THE USE OF THE WHO SURGICAL SAFETY CHECKLIST AND MATERNAL SURGICAL OUTCOMES IN MARA AND KAGERA REGIONS IN TANZANIA.

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THE USE OF THE WHO SURGICAL SAFETY CHECKLIST AND MATERNAL SURGICAL OUTCOMES IN MARA AND KAGERA REGIONS IN TANZANIA.

By

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A Dissertation Submitted in (Partial) Fulfilment of the Requirements for the Degree of Masters of Science in Project Management Monitoring and Evaluation in Health of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled, ***"The use of the WHO Surgical Safety Checklist and Maternal Surgical Outcomes in Mara and Kagera regions in Tanzania"***, in (partial) fulfillment of the requirement for the degree of Masters of Science in Project Management Monitoring and Evaluation in Health of the Muhimbili University of Health and Allied Sciences.

_____

Prof. David Urassa

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Edwin Charles Ernest** declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature_____ Date_____

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DEDICATION

I dedicate this dissertation to my lovely wife and close friend, Irene Sassi, my daughters Drina and Crissa and my mother. They supported and encouraged me through the ups and downs of the busy years of this course. I deeply appreciate them.

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Abbreviations

CDC	Center for Disease Control
CEmONC	Comprehensive Emergency Obstetrics and Neonatal Care
CHMT	Council Health Management Team
CS	Cesarean Section
GE	General Electric
HC	Health Center
HMIS	Health Management Information System
LCoGS	Lancet Commission on Global Surgery
LMICs	Lower and Middle-Income Countries
MOHCDGEC	Ministry of Health Community Development Gender Elderly and Children
OT	Operating Theatre
PO-RALG	Presidents Office Regional Authority and Local Government
RAs	Research Assistants
REDCap	Research Electronic Data Capture
RHMT	Regional Health Management Team
RMO	Regional Medical Officer
SSC	Surgical Safety Checklist
SSI	Surgical Site Infection
SSP	Safety of surgical Practice
STM	Surgical Team Members
WHA	World Health Assembly
WHO	World Health Organization

Abstract

Background: Millions of patients worldwide suffer disability and death due to complications related to surgery. While WHO surgical safety checklist have been shown to improve teamwork and maternal surgical outcomes, the studies that longitudinally measure the change in maternal surgical outcomes following implementation of WHO SSC in LMICs, including Tanzania are limited and largely ineffective. Very few data are locally available to assess the extent of surgical complications and the use of SSC.

Methodology: A mixed-method study design which involved both quantitative and qualitative data collection. The pre and post data collection on the use of WHO SSC, and maternal and perioperative complications was done before intervention and 18 months after implementation of the intervention (leadership and safe cesarean birth trainings). A total of 1,080 patient files were randomly selected and assessed (466 during pre-implementation and 614 after 18 months of implementation). The study was administered to 218 surgical members (nurse, surgeon, and anesthesiologist) in 40 CEmONC health facilities to assess the perceived elements of WHO SSC that transformed the maternal surgical outcomes.

Results: A total of 1080 files for women who either delivered through C-section or normal; 466 before and 614 after leadership and safe cesarean trainings were reviewed for use of surgical safety checklist and screened for maternal sepsis and surgical site infections. At 18 months, a WHO Surgical safety checklist was used to 94.3% (182 of 193) of women who delivered through C-section as compared with 3.7% (5 of 136) before leadership and safe cesarean trainings ($P<0.001$). There were less surgical site infections rates after C-section when the WHO SSC was used, 1% during pre-implementation as compared to when it was not, 14% after 18 months of implementation, this translates to 93% reduction of surgical site infection rates.

The proportion of women with postoperative sepsis after C-section reduced from 2.9% (4 of 136) during the pre-implementation to 0% (0 of 193) at the post-implementation ($P =0.017$). The C-section related Post-operative mortality ratio (POMR) reduced from 161 deaths per 100,000 C-section during pre-implementation to 99 deaths per 100,000 C-sections during post-implementation ($P=0.6$).

Overall, 95.7% of surgical team members were positive about the critical elements of the WHO surgical safety checklist that transformed the maternal surgical outcomes in Kagera and Mara regions. Approximately 98.2% were positive about staff attitudes, 100% positive about cooperation among disciplines within the operating room, teamwork, and adherence to established safety practices.

Conclusion: This study shows successful introduction and use of WHO Surgical safety checklist and improved maternal surgical outcomes in the lake zone of Tanzania.

Operational Definitions

1. Patient Safety

In the context of this evaluation, this is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.

2. Surgical Complications

I used the following definitions by the Center for Disease Control (CDC) for surgical complications as follows:

2.1. Surgical Site Infections (SSIs)

These occurs within 30 days after the operation and are classified into incisional SSIs, which can be superficial or deep, and organ/space SSIs, which affect the rest of the body other than the body wall layers. These classifications are defined as follows;

2.2.1 Superficial incisional SSI

Infection involves only skin and subcutaneous tissue of incision.

2.2.2 Deep incisional SSI

Infection involves deep tissues, such as fascial and muscle layers; this also includes infection involving both superficial and deep incision sites and organ/space SSI draining through incision.

2.2.3 Organ/space SSI

Infection involves any part of the anatomy in organs and spaces other than the incision, which was opened or manipulated during operation.

The SSI includes at least the following:

- Purulent drainage with or without laboratory confirmation, from the superficial incision.
- Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

- At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative

2.3. Maternal Sepsis

Also known as puerperal infections, is any bacterial infection of the female reproductive tract following childbirth or miscarriage. Signs and symptoms usually include a fever greater than 38.0 °C (100.4 °F), chills, lower abdominal pain, and possibly bad-smelling vaginal discharge.[1] It usually occurs after the first 24 hours and within the first ten days following delivery.

2.4. Post-operative Sepsis

This is defined as evidence of infection associated with two or more criteria of systemic inflammatory response syndrome occurring after surgery: body temperature >38°C or <36°C, leukocytes >12,000 cells/mm^3, positive blood cultures, and respiratory rate >20/min, heart rate >100/min.

CHAPTER ONE

Introduction

1.1. Background

Millions of patients worldwide suffer disability and death due to complications related to surgery. While the level of perioperative mortality, surgical site infection and perioperative sepsis in Tanzania are unknown, studies have documented a range of deficiencies in the country's surgical infrastructure, workforce, and service delivery that increase the risk of complications (1). Despite the implementation of various programs to address perioperative morbidity in Tanzania, the studies that longitudinally measure the change in maternal surgical outcomes after the introduction of the WHO surgical safety checklist are limited.

Safe Surgery is a project funded by General Electric (GE) Foundation and ELMA Philanthropies and seeks to make surgery safe, affordable, and accessible across the world. GE Foundation in collaboration with the government of the United Republic of Tanzania through the Ministry of Health, Community Development, Gender Elderly and Children (MOHCDGEC), President's Office, Regional Administration and Local Government (PO-RALG) and, Jhpiego seek to broadly improve surgical care in Tanzania and more specifically in Kagera and Mara regions. The safe surgery goal is to achieve a reduction of surgical morbidity, improve outcomes related to surgery including Caesarean section (CS), and contribute to the global conversation on safe surgery and maternal health.

The project started in January 2018 and will end in December 2020. The project implemented two main interventions namely the clinical safe cesarean birth (CSB) and the leadership training including the use of WHO Surgical safety Checklist (SSC). The surgical teams simulated the use of SSC at class environment and later on during practicum at local hospitals to reinforce clinical updates and SSC use. The CSB training focused on evidence-based strengthening of cesarean birth practices and patient safety. It included a package of essential, evidence-based perioperative activities aimed to reduce surgical morbidity and improve maternal and newborn outcomes. The leadership training aimed at enabling the surgical team members to describe contemporary surgical and anesthesia services gaps and apply the necessary leadership skills to resolve them. This training also helps the surgical

teams to evaluate the true-life problem, analyzing possible interventions, identify patterns, priorities, and low-hanging solutions for a fast improvement cycle.

After years of evidence generation and sustained advocacy, global surgery gained momentum so much and the World Health Assembly (WHA68.15) passed a resolution to prioritize essential surgery and anesthesia care(2). The poor safety of surgical care was identified as a key problem affecting the lives of millions of people who were treated through surgery. This drew attention not only to policymakers but also to heads of agencies around the world. The safety of surgical care was selected during the second Global Patient Safety Challenge, in 2007–2008 as an area to focus on, after infection associated with health care that came first in 2005-2006(2).

Although surgical procedures are intended to save patient lives, unsafe surgical services may result in substantial harm. Existing data show that surgical patients in African countries are twice as likely to die after surgery compared to their global counterparts(3). The Lancet Commission on Global Surgery (LCoGS), published in April 2015, estimated that 5 billion people around the world lack access to safe, affordable, and timely surgical and anesthesia care. Millions of patients worldwide suffer disability and death due to complications related to surgery (4). The death rate in high-income countries related to surgery is less than 1 in 50,000 while that of LMICs is more than 100 times that of higher-income countries (5). Thus improving the access to safe and quality surgical care is key to advancing universal health care and reduce surgical morbidity and mortality in Tanzania.

The WHO Surgical Safety Checklist (WHO SSC) tool is intended for use by clinicians to improving the safety of their surgical procedures and reducing unnecessary surgical deaths and complications. The WHO SSC is a 19-items checklist set to improve surgical care through a definition of core safety standards. The WHO SSC helps to ensure surgical teams consistently follow the critical safety steps to prevent avoidable risks that may endanger the life and wellbeing of surgical clients/patients (Appendix 1). The process was designed to improve the quality of surgical procedures by bringing together surgeons, anesthesia providers and nurses to perform key surgical safety checks during vital phases of the perioperative care namely sign in (before induction of anesthesia), time out (before skin

incision) and sign out (before the team leaves the operating room). The WHO SSC also helps to facilitate the following among the surgical teams

- Communicate better on a day to day basis and share successes and challenges and removes the hierarchical system in the Operating theatre
- Put patient safety and quality of services as their core focus
- Build problem-solving skills to identify challenges in their setting and find solutions to solve them
- Realize when and how to seek assistance if needed

The World Health Organization reports that most surgical complications and mortality can be reduced through the provision of quality surgical, obstetrics, and anesthesia services and estimates that up to 50% of adverse events following surgery are preventable(2). Furthermore, the use of Surgical Safety Checklist is linked to improved quality of surgical, obstetrics and anesthesia services and have been demonstrated to reduce surgical complications including Surgical site infections and deaths by 30-50% (6).

This study details the results of the assessment of the utilization of the WHO Surgical Safety Checklist and its effect in terms of reduced maternal surgical outcomes in the lake zone of Tanzania.

1.2. Problem Statement

The women undergoing cesarean delivery in African countries are 100 times more likely to die compared to those in high-income countries(7). The most common postoperative complication in African countries is infection; one in ten patients develops an infection after surgery(3) which is 2 to 10 times higher rate than high-income countries(8). One in six African women who undergo C – section delivery develops a surgical site infection (SSI) (9) and one in ten develops maternal sepsis (10). Only six percent of the major surgeries occur in lower and Middle-Income Countries (LMICs) but account for two-thirds of adverse events worldwide (11). Improving surgical quality in LMICs and in particular Tanzania is an urgent priority as it remains beyond the reach of many people.

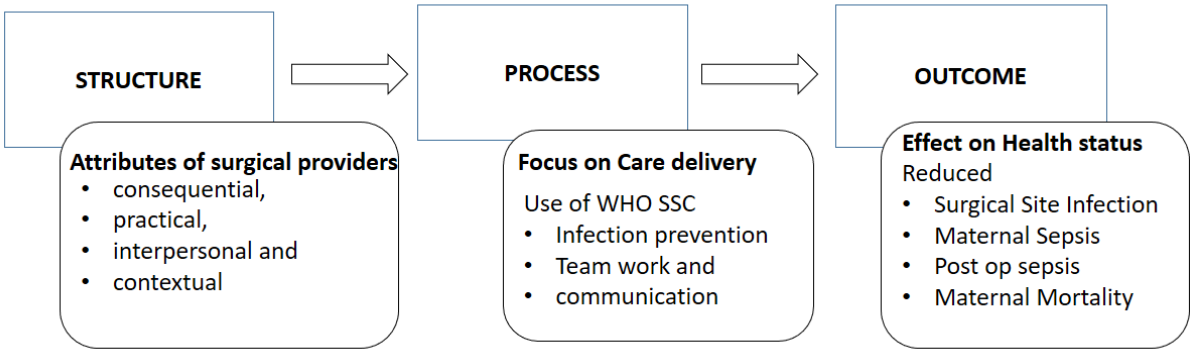
While the level of perioperative mortality, surgical morbidity, and WHO SSC utilization in Tanzania are unknown, studies have documented a range of deficiencies in the country's surgical infrastructure, workforce, and service delivery that increase the risk of surgical complications (1).

The studies that longitudinally measure the change in maternal surgical outcomes following implementation of WHO SSC in LMICs, including Tanzania are limited and largely ineffective(12). Additionally, few studies in Tanzania have highlighted the implementation of the WHO surgical safety checklist and its effect on maternal surgical complications despite the compelling evidence of its benefits from both LMICs and the developed countries. There is a need to evaluate the use of WHO SSC and its effect on maternal surgical complication in the regions that implemented safe surgery project.

1.3. Conceptual Framework

The conceptual framework highlights the key concepts and how the variables are related to improving the quality of maternal surgical outcomes. The Donabedian's framework has been used to evaluate the quality of medical care(13) underpins the relationship of various variables in this study and details the effect of the use SSC on maternal surgical outcomes in terms of reduced surgical complications(14). The framework uses the three components in which the structure (attributes of skilled surgical providers), and the process (use of WHO SSC) improve surgical outcome (maternal sepsis, post-operative sepsis, Surgical site infections, and C-section related maternal mortality). The structure measure have an effect on process measures, which in turn affect the outcome measures (Figure 1).

