthcare provider to discuss the risks of your surgery. Louisiana law requires us to set forth the known risks of a medical treatment, including the risks, if any, of death, brain damage, quadriplegia (paralysis in all arms and legs), paraplegia (paralysis of both legs), the loss or loss of function of any organ or limb, and disfiguring scars, which might be associated with a necessary procedure. Any clinical study carries with it risks of which we may be unaware at this time, including those listed in this paragraph. No investigational drugs, chemically related compounds, or surgical procedures are being used in this study.

POTENTIAL BENEFITS
No direct medical benefit can be guaranteed. Knowledge from this study will help healthcare providers determine cost efficiencies of using disposable trials during total knee replacement surgery.

COSTS
This study will not alter the cost of your surgery or insurance coverage. Any other tests, procedures, or medications that may be necessary for the treatment of your medical condition will be billed to your insurance in the normal way. You may be responsible for co-payments or deductibles. These costs are not covered by this research study. If you have any questions about treatment for which you may be responsible for paying, please discuss this with your physician or study staff.

PAYMENT FOR PARTICIPATION AND/OR REIMBURSEMENT OF EXPENSES

You will not be paid or receive any reimbursement for participating in this study. There is no financial penalty if you decide to withdraw from the study for any reason.

LSU, LSUHSC-NO, and Ochsner are being funded by United Orthopedic Corporation to conduct this research.

ALTERNATIVE METHODS/TREATMENTS

If you choose not to participate in this study, your surgery will use the traditional trials, which is the current procedure used by your surgeon.

STUDY RELATED QUESTIONS AND COMPENSATION FOR INJURY

If you have any questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury or a reaction to a study drug, contact:

Dr. George Chimento at Ochsner-Jefferson
Address: 1514 Jefferson Hwy, New Orleans, LA 70121
Phone: 504-842-3970

Or

Dr. Vinod Dasa at Ochsner-Kenner and LSU-HSC.
Address: 200 West Esplanade Avenue, Suite 500, Kenner, LA 70065
Phone: 504-412-1700

Or

Dr. Mark Meyer at Ochsner-Jefferson.
Address: 1514 Jefferson Hwy, New Orleans, LA 70121
Phone: 504-842-3970

In the event of a research emergency call 504-412-1700 (Kenner) or 504-842-3970 (Jefferson)

QUESTIONS ABOUT YOUR RIGHTS

If you have questions about your rights as a research subject, you may contact:

Chancellor of the LSU Health Sciences Center – New Orleans
Telephone: (504) 568-4801

Or

Ochsner Clinic Foundation Institutional Review Board
Telephone: (504) 842-3535

Or

Dennis Landin, Louisiana State University Institutional Review Board
Telephone: (225) 578-8692

The Institutional Review Board is a group of people who perform independent review of research for human subject protection.

RELEASE OF INFORMATION AND SUBJECTS' RIGHT TO PRIVACY

The results of the study may be released to the funding agency, United Orthopedic Corporation. If the results of the study are published, the privacy of subjects will be protected and they will not be identified in any way. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your study-related medical records for quality assurance and data analysis include:

- The sponsor
- LSUHSC-NO Institutional Review Board
- Ochsner Clinic Foundation Institutional Review Board
- The doctors listed on page 1 of this consent form and their staff
- Food and Drug Administration (FDA)
- U.S. Department of Health and Human Services (DHHS)
- U.S. Office of Human Research Protections (OHRP)

While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE RESEARCH

Participation in this study is voluntary. You may decide not to participate in this study or you may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled at this site. If you decide to discontinue participation, data collected about you up to that point may still be used along with data in publically available health registries. However, no new data will be collected from you.

You will be informed of any significant new findings that develop during the investigation that may affect your willingness to continue in the study.

You should tell your study doctor about all of your past and present health conditions and allergies of which you are aware, and all drugs and medications which you are presently using.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent because:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and the use and disclosure of my health care information from this research. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form I have not waived any of the legal rights that I otherwise would have as a subject in a research study.

CONSENT SIGNATURE

____

Patient Signature Printed Name Date

____

Signature of Legally Authorized Representative Printed Name Date
(*when applicable*)

____

Authority of Subject's Legally Authorized Representative or Relationship to Subject

____

Person Obtaining Consent - Signature Printed Name Date

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part. [Note: This signature block cannot be used for translations into another language. A translated consent form, with the translation approved by the IRB, is necessary for enrolling subjects who do not speak English.]