Figure 1: The Conceptual Framework



Structure measures

These reflect the attributes of the surgical care providers such as consequential, practical, interpersonal and contextual. These are also known as input measures. These healthy attributes have been installed to the surgical teams through safe cesarean birth and leadership trainings. The changing perceptions and individual practices at both individual and institutional levels are the ultimate goals of implementing interventions that seek to improve patient safety and improve teamwork(15)(16).

Process measures

These reflect the way the WHO SSC processes work to deliver the desired maternal surgical outcome. The increased use of SSC is linked to improvement of maternal surgical outcomes. The SSC enhances consistency in surgical team performance at critical times, fostering good communication, teamwork, and a culture of patient safety(16).

Outcome measures

These reflect the impact on the maternal surgical outcomes for women who received services and demonstrate the result of the improved use of SSC. This includes the reduction of maternal sepsis, post-operative sepsis, surgical site infections, and C-section related maternal mortality.

Literature shows that there is a sufficient evidence in favor of SSC use towards improved surgical patient outcomes such as reduced complications(17)(18)(19).

1.4. Rationale

As noted by the Lancet Commission, "Investing in surgical services in low and middle-income countries (LMICs) is affordable, saves lives, and promotes economic growth". MOHCDGEC and surgical society in Tanzania have both committed to improve maternal surgical outcomes. However, a review of the literature reveals that recent evidence on the use of the WHO surgical safety checklist and its effect in terms of reduced surgical complications in Tanzania are generally limited, varied and inconsistent.

While the Tanzania's National Surgical Obstetric and Anesthesia Plan (NSOAP) targets to achieve the WHO SSC utilization rate of 100% by year 2025, Tanzania has neither introduced national data collection tools that captures data routinely nor conducted studies that measure progress towards this target. As a result limited information is available to monitor the use of the WHO SSC and its effect on the maternal surgical outcomes both in the lake zone as well as in other regions of Tanzania.

The study results will provide insights into the coverage and use of the WHO SSC which in turn will help to proactively maintain a high, consistent and standard of surgical care that may be driving the maternal surgical outcomes in Mara and Kagera regions as a result of translating the promising safe surgery initiative from research environment into clinical practice. The results can be translated into opportunities for change in the spectrum of surgical care. For example, if the results shows that the surgical team members do not feel comfortable speaking up in the operating room while performing a surgery, the MOHCDGEC may need to emphasize how surgical safety checklist can be used to invite every team member to voice their concerns and make a cohesive surgical team.

The lessons learnt from the reduction of maternal surgical complications following the use of the WHO SSC will help the MOHCDGEC to avoid resource-intensive approaches by scaling up the current safe surgery practice to other regions.

Since surgical providers contribute significantly to the shape and form of safe surgical services in different facilities, their experience can be critical in determining how WHO SSC transforms the surgical service performance including the teamwork, and communication which are key measures to enhancing patient safety.

The results from this study will also bridge the gap between the initial publication of

scientific evidence about WHO SSC and its uptake into widespread practice in health care in the lake zone of Tanzania. This in turn is critical for improving and scaling the utilization of WHO SSC to other regions in order to reduce maternal surgical outcomes.

1.5. Research Question

To what extent has the safe surgery project influenced the utilization of surgical safety checklist and changes in maternal surgical outcomes in the Kagera and Mara region?

Specific Research Questions

1. What are the changes in the use of the WHO surgical safety checklist in health facilities providing CEMONC services?
2. What are the changes in rates of post-operative complications after C-section delivery in health facilities providing CEMONC services?
3. What are the changes in the proportion of women who developed maternal sepsis after normal delivery in health facilities providing CEMONC services?
4. What are the changes in C-section related Perioperative Maternal Mortality Ratio (POMR) at health facilities providing CEMONC services?
5. What are the perceptions of health workers on the elements of WHO SSC that transformed the quality of maternal surgical outcomes in health facilities providing CEMONC services?

1.6. Broad Objective

To determine the changes in the use of the WHO Surgical Safety Checklist and maternal surgical outcomes in Kagera and Mara regions following the implementation of the Safe surgery project.

1.7. Specific Objective

1. To determine changes in the use of WHO surgical safety checklist in health facilities providing CEMONC services
2. To determine the changes in rates of post-operative complications after C-section delivery in health facilities providing CEMONC services
3. To determine the changes in maternal sepsis after normal delivery in health facilities providing CEMONC services
4. To determine the changes in C-section related Perioperative Maternal Mortality Ratio (POMR) at health facilities providing CEMONC services
5. To assess the perceived elements of the WHO surgical safety Checklist that transform the maternal surgical outcomes

1.8. Literature review

1.8.1. The utilization of the WHO surgical safety Checklist

A surgical checklist is a visual aid that reminds users of important issues before and after surgery. The concept of using the WHO Surgical Safety Checklist to improve surgical outcomes was energized by the WHO's publication in 2009 as part of the Safe Surgery Saves life campaign (20). The checklist takes care of common safety issues around surgery that facilitate better teamwork and communication before, during, and after surgery (21). The 19 items surgical safety checklist was designed to help operating room teams remember important details that may be missed during operations to reduce complications associated with surgery (22). The results from the Safe Surgery Saves Lives Study Group at the WHO showed the use of the WHO SSC was associated with a reduction in major surgical complications ranging from 11% before introduction to 7% afterward(21).

The use of the WHO SSC has been scaled up in multiple settings as studies have shown its link to the reduction of postoperative complications and deaths by more than one third (23). Fifteen African countries received an orientation of the WHO SSC in 2011 to introduce the WHO SSC in the Operating theatre, however, only 67% of the hospitals had implemented the WHO SSC with a mean compliance rate of 48.5%(23). Despite the proven benefits of using the WHO surgical safety checklist including the improvement of teamwork and communication, its utilization in LMICs and particularly East African countries is still low, variable and inconsistent, 0% in Mulago Hospital (Uganda), 0% at Centre Hospital-Universitaire de Kamenge (Burundi), 65% at Muhimbili hospital (Tanzania), 19% at Kenyata Hospital (Kenya), 36% at Centre Hospitalier Universitaire de Kigali (Rwanda)(24) and 65% in Ethiopia (25).

In the Tanzania context, the WHO SSC has not been given adequate attention and the majority of the health facilities providing CEmONC services are either completely unaware of its availability or do not use it at all. This poses a threat to patient safety as 40% of the surgical complications occur in operating rooms(26), and the WHO SSC can reduce the complications for up to 50%. There has been limited, if any, the utilization of the WHO SSC in Tanzania using the implementation science framework.

1.8.2. Surgical site infection among women undergoing Cesarean section

Cesarean section is the most common major surgery performed in sub-Saharan Africa that accounts for up to 80% of the surgical workload(9). The surgical site infection (SSI) is an infection that occurs after surgery in the part of the body where the surgery was performed. The SSI often occurs within 30 days post-surgery and are classified as superficial, deep, or organ/space SSI. The SSIs are a significant cause of morbidity and mortality following Cesarean section in sub-Saharan Africa (27)(28)(29).

SSI is among the most common infectious complications following a cesarean with an incidence of 3% - 15% in Lower and Middle-Income Countries(30). The incidence rate of SSI was found to be about 37.5 per 10,000/day (95% CI, 26.8-52.4) among women undergoing C-section at Bugando Hospital in Mwanza -Tanzania (31). In Northern Tanzania, the infection of the surgical site affects nearly every one patient out of five clients attending surgical services(32). The SSI rates in Tanzania are as high as 24% in selected district hospitals in Tanzania(33).

There is a strong association between the use of the WHO SSC with the reduction of postoperative complications including SSI (18). However, with the implementation of the WHO SSC and the Infection prevention bundles, the SSI rates among women undergoing C-section can be significantly reduced up to 98% (34). However, studies on the infection rates after cesarean surgery are scarce in Tanzania and even a few studies have investigated the Surgical site infection following cesarean surgery which is the most common surgery in health facilities providing Comprehensive Emergency Obstetric and Newborn Care (CEMONC).

1.8.3. Post-operative Sepsis among women undergoing Cesarean section

Every pregnant woman is at risk of maternal sepsis which is a life-threatening infection that accounts for up to 11% of all maternal death worldwide and is the third most common direct cause of maternal deaths(35). Maternal sepsis remains to be a disproportionately high in low- and middle-income countries(36) and one of the common source of morbidity and mortality following Cesarean section. In a study that was conducted at Muhimbili National Hospital, in Tanzania, maternal sepsis was among the leading cause of maternal deaths with a

prevalence of 9.2%(37). A similar study conducted in 34 public hospitals in Tanzania revealed a maternal sepsis prevalence of 16.7%(38). ..

1.8.4. Maternal Sepsis among women giving birth

Maternal sepsis remains to be among the leading cause of preventable deaths worldwide accounting for about 15% of all maternal deaths(39). Maternal (puerperal) sepsis is an infection of the genital tracts that occurs between the onset of labor and the 42nd day at the postpartum period. Maternal sepsis is among the leading causes of death among women undergoing childbirth in most developing countries including Tanzania. The burden of maternal deaths as a result of infection is high in LMICs accounting for about 10.7% with sub-Saharan Africa 10.3% compared to Developed countries, 4.7% (10)

In a study that was conducted in rural districts of Southern Tanzania, maternal sepsis accounted for 35% of maternal deaths(40) and 30.9% in a study in one of the tertiary hospitals in Uganda (41). A study at Muhimbili national hospital in Tanzania revealed maternal sepsis as among the leading causes of maternal deaths and contributed to 9.2% of maternal deaths(37). There is a varying incidence of maternal sepsis in Tanzania and the scarce data makes the incidence difficult to determine.

However, early prevention and active management of maternal sepsis can contribute to a significant reduction of maternal mortality as an underlying contributing factor for the cause of mortality as postulated by the Safe surgery project based on the studies from 8 hospitals around the world by the WHO(6).

1.8.5. Perceptions of surgical team members towards patient safety

In most cases, the successful implementation of innovation in facility-based settings is determined by the readiness of the health facility(42). The changing perceptions and individual practices at both individual and institutional levels are the ultimate goals of implementing interventions that seek to improve patient safety and improve teamwork(15)(16). The understanding of the perception of the surgical team members towards facility readiness, teamwork, adherence and the consequences of the safe surgical practice are essential elements to help improve the implementation of a similar intervention

in the Tanzanian context and for provision of feedback about the implementation facilitators and barriers to ensure effectiveness. However, studies anchored in assessing the perceptions of surgical team members towards patient safety are rare and limited in the African context. A study conducted in the US shows that 78% of surgical respondents were positive about surgical safety and the overall response of neutral/negative towards surgical safety ranged from 16% to 40%(43).

CHAPTER TWO

2.0 Materials and Methods

2.1 Study Design

This was a mixed-method study design which involved both quantitative and qualitative data collection. A pre/post study design evaluated the use of WHO SSC, maternal and perioperative complications using quantitative analysis before intervention and 18 months after implementation of a the intervention (leadership and safe cesarean birth trainings). The qualitative element was used to assess perceptions of surgical team members on WHO SSC elements of patient safety.

2.1.1. Study Setting

The study was administered to surgical teams in forty health facilities (20 health facilities in each region) that are providing Comprehensive Emergency Obstetric and Newborn Care (CEmONC) services in Kagera and Mara in Tanzania. The health facilities are located in both urban and rural settings and include the regional referral hospitals, district hospitals, designated district hospitals, and health centers. All the selected health facilities are implementing a safe surgery project

2.2. Study Population, sample size, and selection

2.2.1. Study Population

A total of 1,080 patient files of women who received surgical services and normal delivery were included in the study: 466 in the pre implementation of the safe surgery (Jan – March 2018), and 614 in the post implementation (October – December 2019). The patient for women undergoing C-section services and postoperative care were reviewed to determine the rates of surgical site infections, postoperative sepsis, C-section related mortality and the use of the surgical safety checklist.

Health care providers who provide surgical services and are part of the surgical team were included in the assessment of the perception of surgical team members towards patient safety.

Inclusion criteria:

- Patient files for women who underwent either a C-section delivery, normal delivery or post-operative services at the specified health facilities between October and December 2019 for the post implementation and between January and March 2018 for the pre-implementation.
- Health care providers who provided surgical and anesthesia services

Exclusion criteria:

- Surgical team members who joined the surgical teams within a period of less than three months before the post implementation assessment.

2.2.2 Sample size and selection

All the forty health facilities (100%) providing CEmONC services and implemented the Safe surgery project were included in the study. The 40 CEmONC health facilities contribute to 99% of the C-section services provided in the two regions.

To determine the minimum sample size required for the proportion of surgical complications, maternal sepsis and the WHO SSC utilization rate for the post implementation, the following formula for estimation of proportion was used;

$$N=\frac{Z^2P\,(100-p)}{\ell^2}$$

Where;

N = sample size estimate of women with surgical complications/maternal sepsis

Z = Z score for 95% confidence interval, which is 1.96

p = prevalence of Surgical Complications among women undergoing C-section /use WHO surgical safety Checklist (4%) and for maternal sepsis (11.2%)

ℓ=Tolerable margin of error N (1.9% for surgical Complications/WHO SSC and 4.4% for maternal sepsis)

Therefore the sample size for WHO SSC/surgical complication is

$$\frac{1.96^2 \times 0.04(1-0.04)}{0.019^2} = 408.6$$

The sample size for maternal sepsis is

$$\frac{1.96^2 \times 0.112(1-0.112)}{0.044^2} = 197.3$$

A minimum sample size (N) of 409 was obtained for WHO surgical safety Checklist utilization /surgical complications and 197 for Maternal Sepsis for the post implementation. This resulted to a minimum sample size of 606 patient files.

I randomly sampled 800 clinical file records, 20 files from each facility. However, I managed to review 614 (76.7%) files from all facilities. A total of 186 randomly sampled files went missing and could not be retrieved. The 614 patient files were thoroughly reviewed and documented the presence/absence of the surgical site infections/sepsis and a correctly and completely filled WHO surgical safety checklist.

During the pre-implementation (Jan – March 2018), 466 files were randomly selected and reviewed; 326 for WHO surgical safety checklist/surgical complications and 140 for maternal sepsis.

I reviewed the Operating theater (OR) register where the C-section deliveries are recorded routinely to obtain the aggregate number of C-section deliveries performed in a January – March 2018(pre-implementation) and October – December 2019(post implementation). Cumulatively, 4,272 C-section deliveries were conducted, 1239 during pre-implementation (January – March 2018) and 3033 during the post-implementation (October – December 2019).

I reviewed the inpatient register and ward round reports to obtain the number of C-section related deaths for the period of January – March 2018 and October – December 2019. A total of 5 deaths were recorded to have occurred after C-section delivery, 2 during the pre-implementation (January – March 2018) and 3 after the implementation (October – December 2019)

To assess the critical elements of the WHO surgical safety Checklist that are perceived to transform the maternal surgical outcomes, I administered the Safety of Surgical Practice (SSP) tool at all the 40 facilities. I invited all eligible Surgical Team Members (100%) to participate in responding to the SSP tool. On average, there were approximately 4-6 STMs per health facility making a total of 218 participants who responded to the SSP tool.

Tables 1 and 2 below show the distribution of health facilities included in the sample and their characteristics (level of the facility, district of location, and the number of respondents for each).

Table 1: Distribution of health facilities and the number of respondents in Mara region

District	Number of Hospitals	Number of respondents at Hospitals	Number of Health Centers	Number of respondents at Health Centers
Serengeti District Council	1	6	1	4
Bunda District Council	2	11	3	18
Butiama District Council	1	6	1	5
Musoma District Council	0	0	1	4
Musoma Municipal Council	1	6	1	6
Rorya District Council	2	12	1	4
Tarime District Council	1	6	4	20
Total	8	47	12	61

Table 2: Distribution of health facilities and number of respondents in Kagera region

District	Number of Hospitals	Number of respondents at Hospitals	Number of Health Centers	Number of respondents at Health Centers
Bukoba Municipal Council	2	12	-	-
Missenyi District Council	1	6	1	4
Kyerwa District Council	1	6	1	5
Karagwe District Council	2	12	1	6
Ngara District Council	3	17	-	-
Biharamulo District Council	1	5	2	9
Muleba District Council	3	18	1	6
Bukoba District Council	1	4	-	-
Total	14	80	6	30

2.3. Data Collection Methods

2.3.1. Recruitment Process:

Through Regional Medical Officers (RMOs) and regional health management teams (RHMTs) of Kagera and Mara, the evaluation team informed all the facility in-charges of the selected health facilities. Once the facility in-charge agreed to participate in the study, the study team provided an informational session to staff, orient them to the study and its purpose. The study team members included research assistants with a medical profession background (Medical Doctors, Clinical Officer, Nurses).

2.3.2. Consent Process:

The study team approached each potential study participant, informed them of the purpose of study, and requested consent. Recruitment and consent took place at a scheduled time that was convenient for the participant. The written consent form was signed by both researcher and the participant. For confidentiality, the study participants only wrote their initials and signature.

2.3.3. Data collection

The data collection duration for the pre and post implementation was one month for each. I collected the pre-implementation data covering a period of January to March 2018, which was followed with another data collection after 18 of project implementation which covered October – December 2019. I collected data from patient files of women who received maternal surgical services and normal delivery and reviewed the paper-based registers and ward round notes to obtain the volume of C-section delivery and C-section related maternal deaths. Three weeks were spent on data collection and validation, and one week for data cleaning. The four medical data collectors were hired to support data collection. The medical data collectors were qualified nurses or medical doctors with the necessary skills to identify the pre-identified parameters including the surgical site infections and sepsis.

2.3.4. Data quality control

To ensure high-quality data, the study team utilized data control measures that included among other activities; training of data collectors (medical research assistants), pre-testing of data collection tools and supervision of data collection, and the entire data management processes. Data quality procedures included the adherence to data quality dimensions of timeliness, completeness, validity (accuracy), and reliability (precision).

2.3.5. Data collection tools.

I used a Clinical review tool (Appendix 2) to record the number of Post C-section deaths, Surgical Site Infections, Post-op sepsis, Maternal sepsis (all non-surgical), and anesthesia-related complications information from theatre register, anesthesia records, HMIS registers and ward round book. The RAs collected data that covered three months.

I measured the views and perceptions of Operating Theatre service providers using the Safety of Surgery Practice (SSP) tool (Appendix 3). This adopted tool has been generally used to assess surgical team member's perceptions of readiness, teamwork, adherence to, and consequences of safe surgical practice. The 31-question tool with 7-point Likert-type responses measures four dimensions associated with the implementation of these safer

surgery practices: contextual, interpersonal, practical, and consequential.

The RAs used tablets installed with REDCap to facilitate electronic data capture for both the Clinical review tool and the safety of the surgical practice tool.

2.3.6. Study Variables of Measures

Three main study measures were undertaken in this survey, namely WHO surgical Safety Checklist utilization rates, the rate of surgical complications which are estimated as mortality and morbidity rates (rates of surgical site infections (SSIs), maternal sepsis and post-operative sepsis) and the perceptions of operating theatre service providers towards patient safety were estimated as proportions using the Likert scale.

The use of SSC was assessed by case notes (clinical files) review in which the presence of a checked or filled SSC in the file was considered as its utilization. The proportional of files of women who received Cesarean section services with the filled WHO SSC was computed to determine the WHO SSC utilization rates. The results in WHO SSC utilization rates were compared between the pre and post implementation to determine changes.

The review of the individual case notes for women who received a Cesarean section was done to assess the evidence of sepsis or SSI during the process of history taking for all the post-op (surgery) days up to the time the patient was discharged from the health facility. The presence/absence of sepsis or SSI was documented for each client. The proportionality of Cesarean section clients with SSI or post-operative Sepsis was computed out of all clients who received a C-section from a sample drawn in the three months.

I estimated C-section related mortalities ratio by dividing the number of C-section mortality to the total number of C-section deliveries per 100,000 C-sections. The values obtained for post implementation were compared to the values obtained for pre-implementation. The C-section death data were collected from appropriate HMIS registers (Operating Theatre register/Labor and Delivery register) and covered a period of three months (January – March 2018) for pre implementation and October – December 2019 for post implementation.

I assessed the perceptions of the Operating Theatre service providers towards patient safety outcomes using the Safety of Surgical procedure tool. This is the 7 Likert scale questionnaire

with about 31 questions addressing the perceptions of the surgical teams towards patient safety surgical outcomes.

The Safety of Surgery Practice (SSP) tool, is a brief questionnaire with 31 items each having a 7-point Likert Scale choice of responses ranging from 1 (Strongly Disagree) to 7 (Strongly Agree). Better teamwork and adherence to quality and safe practice guidelines are known to be associated with improved patient safety and reduced adverse outcomes, including surgical complications and perioperative mortality, the surgical outcome parameters which have been measured and reported separately as part of the post implementation evaluation. The SSP tool measured four dimensions associated with the implementation of the safer surgery practices namely contextual, interpersonal, practical, and consequential (Table 3)

Table 3: Dimensions of the safety of surgical practice

Dimensions	Items	(Number of items) and Definitions
1. Contextual	1,2,3,4,5	(5) These include organizational readiness, staff attitudes, cooperation among disciplines
2.Interpersonal (teamwork)	Factors (Total)	(18) The five factors recognize that implementing innovations, even those as outwardly straightforward as surgical checklists, requires complex social and behavioral changes that challenge the status.
	1.Communication-6,7,8	
	2.Coordination-9, 10,11, 12, 13 (0.72)	
	3. Respect-14,15,16,17 (0.57)	
	4. Assertiveness-18, 19, 20 (0.58)	
	5. Clinical leadership-21, 22, 23 (0.47)	

Dimensions	Items	(Number of items) and Definitions
3.Practical (adherence)	24, 25, 26, 27, 28 (0.49)	(5) These were used to measure the extent to which surgical team members adhered to established safety practices in the operating room (e.g., preoperative planning, post-operative debriefing).
4. Consequential (Other items)	19, 30, 31	(3) The items in this dimension measures how team members perceive the impact of surgical interventions on surgical outcomes.

2.3.7. Pre-test of the data collection tools

The data collection tools were pre-tested by the study team at a conveniently selected non-study site in Mara region. This was done to ensure the research assistants clearly understood the questions and how to ask the questions. The issues around the screening of sepsis and surgical site infection emerged. The study team was oriented by an expert on surgery on how to screen and interpret the results.

2.3.7. Supervision of data collection activities

Data collection activities were regularly supervised by a team of two people among which the one was a medical Doctor. The supervision involved a review of the filled questionnaires across all the dimensions of data quality to ensure completion, consistency, and uniformity (where applicable).

2.4. Investigation tools, validity and reliability issues

2.4.1. Data entry and validation

The coded questionnaires were entered into pre-developed data entry screens using Research Electronic Data Capture (REDCap) software. Each questionnaire was entered against its unique identifier. Validation of all the entered scripts were done by a single person who did not participate in the data entry process. The final data sets from REDCap were exported to Stata version 15 statistical software and MS-Excel for analysis. Cleaning of the data sets with the removal of missing data was done. Renaming of the coded variables and the response codes (numbers) were done to allow easy identification of the variables in the data sets. The recoding of the responses was done before the analysis.

2.4.2. Data Validity and reliability

I measured the reliability (internal consistency) for the data I collected using the safety of surgical practice tool by using Cronbach's alpha (α). I computed the Cronbach's alpha using Stata version 15 for a set of grouped questions that measures a dimension of the elements of the WHO SSC i.e. contextual, interpersonal, practical and consequential. Some WHO SSC dimensions scored Cronbach's alpha less than or equal to 0.5. The smaller number of α is partly associated with few questions on the tool. The number of questions per dimension ranged between three and five. This may also literally mean that number of questions were not enough. However, in some studies the Cronbach's alpha value of 0.5 or above was considered as moderate reliability (Hinton 2004).

2.5. Data analysis

To understand the changes in proportions for the three months during the pre-and post-implementation of the interventions, I compared the proportions of individuals with a characteristic of interest during pre-implementation against the post-implementation. The variables of interest are categorical (use the WHO checklist, Surgical Site Infection, Postoperative Sepsis, Maternal Sepsis, and C-section Death). To make a comparison, independent random samples were drawn during the pre-and post-implementation of the interventions from each health facility.

The null hypothesis H0 was that the pre and post-implementation proportions are the same for each of the categorical variables meaning the difference was equal to zero. All the tests and confidence intervals were considered to be significant at $p \leq 0.05$ and all analyses were performed using STATA version 15.

The Safety of the surgical practice questionnaire has 31 items with a 7-point Likert scale measuring four dimensions associated with the implementation of the safe surgery practices including contextual, interpersonal, practical, and consequential. After testing for normality (using a theory-driven numerical Shapiro-Wilk test method), I analyzed the responses by calculating the mean of positive responses and group them as follows

- Strongly positive (7): This was be done after reversing the scoring of negatively worded items
- Positive responses (5-6) and
- Neutral or negative responses (1-4).

The interpretation of the result was based on the assumption that a weak surgical environment was derived from a combination of neutral or negative responses (1-4)(43)(44). For the dimensions and factors, average (mean) scores <4.5 were classified as negative/neutral, 4.5 to 6.5 as positive, and >6.5 strongly positive. The results of this tool were presented using tables.

Analysis of the average percentage of positive responses

Stage one: Reversing the negatively worded items and the mean of the response

I conducted a descriptive analysis of the 31-question tool with 7-point Likert-type responses that measured four dimensions associated with the implementation of these safer surgery practices: contextual, interpersonal, practical, and consequential. I reversed the negatively worded items in each dimension (if it existed) after removing the missing data.

Stage two: Grouping the mean of the response

I calculated the mean score of the responses for all the items within each dimension and grouped them into three groups; neutral or negative responses (1-4), Positive responses (5-6), Strongly positive (7). The categories formed the basis for the interpretation of the results. The

interpretation of the results were based on the assumption that weak surgical environment will be derived from a combination of neutral or negative responses (1-4). For the dimensions and factors, average (mean) scores <4.5 were classified as negative/neutral, 4.5 to 6.5 as positive, and >6.5 strongly positive.

Stage three: The average percentage for each dimension

I obtained the average of each of the grouped item responses to obtain the dimensional score.

Stage four: The overall percentage of positive response

This was taken as the average percentage of positive response for all the 4 dimensions included in the 31 item SSP tool.

2.6. Ethical issues

Ethical clearance was obtained as per Muhimbili University of Health and Allied Sciences (MUHAS) research ethical procedures.

2.7. Risks of the study

There is a limited professional risk to participants who may fear repercussions from highlighting patient safety gaps at their hospital. Participant identifiers were not collected and only aggregated, hospital-level results are reported. The research team did not share participant-level data with those outside the study team- including hospital administrators. In hospitals where the surgical team is comprised of <5 of each cadre (e.g., nurse, surgeon, anesthesiologist), aggregate data was not reported by cadre as this may identify the subject(s).

CHAPTER THREE

3. FINDINGS

3.1. Socio-demographic characteristics of study subjects

Six hundred and fourteen files were reviewed during the post-implementation evaluation. 194 (31.5%) were women who received a C-section, 200 (32.6%) women who delivered through normal delivery, and 220(35.8%) were women who received Post-operative services. One-third, 35.7% of women who received CS services were age 20-24(Table 4).