__________________________ _________________

Signature of Reader Date

__________________________ _________________

Signature of Witness Date

Subject's Initials __________

Subject ID#: ____________

Protocol

Protocol #:	02-2017
Protocol Version:	REV A
Protocol Date:	19 Jan 2017
Study Sponsor:	United Orthopedic Corporation
Study Title:	U2 Knee™ System with Modular Disposable Trials (MDT): Cost and Efficiency Study
Study Device:	Modular Disposable Trial (MDT)
Research Team:	Laura Ikuma, PhD. (PI), likuma@lsu.edu, 225-588-9715 Isabelina Nahmens, PhD., nahmens@lsu.edu. 225-578-0943 Roberto Champney, PhD., rchampney1@lsu.edu Amani Ahmad, PhD. student, aahma12@lsu.edu Yasaswi Gudipudi, MS student, ygudip1@lsu.edu Mechanical and Industrial Engineering 3261 Patrick Taylor Hall Louisiana State University Baton Rouge, LA 70803
Study Sites:	Ochsner Medical Center-Main Campus 1514 Jefferson Hwy, New Orleans, LA 70121 New Orleans, LA Ochsner Medical Center-Kenner 180 W. Esplanade Ave. Kenner, LA 70065
Study Sponsor:	United Orthopedic Corporation Mindy Carlson, Director of Clinical Research, 612-562-0060
Surgeons:	George Chimento, M.D., gchimento@ochsner.org 504-842-3970 Vinod Dasa, M.D., vdasa@lsuhsc.edu 504-412-1700 Mark Meyer, M.D., msmeyer@ochsner.org 504-842-3970
Study Purpose:	United Orthopedics Corporation (UOC) wishes to expand their presence in the US market by providing the best value for total knee arthroplasty (TKA) patients and their healthcare providers. UOC has a unique offering in disposable trials for use during TKA surgeries that may decrease costs and increase efficiencies. In order to successfully sell this solution, UOC needs to obtain empirical data comparing this disposable trial system to traditional systems.
Study Design:	This is a prospective, multi-center, post-approval study to evaluate the efficiency and cost of procedures used in patients receiving primary TKA with the Disposable U2 Knee™ System and the U2 Knee Modular Disposable Trials (MDT) versus standard instrumentation and trials. Study outcomes will be analyzed and published. The procedures will be performed by a team of 5 industrial engineers at two hospitals in the United States. Participants will be

LSU Health
NEW ORLEANS

Institutional Review Board

Memorandum

DATE: March 7, 2017

TO: Laura Ikuma, PhD
Research Institute

FROM: Lynn Arnold, MBA
Coordinator, LSUHSC-NO Institutional Review Board

RE: **IRB #9638: U2 KneeTM System with a Disposable Trial: Cost and Efficiency Study**

Enclosed please find signed and dated copies of the approval documents for the above referenced study, along with other study related documents for your records. You may now begin the study.

Please contact me at 568-3779 or larnol@lsuhsc.edu should you require anything further.

Encl.

433 Bolivar Street, Room 206 • New Orleans, Louisiana 70112
phone 504.568.4970 • fax 504.568.8808 • www.lsuhsc.edu

Ochsner Clinic Foundation
Institutional Review Board
1514 Jefferson Highway
New Orleans, LA 70121
(504) 842-3535 | irb@ochsner.org
DHHS Federal Wide Assurance Identifier: FWA00002050

NOTICE OF INTIAL IRB APPROVAL – Exempt

Title: U2 KneeTM System with a Disposable Trial: Cost and Efficiency Study

IRB#: 2016.480.B **Approval Date:** 1/25/2017

PI: Laura Ikuma **Expiration Date:** 1/24/2099

Sub-Investigators: Yasaswi Gudipudi, Roberto Champney, Vinod Dasa, George Chimento, Amani Ahmad, Mark Meyer, Isabelina Nahmens

Sponsor(s): United Orthopedic Corporation

The study referenced above was reviewed and deemed exempt research by the Ochsner IRB.