Table 1: Age distribution of mothers at health facilities

	C-Section		Normal Delivery		Post- Operative	
Age (Years)	**n**	**%**	**n**	**%**	**n**	**%**
15-19	46	24	46	23%	7	3%
20-24	69	36	53	27%	23	10%
25-29	36	19	49	25%	46	21%
30-34	24	12	32	16%	46	21%
35-39	12	6	17	9%	35	16%
40-44	5	3	3	2%	20	9%
46-49	2	1		100%	18	8%
50-54					13	6%
55+					12	5%
Total	194	100	200	100	220	100

3.2. The changes in the utilization rate of the WHO surgical safety checklist

The rate of the surgical safety checklist utilization among the women undergoing C-section has improved from 5(3.7%) during the pre-implementation (January – March 2018) to 182(94.3%) post-implementation of the leadership and safe cesarean birth trainings. The results show there was an improvement in the utilization of the WHO surgical safety checklist for both Kagera and Mara regions. In Mara region, the utilization improved from 1.6% during baseline to 92.6%. In Kagera region, the WHO surgical Safety Checklist utilization has increased from 5.4% during baseline to 95.9% after the project implementation. The improvement is statistically significant with a P-value <0.001 across the regions and health facilities (Table 5).

Table 2: Surgical Safety Checklist Utilization for Post- C section client

	Pre-implementation (January – March 2018)		Post-implementation (October – December 2019)		P-values
	n	%	n	%	
Mara region					
SSC Completed	1	1.6	88	92.6	<0.001
SSC Not Completed	61	98.4	7	7.4	
Kagera region					
SSC Completed	4	5.4	94	95.9	<0.001
SSC Not Completed	70	94.6	4	4.1	
Hospitals					
SSC Completed	4	5.3	105	96.4	<0.001
SSC Not Completed	71	94.7	4	3.6	
Health Centers					
SSC Completed	1	1.6	77	91.7	<0.001
SSC Not Completed	60	98.4	7	8.3	

The overall utilization of the WHO surgical safety checklist among postoperative women was recorded at 87.5% as compared to 2.1% during the pre-implementation period in the two regions (Table 6). The WHO surgical safety checklist utilization rate was higher in Kagera, 90.6% as compared to Mara region, 83.9%. Similarly, the improvement in the utilization of the WHO surgical safety checklist was observed in both health centers and hospitals almost equally (85.7% vs 88.6%).

Table 3: Surgical Safety Checklist Utilization for Post OP

	Pre-implementation (January – March 2018)		Post-implementation (October – December 2019)		P-values
	n	%	n	%	
Mara region					
SSC Completed	3	2.9	141	83.9	<0.001
SSC Not Completed	102	97.1	27	16.1	
Kagera region					
SSC Completed	1	1.1	175	91.6	<0.001
SSC Not Completed	88	98.9	16	8.4	
Hospitals					
SSC Completed	3	2.3	194	88.6	<0.001
SSC Not Completed	125	97.7	25	11.4	
Health Centers					
SSC Completed	1	1.5	120	85.7	<0.001
SSC Not Completed	65	98.5	20	14.3	

3.3. The changes in post-operative complications after C-section delivery in health facilities providing CEMONC services

3.3.1. The changes in the proportional of women who have had surgical site infection after C-section

The proportion of women with surgical site Infection after C-section has reduced from 14% during baseline to 1% after the implementation of safe surgery interventions. The surgical site infection rates were higher in Mara region (16.1%) during baseline as compared to 12.2% in Kagera region. The changes in surgical site infection rate after the implementation of the safe surgery interventions is statistically significant in both health centers and hospitals (P=0.003 for health centers and P<0.001 for hospitals). The proportions of surgical site infection in Mara were 1.3 times that of Kagera region during baseline and have reduced to 1.1% during the post-intervention survey (Table 7).

Table 4: Proportion of women with Surgical site Infection after C-section during pre and post implementation period

	Pre-implementation (January – March 2018)		Post-implementation (October – December 2019)		P-values
	n	%	n	%	
Mara region					
SSI present	10	16.1	1	1.0	0.003
No SSI	52	83.9	94	98.8	
Kagera region					
SSI present	9	12.2	1	1.0	0.002
No SSI	65	87.8	97	99.0	
Hospitals					
SSI present	11	14.7	1	0.9	0.001
No SSI	64	85.3	108	99.1	
Health Centers					
SSI present	8	13.1	1	1.2	0.0034
No SSI	53	86.9	83	98.8	

3.3.2. The changes in the proportional of women who have had postoperative sepsis after C-section

A total of 329 files were reviewed and screened for the presence of postoperative sepsis; 136 during the pre-implementation (January – March 2018) and 193 after 18 months of implementation (October – December 2019). The proportion of women with postoperative sepsis after C-section has reduced from 2.9% during pre-implementation to 0% during the post-implementation survey (P value=0.017). The changes in the proportion of women who have had post-op sepsis in Mara region have significantly reduced (6.5% to 0%). Similar results have been observed at the health centers and hospital levels though the changes are not statistically significant (P=0.094). Both health centers and hospitals did not record any post-operative sepsis over the three months of implementation as compared to three months before the implementation of safe surgery interventions (Table 8).

Table 5: Proportion of women with Post-Op sepsis after C-section

	Pre-implementation (January – March 2018)		Post-implementation (October – December 2019)		P-values
	n	%	n	%	
Mara region					
Post-Op Sepsis present	4	6.5	0	0.0	0.012
No Post-Op Sepsis	58	93.5	95	100.0	
Kagera region					
Post-Op Sepsis present	0	0.0	0	0.0	--
No Post-Op Sepsis	74	100.0	98	100.0	
Hospitals					
Post-Op Sepsis present	2	2.7	0	0.0	0.085
No Post-Op Sepsis	73	97.3	109	100.0	
Health Centers					
Post-Op SSI present	2	3.3	0	0.0	0.094
No Post-Op SSI	59	96.7	84	100.0	

3.4. The changes in the proportional of women who have had maternal sepsis after normal delivery

A total of 344 files of women delivered at through normal delivery were reviewed and screened for maternal sepsis, 144 during pre-implementation (January – March 2018) and 200 after 18 months of implementation (October – December 2019). Although the rate of maternal sepsis has reduced, the reduction is not statistically significant (p=0.2). Overall, the proportion of women who have had maternal sepsis in the two regions has reduced from 1.3% to 0.0%. Only one maternal sepsis was reported during the pre-implementation and none was found at 18 months post implementation. (Table 9). In Kagera region, neither during pre-implementation nor after 18 months of implementation maternal sepsis was recorded in the files reviewed. As such the sites have maintained the patient safety for the mothers who deliver through normal delivery. This safety of women who deliver normally has also been sustained in Mara region. However

Table 6: Proportion of women with maternal sepsis

	Pre-implementation n=144 (January – March 2018)		Post-implementation n=200 (October – December 2019)		P-values
	n	%	n	%	
Mara region					
Maternal Sepsis present	1	1.3	0	0.0	0.25
No Maternal Sepsis	74	98.7	100	100.0	
Kagera region					
Maternal Sepsis present	0	0.0	0	0.0	--
No Maternal Sepsis	70	100.0	100	100.0	
Hospitals					
Maternal Sepsis present	0	0.0	0	0.0	--
No Maternal Sepsis	70	100.0	110	100.0	
Health Centers					
Maternal Sepsis present	1	1.3	0	0.0	0.27
No Maternal Sepsis	74	98.7	90	100	

3.5. The changes in mortality related to Cesarean Section delivery

Generally, the mortality ratio related to C-section have been reduced over the past 18 months post-implementation as compared to the pre-implementation of safe surgery project. The C – section mortality has been reduced from 161 deaths per 100,000 C-section during baseline to 99 deaths per 100,000 C sections after the project implementation. However, the changes in the proportion of C-section related deaths are not statistically significant (P=0.6)

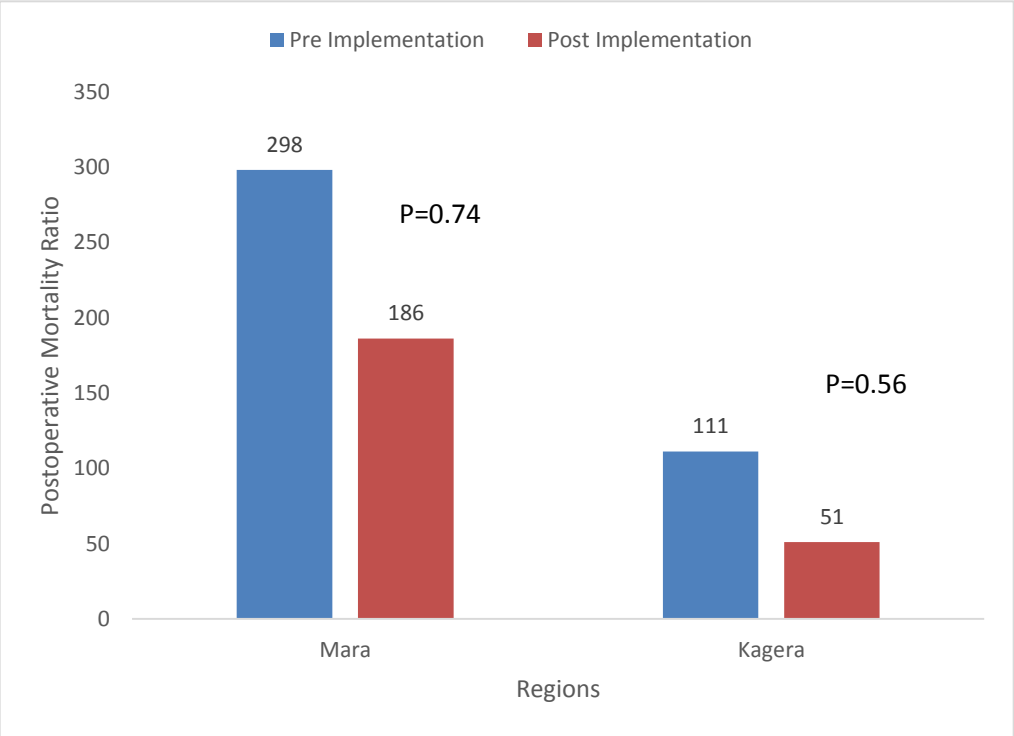
The mortality ratio related to C- section before the implementation of the safe surgery was zero for health centers, as opposed to hospitals, 199 deaths per 100,000 C-section surgeries. However, mortality ratio related to C- section after 18 months of implementation has increased from zero to 399 deaths per 100,000 C-section surgeries which raises concerns. The higher mortality rates during post implementation suggest a further detailed study.

In Mara region, the mortality ratio related to C- section has reduced from 298 399 deaths per 100,000 C-section surgeries during pre-implementation period (January – March 2018) to 186 deaths per 100,000 C-section surgeries after 18 months of safe surgery project

implementation (October – December 2019). Likewise, in Kagera region, the C-section related mortality ratio has halved (111 vs 51) when comparing the pre implementation against the 18 months after implementation of the safe surgery project. (Figure 3). However, the results are not statistically significant.

The volume of C-section over the three months has also increased from 1,239 during baseline to 3,033 after the implementation of interventions. This translates to a more than the two-fold increase of C-section volume within two years.

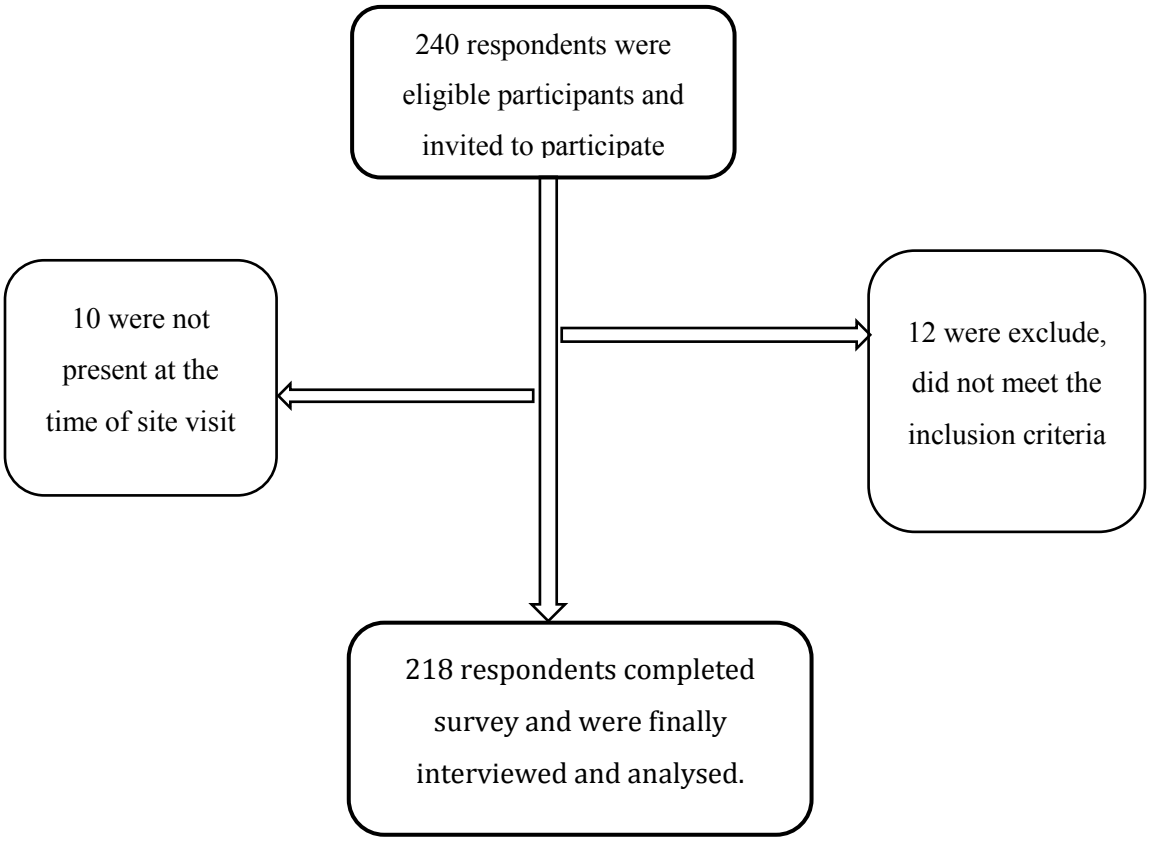
Figure 2: The change in the C-section related mortality rates in Kagera and Mara regions, a comparison between pre implementation and 18 months after the implementation of the interventions



3.6. The most critical elements of the WHO surgical safety Checklist that are perceived to transform the maternal surgical outcomes

All members of surgical teams (STMs) from selected health facilities were eligible and invited to participate. On average, there were 4-6 members per STM per health facility. We included 40 health facilities with an estimated 6 potential subjects from each, giving an estimated sample size of approximately 240- subjects. Out of 240 respondents expected from STMs across 40 health facilities, I collected data from 218 respondents (Figure 3), thus providing an overall enrolment rate of 90.8%,

Figure 3: Flow diagram showing recruitment of study



3.6.1 Socio-demographic characteristics of study subjects

The majority of the surgical team members were nurses who accounted for 32.6% of all respondents, followed physicians 29.8% who played a role of surgery assistants. Nearly one fifth 19.3% of the surgical workforce was surgeons. While the surgical team composition has a unique importance, anethetistics were few and the anesthesia work was largely done by nurse anesthetist nurse who contributed to 13.3% of the surgical team members responded to the survey (Table 11)

Table 7: Distribution of Surgical team members (n=218)

Characteristics	n	%
Facility ownership		
Government	129	59.2
Faith based organization	83	38.1
Private	6	2.8
Level of health facility		
Health centers	92	42.2
Hospitals	126	57.8
Role in the Surgical team		
Surgeons	42	19.3%
Surgical assistants	65	29.8%
Anesthetists	8	3.7%
Anesthetist Nurse	29	13.3%
Nurses	71	32.6%
Other health aides	3	1.4%

3.6.2. General distribution of positive responses

Several tables summarizes participants' responses regarding their work environment. The responses were generally positive about the transformation of surgical outcomes, 95.7% being agree (4.5-6.5) and 3.4% strongly agree (> 6.5).

3.6.3. Contextual dimension

The contextual dimension measures how the facilities were ready to adopt the initiatives to transform the surgical outcomes. It measures the perceptions of surgical team members

towards innovations to improve patient safety, and cooperation among team members of different disciplines working towards the achievement of a common goal. Concerning this dimension, 98.2% of the respondents were predominantly positive or strongly positive. The percent of respondents whose average score among items was negative or neutral was estimated at 1.8%. This implies that there is generally a high drive on readiness to innovations as reflected in attitudes, beliefs, and corporations to support the implementation of surgical standards. However, 37.3% of surgical team members (STM) feebly felt that the joint commission 'time-out' was easy to implement (Table 12).

Table 8: Distribution of Contextual responses

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
Overall (all survey items), N=218 Dimension/factors/item	**0.96**	**95.67**	**3.37**
1.Contextual (Readiness) Cronbach's α = 0.44	**1.8**	**27.5**	**70.7**
Surgical team members are open to changes that improve patient safety, even	4(1.8)	65(29.8)	149(68.4)
Commission 'Time Out' is used in every case by every surgical team	5(2.3)	90(41.5)	122(56.2)
The joint commission "time out" was difficult to implement ®	81(37.3)	71(32.7)	65(29.9)
Surgical team members (STM) all agree on the importance of using checklist®	3(1.4)	35(16.1)	180(82.6)
Interest in checklist implementation is limited to one profession®	20(9.20	55(25.2)	143(65.6)

3.6.4. Interpersonal dimensions (Teamwork)

The interpersonal dimension measures the attitudes of surgical team members towards team-based interactions, communication, and a means of responding to potential surgical complications during a surgical procedure. The implementation of the WHO surgical safety checklist aimed to improve teamwork among the surgical team members. The results show that 100% of the surgical team members were positive or strongly positive about the implementation of the surgical safety checklist to improve teamwork. Five factors are considered to affect teamwork, these are communication, coordination, respect, assertiveness, and clinical leadership.

3.6.4.1 Communication

Even though approximately 98.1% of STM responses opined that there was a positive climate to favor good communication among them overall. These results show that the WHO surgical safety checklist facilitates communication in the operating theatre room and encourages every surgical team member to speak in the efforts to improve surgical outcomes. However, about 3.7% of STM felt that there was a weak working environment or tendency that 'team discussions were common.

3.6.4.2. Coordination

About 99.9% of the Surgical Team members felt that using the checklist has helped them work better as a team. Surgical team members appear eager to help one another and physicians, nurses, surgeons, and anesthesia providers work together as well as a well-coordinated team. The surgical team members were generally positive about sharing the operative plan, discuss the needs of medical supplies, or anything necessary for the improved safety of patient safety.

3.6.4.3. Respect

Overall, 99.5% among the surgical respondents, pointed out the presence of a good working environment to enhance respect among them. The 79.4% of the surgical team members felt that communication among themselves was done politely. The WHO Surgical safety checklist aimed at making every member feel respected by other team members and the results shows that this was well attained by the teams and so everyone felt valued.

3.6.4.4. Assertiveness

The checklist invites every team member to speak any concerns about patient safety so the team can jointly discuss any mistake in the operating theatre. Overall, 76.6% of responses from STM suggested a good environment for the assertiveness factor overall. However, approximately 23.4% of them felt that there was a weak environment in the operating theater to discuss medical mistakes. Additionally, about 99.5% of STM opined that it was difficult to speak up when a team member perceives problems with patient care.

3.6.4.5. Clinical leadership

Overall, 98.2% of STM suggested that there was a good working environment in the operating theatre for clinical leadership, meaning that the existing surgeons and anesthesiologists were seen as good leaders. About 7.4% of STM felt that there was a weak climate for Physicians to open-up and receive suggestions from other physicians.

Table 9: Distribution of percentage of positive responses towards Interpersonal factors

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
2. Interpersonal (teamwork)	**0 (0.0)**	**14 (6.7)**	**194 (93.3)**
Factor a: Communication (Cronbach's α = 0.55)	1.85	**29.6**	**68.5**
Team discussion is common	8(3.7)	89(40.8)	121(55.5)
Surgical team members make sure their comments or instructions are heard	4(1.8)	73(33.5)	141(64.7)
STM shares key information as it becomes available	1(0.5)	52(24.1)	163(75.5)
Factor b: Coordination (Cronbach's α = 0.72)	**0**	**23.8**	**76.1**
Surgical team members appear eager to help one another	1(0.5)	39(17.9)	178(81.7)
Physicians and nurses work together as a well-coordinated team	1(0.5)	43(19.7)	172(79.8)
Surgeons and anesthesia providers work together as well as a well-coordinated team	1(0.5)	26(11.9)	191(87.6)
Surgical team members from different disciplines always discuss patients' conditions and progress of the operation	1(0.5)	98(44.9)	119(54.6)
Plans for patient's care are adapted as need	1(0.5)	102(46.8)	115(52.7)
Factor c: Respect (Cronbach's α = 0.57)	**0.46**	**33.8**	**65.7**
STMs communicate with me in a respectful manner	1(0.5)	44(20.2)	173(79.4)
My inputs about patient's care is well received by other STM	1(0.5)	60(27.8)	155(71.8)
I am always treated as a valuable member of the surgical team	1(0.5)	46(21.1)	171(78.4)

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
Potential errors or mistakes are pointed out without raised voices or condescending remarks	1(0.5)	93(42.7)	115(52.8)
Factor d: Assertiveness (Cronbach's α =0.58)	**23.39**	**76.6**	**0**
It is difficult to discuss medical mistakes (Missing=1) ®	19(8.7)	83(38.1)	116(53.2)
Surgical team members appear to struggle and do not ask one another for help ®	2(0.9)	60(27.5)	156(71.6)
It is difficult to speak up when I perceive problems with patients care ®	217(99.5)	1(0.46)	0(0)
Factor e: Clinical Leadership (Cronbach's α=0.47)	**1.84**	**29**	**69.1**
Physicians are only open to suggestions from other physicians. ®	16(7.4)	62(28.4)	140 (64.2)
Physicians are present and actively participating in patient care before skin incision.	4(1.8)	14(18.8)	173(79.3)
Physicians maintain a positive tone throughout operations.	5(2.3)	62(28.6)	150(59.7)

3.6.5. Practical dimensions

The majority (93.4%) of STM at least agreed that there was a friendly working environment for them to adhere to established safety practices in the operating room. However, more than one-third of the respondents opined that for complex patients or cases, preoperative briefings did not always include a mitigation plan for a potential problem. In one example, analysis shows that 52.7% refer to each other by role instead of a name, 7.3% of STM established that there was a weak working environment for equipment issues or other problems that were discussed during postoperative debriefing to be addressed promptly (Table 14).

Table 10: Distribution of percentage of positive responses towards Practical dimension

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
3. Practical (adherence) (Cronbach's α =0.49)	6.51	93.4	-
STM refer to each other by role instead of the name ®	115(52.7)	45(20.7)	58(26.6)
Surgical teams always discuss the operative plan	8(3.7)	91(41.7)	119(54.6)
For complex patients or cases, preoperative briefings always include planning for potential problem	8(3.7)	79(36.2)	131(60.1)
Postoperative debriefings always include a discussion of key concerns for patient's recovery and post-to management.	6(2.8)	92(42.2)	120(55.0)
Equipment issues or other problems discussed in postoperative debriefings are addressed in a timely manner	16(7.3)	90(41.3)	112(51.4)

3.6.6. Consequential dimension

Overall, only 10% of STM opined that there was low perception towards the impact played by innovations on surgical outcomes. Nearly two-thirds, (69.3%) of the STM suggested that there is a weak environment that pressure to move quickly from case to case does not get in the way of patient safety, highlighting the role played by production pressure in influencing patient safety(Table 15).

Table 11: Distribution of percentage of positive responses towards Consequential dimension

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
4. Consequential (other items) (Cronbach's α =0.15	10.1	89.9	
I would feel safe being treated here as a patient	5(2.3)	61(28.0)	152(69.7)
If I were having an operation, I would want a surgical safety checklist to be used	1(0.5)	7(3.2)	210(96.3)
Pressure to move quickly from case to case gets in the way of patient's safety®	151(69.3)	48(22.0)	19(8.7)

3.6.7. Distribution of responses among members of surgical teams by regions

Table 16 and 17 summarizes the distribution of STM responses on various items (dimensions) used in this survey based on regional comparisons.

3.6.8. The perceptions of health workers on elements of patient safety that transformed the quality of maternal surgical outcomes in the selected hospitals

The surgical team members perceived the surgical safety checklist as among the key driver of the transformation of surgical outcomes. It was perceived as a tool that is smart for both service providers and patients. The surgical team members embraced patient safety as a priority and use the surgical safety checklist for their safety as well.

3.6.8.1. Communication and teamwork

The surgical team members have improved communication among themselves and with the patient. During the introduction of the SSC, some team members were a bit reluctant. From the service provider's perspectives, the WHO surgical safety checklist is serving as a useful tool for improved teamwork and communication through which the improved health outcomes are clearly seen. It has helped the team to ensure all the steps are performed correctly, drugs administered timely and all surgical team members are coordinated and surgeons, nurse anesthetists, nurses communicate effectively to prevent avoidable complications

"*At first checklist was difficult to implement, but as the days went on, we adapted and it is now well-practiced and I am happy to use it as it is safe to the patient and providers. Checklist has also helped us maintain good communication to all disciplines*", a Female, age 28 service providers from Mara region

The Checklist was perceived to reduce miscommunication among the team members and thus resulting in a reduction of complications related to surgery. The monitoring of medical equipment and supplies, timely administration of Infection Prevention bundles (Proper antibiotic prophylaxis (type, timing, and duration), surgical skin preparation with alcohol-based solution, and vaginal cleansing with povidone-iodine) has improved as a result of the safe surgery interventions.

"*Checklist helps to improve communication, know the equipment you have, and to prevent infection after an operation and maintain patient safety at large" A service provider from Kayanga Health center*

The items in the SSC were perceived to prevent errors during surgery by reminding surgical team members to perform safety checks before the actual surgical procedure, during the procedure, and after the procedure. In doing so, helps prevent not only the uncommon but also the serious errors that may affect patient safety outcomes. The SSC has influenced the performance of surgical team members by reminding them to confirm patient identity, comorbid condition, and the surgical site.

3.6.8.2. Administration of Antibiotic

The proper and timely administration of antibiotics was perceived to have transformed the surgical outcomes by reducing complications such as Surgical Site Infection. Providers perceive the training to have helped them provide the optimal amount of antibiotics and so have reduced expenditure on the unnecessary excess amount they used to offer before the training they receive.

3.6.8.3. Reduction of Medical Errors

The implementation of a safe surgery project is perceived to have increased comfortability of staff and patients during operations and the WHO Surgical Safety Checklist has reduced mistakes especially those that were often made after a surgical operation. The surgical teams have been transformed to perform safety checks hence avoid unnecessary mistakes.

"*We see a great improvement after the implementation of safe surgery program, many errors being eradicated which were there before, Example the improper time to give antibiotic"* 32 years Male, A service provider from Mara region.

CHAPTER FOUR

DISCUSSION

4.1. The utilization rate of the WHO surgical safety checklist in Kagera and Mara regions

After a two years implementation of the safe surgery project in forty CEmONC health facilities in Kagera and Mara region, significant changes in the use of the WHO surgical safety Checklist was observed through the patient file reviews. The result shows that the intervention to improve the use of the WHO surgical safety Checklist is effective in the Lower and Middle-Income Countries (LMICs) such as Tanzania despite deficiencies in the country's surgical infrastructure, workforce, and service delivery that increase the risk of surgical complications (1).