Basis for Exemption: 45 CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Approved documents:
Protocol in the IRB file
Employee interview questions
Employee interview consent
Employee non-coercion statement (required by Ochsner institutional policy)
Patient consent
Ochsner HIPAA authorization

HIPAA: The IRB acknowledges receipt of your notice of PHI access preparatory to research. Federal regulations require you to track unauthorized disclosures of protected health information. As long as the use of PHI is only within Ochsner by Ochsner workforce members, or after a subject signs a HIPAA authorization form, no tracking of disclosures is needed. If you are not familiar with the HIPAA rules, review them here: Privacy Rules.

CHANGES/AMENDMENTS/MODIFICATIONS/REVISIONS: You must obtain IRB approval under 45 CFR 46/ 21 CFR 50, 56 if you change any aspect of this study that would impose risks to subjects or include major changes to the study design.

COMPLETION OF STUDY: Notify the IRB when your study is completed. Neither study closure by the Sponsor nor the investigator removes your obligation for submitting a timely continuing review or a final report.

INSTITUTIONAL APPROVAL INFORMATION: Human subject research at Ochsner requires both IRB approval for human subject protection, and Institutional approval from Research Administration. Research Administration is responsible for finances, contracts, grants, legal matters, and other institutional oversight. It is especially important to have your research cleared by Research Administration if it involves FDA regulated drugs or devices, hospital or clinic personnel, or any contractual agreements with others outside the Institution.

***** This memorandum constitutes official Ochsner IRB correspondence. ****

Appendix C. Expert Panel Analysis- Abstract

Thesis Background

Maintaining quality without increasing costs is a major challenge for healthcare organizations. Quality and sustainability are interchangeably and equally important factors in healthcare. The lack of quality will lead to drop in acceptance by the population and to higher costs for the entire system, and by not sustaining quality improvements the system will lose the ability for the integration and acknowledgement of economic, environmental, and social concerns throughout the decision-making process.

Motivation

The objective of this study to measure and identify variables that need to be addressed in order to improve the quality and assure long-term sustainability for Total Knee Arthroplasty (TKA). This study evaluates surgical processes for non-value-added activities by considering efficiency, effectiveness, equity, safety, patient-centeredness, and timeliness perspectives.

Quality and Sustainability in Healthcare

In healthcare, quality can be defined as "the degree to which healthcare services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge." Many care organizations have already been implementing different types of techniques, like six-sigma to reduce the error rate of the process, lean techniques to reduce wastes or total quality management to improve efficiency, in order to achieve optimal quality. Therefore, the main healthcare quality challenge is sustaining the gains. A sustainable healthcare organization has a clear purpose, and it consistently maintains that purpose despite changes. The

concept of sustainability is defined by three main pillars: economic development, social development and environmental protection.

Purpose of the study

In order to assess the sustainability of operating rooms, this study develops a sustainability checklist for the OR staff. Through the evaluation of the checklist, possible wastes that can occur in the OR that might affect quality are revised and economic, social and environmental sustainability of the OR can be assured.

The checklist consists of three sheets: Economic Sustainability, Social Sustainability, and Environmental Sustainability. They are divided into 6 factors reflecting quality dimensions as defined by the Institute of Medicine (2001): safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. For example, economic sustainability falls behind when there is a decrement in the efficiency of the OR. One of the variable that leads to decreased OR efficiency is higher wait time before the surgery. In this way, wastes incurred to bring down the long-term sustainability is explained through each component.

Where/ Why I need your input

In order to create a valid checklist that can be used in the OR, an expert panel provides their specialized input and opinion of the variables. Each panel member is given a table of variables classified into three components of sustainability: economic, social and environment. Each component is sub-categorized into six quality dimensions: effectiveness, efficiency, timeliness, patient-centeredness, equitability, and safety. Various possible wastes are grouped into the sub-categories of every component. Please review the table and provide a score ranging from 1 (not at all important) up to 5 (very important) beside each variable. Based on the scores, the variables are

selected for the checklist. Please ask me any questions you have about the study or the variables.

Thank you for your participation!

Vita

Yasaswi Gudipudi, was born in Andhra Pradesh, India. She completed her bachelor's degree in Mechanical Engineering from Jawaharlal Nehru Technological University, Hyderabad, India. She started her work towards the master's degree in Industrial Engineering in 2015. She also worked as a graduate administrative assistant during her time as a master's student in the Department of Mechanical and Industrial Engineering.