The utilization rate of the WHO surgical safety Checklist in this evaluation was high, 94% than that in Ethiopian hospitals, 39.7% (45), and 80% at Mbarara Hospital in Uganda(46) in which the interventions were in a similar LMIC setting. The results from the forty health facilities in the lake zone are comparable with the results from the International Surgical Outcome study where 89.9% of patients were exposed to the use of WHO surgical safety Checklist in 497 hospitals in 27 countries (47).

These results suggest that even with weak surgical infrastructure, the intervention to improve surgical services is possible with minimal resources. The review of patient files following the interventions has also revealed that WHO surgical safety checklist tools were available and utilized in 94.3% of all C-Sections performed and 87.5% among post-operative women at the 40 health facilities during the three months as compared to 3.7% for C-section and 2.1% for women who received post-operative services in the baseline.

The minimal variation in changes of the WHO surgical safety checklist utilization between hospitals and health centers shows that health facility size did not affect the adoption and utilization of the WHO surgical safety checklist in the lake zone.

As per the National Surgical Obstetric and Anesthesia Plan that was developed in 2018, Tanzania has set a benchmark of 100% utilization rate of the WHO surgical safety checklist

in all the facilities providing CEmONC services. The results in the two regions show the feasibility of attaining similar results in other regions in Tanzania through the implementation of the proven safe surgery intervention that has demonstrated a positive impact.

4.2. Changes in the proportional of women who have had surgical site infection after C-section

Surgical complications including Surgical Site Infections are common in LMIC and particularly Tanzania but often preventable. The proportion of women with surgical site infections after C-section has significantly reduced after the implementation of the safe surgery project. The surgical site infection rate in the lake zone has decreased from 14% during baseline to 1% post-implementation (reduction of 93%) with ($p<0.001$) proving that the interventions had a positive impact and consistent with findings from a similar study where the surgical complications decreased by 57% (P=0.03) after interventions(48).

The results suggest that replication of the intervention in more health facilities is likely to reduce maternal morbidity and mortality related to C-sections. Various studies have shown that the use of the WHO surgical safety checklist improves patient safety by reducing surgical site infection, for example, a study of the implementation of the WHO surgical safety checklist in eight diverse hospitals in the world resulted to a reduction of Surgical site infection by 36% (18.4% at baseline to 11.7% after the intervention)(49).

The reduction of surgical site infection in the forty health facilities of the lake zone Tanzania reveals that the implementation of the safe surgery project interventions plays a crucial role in reducing maternal morbidity related to surgery. The reduction of the surgical site infection also shows that the intervention has helped to improve the standards of care during C-section(49) delivery in resource-limited settings.

4.3. Changes in the proportional of women who have had post-operative Sepsis

The patient file review shows that postoperative sepsis significantly reduced in the post-intervention as compared to pre-intervention (P=0.017). The safe surgery intervention has improved patient safety at the maternity ward which has resulted in a reduction of maternal

morbidity related to surgeries.

These findings are consistent with a study in Nigeria where the WHO surgical safety checklist significantly reduced postoperative complications including sepsis by more than half (50). The use of the WHO surgical safety checklist was found to reduce infection from 27.3%(95% CI, 25.9 to 28.7) to 16.7%(95% CI,15.6 to 17.9) in a similar study(51).

The postoperative sepsis was reduced from 2.9% to 0% within two years of implementation of proven interventions in forty CEmONC health facilities in the lake zone of Tanzania. The results suggest that even with maternal complications and mortality can be reduced significantly in the LMICs with the implementation of the safe surgery interventions.

4.4. Changes in the proportional of women with maternal sepsis after normal delivery

Among the 200 files of women who underwent a normal delivery in the forty health facilities, none of them was diagnosed with maternal sepsis. The incidence of maternal sepsis seems to be low in the forty CEmONC health facilities implementing the Safe surgery project. One incidence was observed before the implementation of the intervention and none was found during the post-implementation period.

The results show that the proportion of women with maternal/puerperal sepsis has reduced from 0.36% before the implementation of interventions to 0.00% post-implementation. The maternal sepsis rate was lower as compared to the findings in Nigeria with 1.7% (52) However, the changes in proportion are not statistically significant signifying that the result may have happened by chance. Although other studies have documented higher rates of maternal/puerperal sepsis in Tanzania (40), the results from Mara and Kagera region shows a different view.

4.5. The changes in mortality rates related to Cesarean Section delivery

Generally, the mortality rates related to C-section have reduced over the past three months post-implementation as compared to three months before the implementation of safe surgery interventions. The C –section mortality has reduced from 161 deaths per 100,000 C-section during baseline to 99 deaths per 100,000 C sections after the implementation of the

interventions. The literal interpretation is that 62 post-C-section deaths for every 100,000 C-sections have been averted after the implementation of the interventions. The decline in Post C-section deaths represents a reduction of 38.5% of C-section related deaths as compared to the baseline period. Similarly, the rates of deaths have reduced from 0.16% at baseline to 0.10% after the implementation of the interventions. In Mara rand Kagera region, the death rates have reduced by 36.6% and 54.5% respectively. However, the changes in the post-C-section related deaths are not statistically significant (P=0.6).

While Post Caesarean death rates over the 'past' three months for health centers were 0 during baseline, it was 199 deaths per 100,000 C-section surgeries in Hospitals. During the end line, Health Centers had generally higher rates of Post Caesarean death (399 deaths per 100,000 C-section surgeries) compared to a rate of 0 deaths per 10,000 C-section surgeries found in hospitals. These results suggest a further study to understand the barriers in patient safety in health centers as compared to Hospitals.

The results from this evaluation are consistent with other studies where the rate of death declined from 1.5% before the intervention to 0.8% after the interventions(6), a decline by 47% in Brazilian Federal district(48) and a reduction of death from 1.9% to 0.2% (P=0.02) in Norway. The Changes in Post C- section deaths results from this evaluation are slightly low as compared to the changes that were observed in Mbarara Regional Referral Hospital in Uganda in which a reduction was about 55%(46).

A major challenge was encountered in the documentation of these important study measures and the challenge affects every facility that implements the Safe Surgery project. In many cases, a patient who died from surgical complications is not easily tracked in the death registers and other facility records. There is a problem in the documentation of post-cesarean-section deaths and other important surgical causes of death that are used to measure mortality arising from surgery. The results presented herein are very likely to be an underestimation of the actual magnitude of the problem.

4.6. The most critical elements of the WHO surgical safety Checklist that are perceived to transform the maternal surgical outcomes

Data shows that most (99.1%) surgical team members (surgeons, anesthesia nurses/professionals circulating nurses and others) were positive about the overall elements of the WHO surgical safety that have transformed the maternal surgical outcomes. The elements with highest score were the interpersonal/teamwork (100%) contextual dimension 98.2%, and practical dimension (93.4%).

The surgical team members were persistent positive about the transformation as a result of implementation of WHO surgical safety checklist as it promoted safe surgical practice. Although the joint commission time out is meant to safe guard patients against wrong site/patient or wrong surgical procedure as a safety measure to prevent harm to patients, more than one third (37%) perceived the joint commission "time out" as difficult to implement in their health facility environment.

This shows that despite the acceptance of the overall dimension of patient safety, there is a need to reinforce this crucial step that is effective in preventing the surgical operation to wrong patient, wrong site or wrong surgical procedure as reported by the joint commission. This results shows that it’s likely to make this mistake even with the implementation of the safe surgery intervention.

90.8% of the surgical team members opined that the implementation of the surgical safety checklist was not limited to one profession. This means that the WHO surgical safety checklist has improved team work and communication among the surgical team regardless of profession. The hierarchical barriers have been uprooted among the surgical teams.

CHAPTER FIVE

5. Strength and Limitations

5.1. Strength

The sample size for this evaluation was adequate to provide current data on the rates of surgical complications, maternal sepsis, the utilization of the WHO surgical safety checklist and the perceptions of surgical team members towards the elements of patient safety /WHO SSC that transformed the quality of maternal surgical outcomes in the selected health facilities in Kagera and Mara region.

5.2. Limitations of this Evaluation

This study has several limitations:

- First, the surgical team members (STMs) might not have remembered (possibility of recall bias thus affecting reliability and validity of the collected information). This means the reported estimates might as well been overestimation of the current situation.
- There is a chance of social desirability including obtaining answers that did not reflect the reality of the existing situation. However, every attempt was carried out by the study team to overcome this effect including having a mix of a medical health services research assistants) and well-trained non-medical research assistants.
- The relatively average value of Cronbach's alpha obtained for some elements of the WHO surgical safety checklist might imply a limited adaptation on the reliability of Safety of surgical practice tool to the local settings. This calls for a tailor-made (may include improvement of the same tools) tools that can be used to assess patient's surgery practices in the future.

Despite all these limitations, the current study provides significant information toward our understanding of the elements of the WHO surgical safety checklist that have transformed the surgical outcomes in the forty CEmONC health facilities that have implemented the safe surgery interventions.

CHAPTER SIX

6.0. Conclusion and Recommendations

6.1. Conclusion

Our findings suggest that current practice by the health facilities implementing the safe surgery interventions warrants patient safety and have transformed the surgical outcomes in the two regions. The surgical complication, and C-section mortality has been reduced significantly which implies that innovations such as the WHO surgical safety checklists is effective in improving maternal surgical outcomes in LMICs such as Tanzania. The results from this evaluation also suggests that the implementation of the WHO surgical safety checklist is effective in improving the surgical working environment which results in improved patient safety. The leadership training has improved the teamwork and communication among the surgical team members and so it's likely this will sustain the use of Surgical Safety Checklist even after safe surgery closeout.

6.2. Recommendation

After the 18 months of safe surgery project implementation, it is clear that even with scarce resources in LMICs such as Tanzania, it's possible to improve the use of WHO SSC and achieve the Tanzania's National Surgical Obstetric and Anesthesia Plan (NSOAP) targets 100% by year 2025. The results from this study further reveals that maternal surgical outcomes such as surgical site infections, postoperative sepsis and maternal sepsis can be reduced significantly and thus its recommended to scale the leadership and safe cesarean trainings that included the use of the SSC to other regions with a stagnating perioperative and maternal mortality.

I recommend the scaling up of the safe surgery interventions to other regions in Tanzania especially those with a higher burden of maternal mortality as a priority. The effects of the WHO SSC in terms of reduction of maternal surgical outcomes cannot be under estimated.

While there was general decrease of C-section maternal mortality, after the implementation of the WHO SSC, it was the opposite for the health centers. The health centers recorded an

increased number of C-section related maternal mortality during the post implementation as opposed to hospitals. This finding suggest a further study to assess the barriers in surgical patient safety in health centers as compared to Hospitals.

The current study did not measure the compliance of surgical teams in terms of timely (real time) administration of WHO surgical safety checklist but rather its use. In future research, I recommend the use of the surgical procedure model as part of the observation research to measure not only the use but the compliance to each safety item/step included in the WHO SSC at sign in, time out and sign out. The real-time will reveal the gaps and help reinforce the best practice.

I recommend the RHMTs and CHMTs to proactively maintain the current safe surgery practice which have shown promising results by translating the promising safe surgery initiative from research environment into clinical practice.

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8.0 Appendices

Table 12: Distribution of responses by region – Mara region

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
Overall (all survey items), n=218	**0**	**97.1**	**2.9**
Dimension/factors/item			
Contextual (Readiness)	**-**	**-**	**-**
Q1. Surgical team members are open to changes that improve patient safety, even.	4(3.7)	31(28.7)	73(67.6)
Q2. Commission 'Time Out' is used in every case by every surgical team.	3(2.8)	40(37.4)	64(59.8)
Q3^{r}. The joint commission "time out" was difficult to implement.	33(30.8)	34(31.8)	40(37.4)
Q4. Surgical team members (STM) all agree on the importance of using checklist.	1(0.9)	10(9.2)	97(89.8)
Q5^{r}. Interest in checklist implementation is limited to one profession.	11(10.1)	19(17.6)	78(72.2)
Interpersonal (teamwork)	**0 (0.0)**	**20 (18.9)**	**91 (91.9)**
Factor 1: Communication	0.9	**30.8**	**68.2**
Q6. Team discussion are common	4 (3.7)	38(35.2)	66(61.1)
Q7. Surgical team members make sure their comments or instructions are heard.	3(2.7)	38(35.2)	67(62.0)
Q8. STM share key information as it becomes available.	0(0.0)	25(23.3)	82(76.6)
Factor 2: Coordination	**0**	**23.8**	**76.1**
Q9. Surgical team members appear eager to help one another.	1(0.9)	20(18.5)	87(80.5)
Q10. Physicians and nurses work together as a well-coordinated team.	1(0.9)	22(20.4)	85(78.7)
Q11. Surgeons and anesthesia providers work together as well as well-coordinated team.	1(0.9)	7(6.5)	100(92.6)
Q12. Surgical team members from different disciplines always discuss patients' conditions and progress of operation.	1(0.9)	45(41.7)	62(57.4)

Q13. Plans for patient's care are adapted as need.	0(0.0)	56(51.8)	52(48.1)

Table 16: Continue.... Distribution of responses - Mara

Dimensions	**Negatively or neutral (1-4)**	**Agree (5-6)**	**Strongly agree (7)**
Overall (all survey items), n=218	**0**	**97.1**	**2.9**
Dimension/factors/item, n=218			
Factor 3: Respect	**0.9**	**33.6**	**65.4**
Q14. Surgical team members communicate with me in a respectful manner	1(0.9)	18(16.7)	89(82.4)
Q15. My inputs about patient's care is well received by other surgical team members	1(0.9)	30(28.0)	76(71.0)
Q16. I am always treated as a valuable member of the surgical team	1(0.9)	22(20.4)	85(78.7)
Q17. Potential errors or mistakes are pointed out without raised voices or condescending remarks	17(6.5)	41(37.9)	60(55.5)
Factor 4: Assertiveness	**23.39**	**76.6**	**0**
Q18^{r}. It is difficult to discuss medical mistakes	10(9.2)	36(33.3)	62(57.4)
Q19^{r}. Surgical team members appear to struggle and do not ask one another for help.	0(0.0)	29(26.8)	76(73.1)
Q20. It is difficult to speak up when I perceive problems with patients care.	108(100.0)	0(0.0)	0(0.0)
Factor 5: Clinical Leadership	**0.9**	**32.7**	**66.4**
Q21^{r}. Physician are only open to suggestions from other physicians	9(8.3)	31(28.7)	68(62.9)
Q22. Physician are present and actively participating in patients care prior to skin incision	2(1.8)	21(19.4)	85(78.7)
Q23. Physicians maintain a positive tone throughout operations	1(0.9)	31(28.9)	75(70.0)
Practical (adherence)	5.6	**94.3**	**-**

Q24[r]. Surgical team members refer to each other by role instead of name (Missing =1)	138	61.88	20.18
Q25. Surgical teams always discuss the operative plan	6(5.5)	38(35.2)	64(59.2)
Q26. For complex patients or cases, preoperative briefings always include planning for potential problem.	4(3.7)	37(34.3)	67(62.0)
Q27. Postoperative debriefings always include a discussion of key concerns for patient's recovery and post-post management	2(1.8)	47(43.5)	59(54.6)

Continue – Distribution of responses – Mara region

Dimensions	**Negatively or neutral (1-4)**	**Agree (5-6)**	**Strongly agree (7)**
Overall (all survey items), n=218	**0**	**97.1**	**2.9**
Dimension/factors/item, n=218	**End-line**	**End-line**	**End-line**
Practical (continued)	**100**	**-**	**-**
Q28. Equipment issues or other problems discussed in postoperative debriefings are addressed in a timely manner (2=missing)	8(7.4)	43(39.8)	57(52.8)
Consequential (other items)	**100**	**-**	**-**
Q29. I would feel safe being treated here as a patient	2(1.8)	36(33.3)	70(64.8)
Q30. If I were having an operation, I would want a surgical safety checklist to be used (missing=1)	0(0.0)	1(0.9)	107(99.0)
Q31[r]. Pressure to move quickly from case to case gets in the way of patient's safety	80(74.0)	20(18.5)	8(7.4)

Table 13: Distribution of responses by region – Kagera region

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
Overall (all survey items), n=218	**17.19**	**82.29**	**0.52**
Dimension/factors/item			
Contextual (Readiness)	**2(1.9)**	**2(94.3)**	**4(3.8)**
Q1. Surgical team members are open to changes that improve patient safety, even.	0(0.0)	34(30.9)	76(69.1)
Q2. Commission 'Time Out' is used in every case by every surgical team.	2(1.8)	50(45.4)	58(52.7)
Q3^{r}. The joint commission "time out" was difficult to implement.	48(43.6)	37(33.6)	25(22.7)
Q4. Surgical team members (STM) all agree on the importance of using checklist.	2(1.8)	25(22.7)	83(75.4)
Q5^{r}. Interest in checklist implementation is limited to one profession.	9(8.1)	36(32.7)	65(59.1)
Interpersonal (teamwork)		**79(73.1)**	**29(26.8)**
Factor 1: Communication	**3(2.7)**	31(28.4)	75(68.8)
Q6. Team discussion are common	4(3.6)	51(46.3)	55(50.0)
Q7. Surgical team members make sure their comments or instructions are heard.	1(0.9)	35(31.8)	74(67.2)
Q8. STM share key information as it becomes available.	1(0.9)	27(24.7)	81(74.3)
Factor 2: Coordination	**0 (0.0)**	**52(23.8)**	**166(76.1)**
Q9. Surgical team members appear eager to help one another.	0(0.0)	19(17.3)	91(82.7)
Q10. Physicians and nurses work together as a well-coordinated team.	0(0.0)	21(19.1)	89(80.9)
Q11. Surgeons and anesthesia providers work together as well as well-coordinated team.	0(0.0)	19(17.3)	91(82.7)
Q12. Surgical team members from different disciplines always discuss patients' conditions and progress of operation.	0(0.0)	53(48.1)	57(51.8)
Q13. Plans for patient's care are adapted as need.	0(0.0)	30(27.5)	79(72.4)

Table 18: Distribution of responses by region – Kagera region

Dimensions	Negatively or neutral (1-4)	Agree (5-6)	Strongly agree (7)
Overall (all survey items), n=218	**17.19**	**82.29**	**0.52**
Factor 3: Respect	**0(0.0)**	**37(33.9)**	**72(66.1)**
Q14. Surgical team members communicate with me in a respectful manner.	0(0.0)	26(23.6)	84(76.4)
Q15. My inputs about patient's care is well received by other surgical team members.	0(0.0)	30(27.5)	79(72.5)
Q16. I am always treated as a valuable member of the surgical team.	0(0.0)	47(41.9)	63(56.2)
Q17. Potential errors or mistakes are pointed out without raised voices or condescending remarks.	3(2.7)	52(47.4)	55(50.0)
Factor 4: Assertiveness	**29(26.3)**	**81(73.6)**	**0(0.0)**
Q18[r]. It is difficult to discuss medical mistakes.	9(8.2)	47(42.7)	54(49.0)
Q19[r]. Surgical team members appear to struggle and do not ask one another for help (missing=1)	2(1.8)	31(28.2)	77(70.0)
Q20. It is difficult to speak up when I perceive problems with patients care.	109(99.0)	1(0.9)	0(0.0
Factor 5: Clinical Leadership	**3(2.7)**	**28 (25.4)**	**79(71.8)**
Q21[r]. Physician are only open to suggestions from other physicians.	7(6.4)	31 (28.2)	72(65.4)
Q22. Physician are present and actively participating in patients care prior to skin incision	2(1.8)	20 (18.2)	88(80.0)
Q23. Physicians maintain a positive tone throughout operations.	4(3.6)	31 (28.2)	75(68.2)
Practical (adherence)	**14(6.5)**	**201(93.5)**	**-**
Q24[r]. Surgical team members refer to each other by role instead of name.	109(100.0)	-	-
Q25. Surgical teams always discuss the operative plan.	8(3.7)	91(41.7)	119(54.6)
Q26. For complex patients or cases, preoperative briefings always include planning for potential problem.	8(3.7)	79(36.2)	131(60.1)
Q27. Postoperative debriefings always include a discussion of key concerns for	6(2.7)	92(42.2)	120(55.0)

patient's recovery and post-po management.			
Dimensions	**Negatively or neutral (1-4)**	**Agree (5-6)**	**Strongly agree (7)**
Overall (all survey items), n=218	**17.19**	**82.29**	**0.52**
Practical (adherence)-continued			
Q28. Equipment issues or other problems discussed in postoperative debriefings are addressed in a timely manner.	16(7.3)	118(53.3)	112(51.4)
Consequential (other items)	217(100.0)	-	-
Q29. I would feel safe being treated here as a patient	5(2.3)	61(28.0)	152(69.7)
Q30. If I were having an operation, I would want a surgical safety checklist to be used.	0(0.0)	7(3.2)	201(96.8)
Q31. Pressure to move quickly from case to case gets in the way of patient's safety.	151(69.3)	48(22.0)	19(8.7)

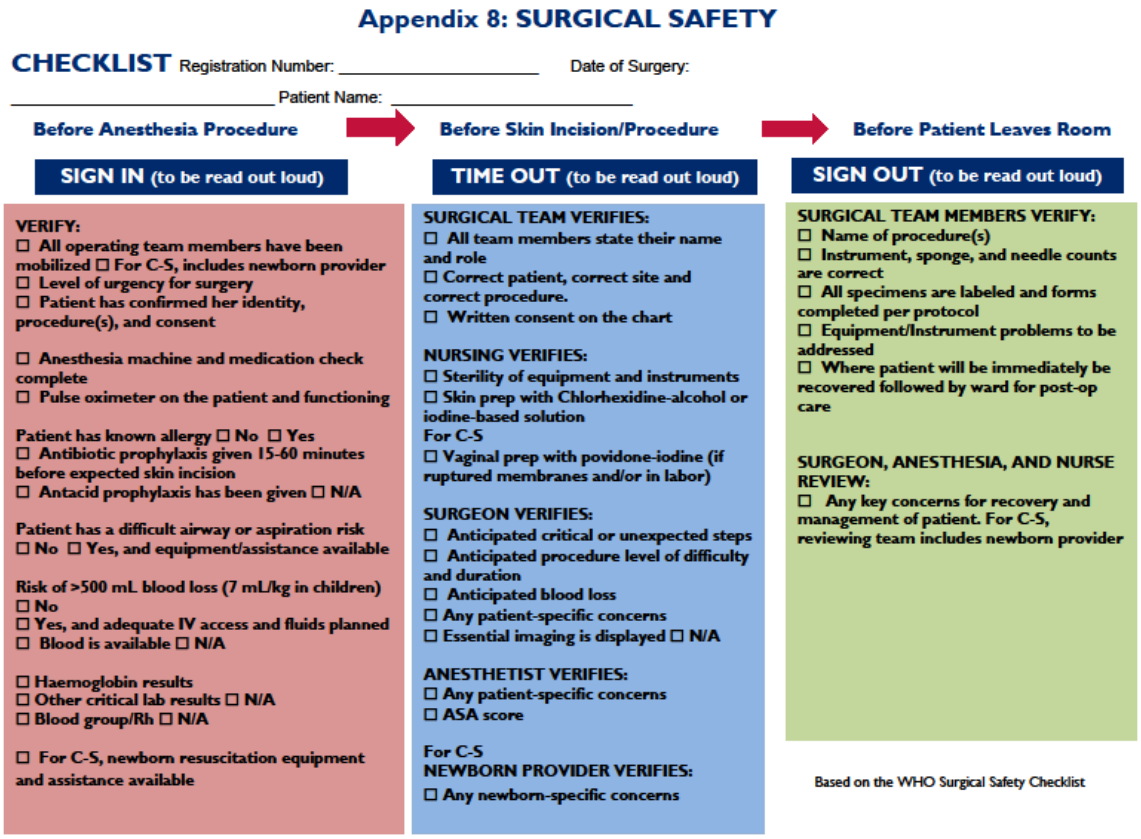
Table 14: C-section procedure in the theatre register for the past 3 months

	Baseline			End line		
	Month 1	Month 2	Month 3	Month 1	Month 2	Month 3
Mara	97	131	108	361	375	340
Kagera	320	278	305	642	657	658
Overall	417	409	413	1003	1032	998
Total		1239			3033	
	Health Facility Level					
Hospitals	332	326	345	761	785	736
Health Centers	85	83	68	242	247	262

Table 15: Deaths associated with C-section the past three months

	Baseline			Endline		
	Month 1	Month 2	Month 3	Month 1	Month 2	Month 3
Mara	0	0	1	2	0	0
Kagera	1	0	0	0	1	0
Overall	1	0	1	2	1	0
Hospitals	1	0	1	0	0	0
Health Centers	0	0	0	2	1	0

Appendix 1: Surgical Safety Checklist



Appendix 8: SURGICAL SAFETY

CHECKLIST Registration Number: _____ Date of Surgery: _____ Patient Name: _____

Before Anesthesia Procedure	Before Skin Incision/Procedure	Before Patient Leaves Room
SIGN IN (to be read out loud)	**TIME OUT** (to be read out loud)	**SIGN OUT** (to be read out loud)
VERIFY: ☐ All operating team members have been mobilized ☐ For C-S, includes newborn provider ☐ Level of urgency for surgery ☐ Patient has confirmed her identity, procedure(s), and consent ☐ Anesthesia machine and medication check complete ☐ Pulse oximeter on the patient and functioning Patient has known allergy ☐ No ☐ Yes ☐ Antibiotic prophylaxis given 15-60 minutes before expected skin incision ☐ Antacid prophylaxis has been given ☐ N/A Patient has a difficult airway or aspiration risk ☐ No ☐ Yes, and equipment/assistance available Risk of >500 mL blood loss (7 mL/kg in children) ☐ No ☐ Yes, and adequate IV access and fluids planned ☐ Blood is available ☐ N/A ☐ Haemoglobin results ☐ Other critical lab results ☐ N/A ☐ Blood group/Rh ☐ N/A ☐ For C-S, newborn resuscitation equipment and assistance available	**SURGICAL TEAM VERIFIES:** ☐ All team members state their name and role ☐ Correct patient, correct site and correct procedure. ☐ Written consent on the chart **NURSING VERIFIES:** ☐ Sterility of equipment and instruments ☐ Skin prep with Chlorhexidine-alcohol or iodine-based solution For C-S ☐ Vaginal prep with povidone-iodine (if ruptured membranes and/or in labor) **SURGEON VERIFIES:** ☐ Anticipated critical or unexpected steps ☐ Anticipated procedure level of difficulty and duration ☐ Anticipated blood loss ☐ Any patient-specific concerns ☐ Essential imaging is displayed ☐ N/A **ANESTHETIST VERIFIES:** ☐ Any patient-specific concerns ☐ ASA score For C-S **NEWBORN PROVIDER VERIFIES:** ☐ Any newborn-specific concerns	**SURGICAL TEAM MEMBERS VERIFY:** ☐ Name of procedure(s) ☐ Instrument, sponge, and needle counts are correct ☐ All specimens are labeled and forms completed per protocol ☐ Equipment/Instrument problems to be addressed ☐ Where patient will be immediately be recovered followed by ward for post-op care **SURGEON, ANESTHESIA, AND NURSE REVIEW:** ☐ Any key concerns for recovery and management of patient. For C-S, reviewing team includes newborn provider

Based on the WHO Surgical Safety Checklist

SAFE SURGERY CLINICAL REVIEW TOOL

Facility Name: _____Facility Level: _____District: _____Review Date/Month/Year: ___/___/_____

Reviewer's Names: 1. _____ 2. _____ 3. _____

PART ONE: FACILITY LEVEL DATA

Reviewer's Guidance:

- Review the theatre register and fill in the columns below the number of surgical procedures performed in the facility
- Record the month and year for which the data is reported
- Disaggregate the surgical data by major vs minor procedures, emergency vs elective surgeries and types of surgical procedures
- Record the number of deaths, complications and referred patients *related to surgery* over the last three months, from hospital register and any other sources in the appropriate columns in the table below. Fill in the data source for all mortality, complications and referral data (e.g. hospital register, ward round books or any hospital reports) in the appropriate space as indicated.

Surgical volume data

Types of **major** surgical procedures recorded in the theatre register the past 3 months:

	Month ____/Year____	Month_____/Year_____	Month_____/Year_____
Caesarean section			
TOTAL			

Data source [check all that apply]*:* ☐ Theatre register ☐ Anesthesia Records ☐ HMIS registers ☐ Ward round book ☐ Other hospital reports (include report title and year if available)_____

Mortality associated with surgery: Number of deaths associated with surgery over the past 3 months

	Month ____/Year____	Month_____/Year_____-	Month_____/Year
Post-c section deaths			
Post-laparotomy deaths			
Deaths resulting after trauma with open fractures			
TOTAL			

Data source [check all that apply]*:* ☐ Theatre register ☐ Anesthesia Records ☐ HMIS registers ☐ Ward round book ☐ Other hospital reports (include report title and year if available)_____

Complications related to surgery: Complications related to surgery over the past 3 months

	Month ____/Year____	Month_____/Year_____-	Month_____/Year

Surgical Site Infections			
Post-op sepsis			
Maternal sepsis (all non-surgical)			
Anaesthesia related complications			
Other complications (write the types of complications below)			
TOTAL			
Data source [check all that apply]*:* ☐ Theatre register ☐ Anesthesia Records ☐ HMIS registers ☐ Ward round book ☐ Other hospital reports (include report title and year if available)_____			

PART TWO: INDIVIDUAL PATIENT FILE REVIEW

Reviewer's Guidance:

- Review charts over the past 3 months (or starting on the next month after the last month of the previous review)
- Randomly select **20 Patient files** from the following units: Post Natal – Normal Delivery (5 files), Post-Natal – C-section (10 files), and Female Surgical Ward – Post-operative (5 files)
- Fill in the required information as indicated in table for each individual patient. If the information cannot be found in the patient file, write **NR** (*not recorded*) in the space provided. If you think the information is not applicable (e.g. vaginal discharge in a male patient) write **NA** (*not applicable)* as the response.
- Refer to the codes below the table in *Appendix 1* for **types of common procedures**
- Calculate the Risk Index Score for each patient by adding the Wound Class, ASA score and Duration of Surgery. Write **U** (*Unable to calculate*) if the Risk index score cannot be calculated. (Refer to the ASA scores and Wound Class definitions in *Appendix 3* and the Risk Index Score in *Appendix 2*)
- Provide a conclusion whether you think the patient had SSI or Sepsis. Circle **Sup-SSI** for superficial SSI; **De-SSI** for deep SSI; **Org-SSI** for organ/Space SSI; **Post sep** for Post-op sepsis; **Mat sep** for maternal sepsis. Circle **None** of these diagnoses is present or **Undert** (*Unable to determine*) if a diagnosis of SSI or sepsis cannot be determined

Review the charts to fill in the details required below

Sampled Patient Files																				
Wards/Units	**Post- Normal Delivery**					**Post-C-Section**					**Post-op Female Ward**									
Serial No →	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
PATIENT DETAILS																				
ID Number																				
Age (years)																				
Type of procedure done **(Appendix 1)**																				
Date of Procedure																				
Date of Admission																				
Date of Discharge																				

Was any of the following symptoms reported in the patient file, during admission or ward rounds? (Y, N or NR)																				
Wound discharge post – operatively ?																				
Vaginal Discharge (post-delivery)?																				
Pain or tenderness over the incision wound?																				
Fever?																				
Diagnosis of an SSI or sepsis by the physician																				
Were there any of the following examination findings recorded in the patient file? (Y, N or NR)																				
Raised temperature (>38 C)																				
Abscess?																				
Tenderness/redness/swelling over incision site																				
Tachycardia (HR >90 beats/min)																				
Tachypnoea (RR>20 b/min)																				
Signs of septic shock																				
Was there any laboratory evidence of sepsis from the investigations in the patient file? (Y, N or NR)																				
Positive culture																				
Leukocytosis (WBC count >12,000 µ/L)																				
Diagnosis																				
Was there a diagnosis of SSI or sepsis in the file?																				
RISK INDEX SCORE																				
Wound Class (I-IV) (Refer to Appendix 3)																				
ASA Score (1-5) (Refer to Appendix 3 or Anesthesia Record)																				
Duration of surgery (<1hr or >1hr																				
Risk Index Score (sum of Wound class, ASA score																				

and duration of surgery (Refer to Appendix 3)																			
SURGICAL SAFETY CHECKLIST USED? (Y/N)																			
Was the surgical safety checklist used during the procedure																			
CONCLUSION																			
Circle your conclusion based on the findings above	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None
	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI	Sup-SSI
	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI	De-SSI
	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI	Org-SSI
	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep	Post sep
	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep	Mat sep
	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet	Undet

APPENDICES

Appendix 1: Codes for Common Surgical Procedure

Procedure	**CODE**
Caeserean section	CS
Laparatomy (due to any cause)	LP
Hysterectomy	HS
Herniorrhaphy	HN
Splenectomy	SP
Appendicectomy	AP
Myomectomy	MY
Debridement for Open Fractures	DR
Open Reduction and Internal Fixation for Open Fractures	ORIF

Appendix 2: Risk Index for Surgical Site Infections

Risk Index Score	
Wound Class	**Score**
Wound Class I or II	0
Wound Class III or IV	1
Wound Class V	2
ASA Class	
ASA Class 0	0
ASA Class 1 or 2	1
ASA Class 3,4 or 5	2
Procedure Duration	
Less than or equal to 1 hour	0
More than 1 hour	1
Risk Score is the total of above scores	

Appendix 3: ASA SCORES AND SURGICAL WOUND CLASSFICATION DEFINITION

ASA Class		
Class	**Description**	**Example**
1	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
2	A patient with mild systemic disease without substantive functional limitations	current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
3	A patient with severe systemic disease (Substantive functional limitations; One or more moderate to severe diseases)	poorly controlled DM or HTN, COPD, active hepatitis, alcohol dependence or abuse, moderate reduction of ejection fraction, history (>3 months) of MI, CVA, TIA, or CAD/stents
4	A patient with severe systemic disease that is a constant threat to life	Recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC
5	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
Wound Class		
Class	**Description**	**Example**
I (Clean)	Uninfected wound, with no inflammation; Resp, GI, GU tracts not entered, Wound closed primarily	Exploratory laparotomy, mastectomy, neck dissection, thyroid, vascular surgery, hernia, splenectomy
II (Clean Contaminated)	Resp, GI, GU tracts entered but well controlled; No unusual contamination	Cholecystectomy, Small bowel resection, Cesarean section, Hysterectomy, gastric surgery, bronch, colon surgery
II (Contaminated)	Open, fresh, accidental wounds; major break in sterile technique; gross spillage from GI tract; acute non-purulent inflammation	Inflamed appendix, bile spillage in cholecystectomy, penetrating wounds
IV (Dirty)	Old traumatic wounds, devitalized tissue; existing infection or perforation; organisms present BEFORE procedure	Abscess I&D, perforated bowel, peritonitis, wound debridement

Appendix 3: Safety of Surgery Practice

Facility Name: _____Facility Level: _____District: _____

Review Date/Month/Year: ___/___/_____

Reviewer's Names:
1. _____
2. _____
3. _____

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
Q1. Surgical team members are open to changes that improve patient safety, even if it means slowing down.	1	2	3	4	5	6	7
Q2. The Joint Commission "Time Out" is used in every case by every surgical team.	1	2	3	4	5	6	7
Q3. The Joint Commission "Time Out" was difficult to implement.	1	2	3	4	5	6	7
Q4. Surgical team members all agree on the importance of using checklists	1	2	3	4	5	6	7

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
in surgery.							
Q5. Interest in checklist implementation is limited to one profession (e.g., surgery, anesthesia, nursing).	1	2	3	4	5	6	7
Q6. Team discussions (e.g., briefings or debriefings) are common.	1	2	3	4	5	6	7
Q7. Surgical team members make sure their comments or instructions are heard.	1	2	3	4	5	6	7
Q8. Surgical team members share key information as it becomes available.	1	2	3	4	5	6	7
Q9. Surgical team members appear eager to help one another.	1	2	3	4	5	6	7

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
Q10. Physicians and nurses work together as a well-coordinated team.	1	2	3	4	5	6	7
Q11. Surgeons and anesthesia providers work together as a well-coordinated team.	1	2	3	4	5	6	7
Q12. Surgical team members from different disciplines always discuss patients' conditions and the progress of operations.	1	2	3	4	5	6	7
Q13. Plans for patient care are adapted as needed.	1	2	3	4	5	6	7
Q14. Surgical team members communicate with me in a respectful manner.	1	2	3	4	5	6	7

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
Q15. My input about patient care is well received by other surgical team members.	1	2	3	4	5	6	7
Q16. I am always treated as a valuable member of the surgical team.	1	2	3	4	5	6	7
Q17. Potential errors or mistakes are pointed out without raised voices or condescending remarks.	1	2	3	4	5	6	7
Q18. It is difficult to discuss medical mistakes.	1	2	3	4	5	6	7
Q19. Surgical team members appear to struggle and do not ask one another for help.	1	2	3	4	5	6	7
Q20. It is difficult to speak up when I	1	2	3	4	5	6	7

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
perceive problems with patient care.							
Q21. Physicians are only open to suggestions from other physicians.	1	2	3	4	5	6	7
Q22. Physicians are present and actively participating in patient care prior to skin incision.	1	2	3	4	5	6	7
Q23. Physicians maintain a positive tone throughout operations.	1	2	3	4	5	6	7
Q24. Surgical team members refer to each other by role instead of name (e.g., “Nurse” instead of “Sarah”).	1	2	3	4	5	6	7
Q25. Surgical teams always discuss the operative plan	1	2	3	4	5	6	7

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
(i.e., more than the location of the incision and name of the procedure) before incision.							
Q26. For complex patients or cases, preoperative briefings always include planning for potential problems.	1	2	3	4	5	6	7
Q27. Postoperative debriefings always include a discussion of key concerns for patient recovery and post-op management.	1	2	3	4	5	6	7
Q28. Equipment issues or other problems discussed in postoperative debriefings are addressed in a timely manner.	1	2	3	4	5	6	7

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor Disagree	Somewhat agree	Agree	Strongly Agree
Q29. I would feel safe being treated here as a patient.	1	2	3	4	5	6	7
Q30. If I were having an operation, I would want a surgical safety checklist to be used.	1	2	3	4	5	6	7
Q31. Pressure to move quickly from case to case gets in the way of patient safety.	1	2	3	4	5	6	7
Q32. How do you explain acceptance, interest and enthusiasm, in the use of checklist after the implementation of safe surgery leadership program?							

Appendix 4: Consent Form

INFORMED CONCENT FORM

Muhimbili University of Health and Allied Sciences- Directorate of Research and Publications

Consent to participate in the study titled: **Assessment of the use of WHO Surgical Safety Checklist and Maternal Surgical Outcomes in Mara and Kagera regions in Lake Zone Tanzania**

Greetings

I am Edwin Ernest, a second year postgraduate student in the school of public health and social sciences at Muhimbili University of Health and Allied Sciences (MUHAS)

Purpose of the study

To determine the changes in the use of the WHO surgical Safety Checklist and maternal surgical outcomes in Kagera and Mara regions following the implementation of the Safe surgery project

What participation involved

If you agree to participate in this study, your medical information will be used for research purpose-but will not be linked to you directly

Confidentiality

Participant identifiers will not be collected and only aggregate, hospital-level results are reported. The research team will not share participant-level data with those outside the study team- including hospital administrators. In hospitals where the surgical team is comprised of <5 of each cadre (e.g., nurse, surgeon, anesthesiologist), aggregate data will not be reported by cadre as this may identify subject(s).

Risk

We expect no harm to happen to you during the course of this study.

Right to withdrawal

Taking part in this study is voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled.

Benefits

The findings from this study will provide useful information to contribute the improvement of the maternal surgical care.

Approval

This study has sought approval from proper and informed authorities

Who to contact

If you have any questions regarding this study, feel free to contact the Principal investigator, Edwin Ernest, MUHAS, P.O BOX 34305, Dar-es-salaam, Tanzania. Mobile phone 0755914737. E-mail: enestedwinc@gmail.com

If you have any questions concerning your right as a participant, you may contact Prof. David Urassa, supervisors of the study, MUHAS, PO Box 65000, Dar es salaam, Tanzania. Mobile phone 0754279553. E-mail: durassa2@yahoo.co.uk.

Director of Research and Publication (DRC) of MUHAS, contacts P. o. Box 65001, Dar es Salaam, Tanzania. Tel: +255-022-2152489, Fax +255-022-2152489, Email drp.muhas.ac.tz

	Yes	No
Health Care Worker: Do you agree?	☐	☐

I' …… have read the consent form and my question have been answered and agree to participate in this study