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# INCIDENCE AND PREDICTORS OF POSTOPERATIVE SURGICAL SITE INFECTIONS AFTER MAJOR SURGERIES AT DEBRE TABOR GENERAL HOSPITAL

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# INCIDENCE AND PREDICTORS OF POSTOPERATIVE SURGICAL SITE INFECTIONS AFTER MAJOR SURGERIES AT DEBRE TABOR GENERAL HOSPITAL

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## List of Abbreviations And Acronyms

AIC- Akaike's Information Criterion

BIC- Bayesian Information Criterion

BMI- Body Mass Index

CDC- Center for Disease Control

COPD- Chronic Obstructive Pulmonary Disease

GI- Gastrointestinal

HAIs/ Hospital-Acquired Infections

LMICs–Low- and Middle-Income Countries

MUAC- Mid Upper Arm Circumference

OR- Operation Room

PH- Proportional Hazard

SSIs- Surgical Site Infections

USA – United States of America

UTIs - Urinary Tract Infections

WHO- World Health Organization

## Abstract

**Background:** Due to the epidemiologic transition, diseases requiring surgical intervention has increased globally which led to the increment of surgery related complications. Surgical site infections remain a major post-operative complication even in hospitals with most modern facilities and standard protocols of preoperative preparation. The incidence of SSI in low-income countries is two times higher than that of middle and high-income countries. Though, Debre Tabor General Hospital has been providing surgical services there is no data on the incidence and predictors of surgical site infection.

**Objective:** To determine the incidence and predictors of postoperative surgical site infections in patients having major surgeries at Debre Tabor General Hospital.

**Methods:** A hospital-based prospective cohort study was conducted on 250 postoperative patients who had undergone major surgery from $10^{th}$, June 2018 to $10^{th}$, December, 2018. Patients were enrolled consecutively until the sample size is reached. Patients were followed for ten consecutive days and data were collected through patient interview, medical record review and direct observation. Data were coded, entered, cleaned, and, analyzed using SPSS 23.0 STATA 14.0 and Weibull's parametric survival modeling was done to identify independent predictors. Kaplan Meier's curve was done to compare survival between groups.

**Results:** A total of 250 patients were followed for an average durations of 8.2 ± 2.8 days and produced 2041patient days of follow up. Forty-nine patients developed surgical site infection during this period. Incidence density of surgical site infection was 24 new cases per 100 patient days of observation. Duration of surgery (AHR= 4.07 95% confidence interval (CI): 1.28, 14.91), level of wound contamination (AHR= 13.83, 95% CI: 2.51, 76.35), anemia (AHR= 3.29 95% CI: 1.52, 7.12), and cancer (AHR=10.89, 95%CI: 2.47, 48.14) were independent predictors of postoperative surgical site infection in major surgery patients.

**Conclusions and Recommendations:** The incidence rate of surgical site infection is high in the surgical ward of Debre Tabor General Hospital. Surgical team shall focus on maximizing their skill in order to shorten duration of surgery and reduce wound contamination. The SSIs surveillance system should also be strengthened to detect areas of improvement.



**Keywords- Major surgery, surgical site infections, incidence, Weibull's regression, hospital**

# 1. Introduction

## 1.1 Background of the Study

For a century, surgery has been incorporated as the main part of health system globally. However, it is still the most untouched part. Due to the epidemiologic transition, the number of diseases requiring surgical intervention has been increasing briskly. It was estimated that 266.2 to 359.5 million operations were performed in 2012 globally (1). Majority of the increment in operations was noted in low and middle-income countries and about one in every twenty operations was done in low-income countries (2). Estimates from the Lancet Commission on Global Surgery indicated that still more than five billion people have no adequate access to safe and affordable surgical care when needed and about 143 million operations are required in low and middle-income countries to address emergency and essential conditions (3).

Along with the increment of surgical operations, postoperative complications and infections have become serious concerns around the world. It is noted that 5-10% of deaths in the developing nations are attributed to complications of major surgeries which could have been prevented. Preventable surgical complications thus constitute a large proportion of preventable medical injuries and deaths globally. It was estimated that 3-16% of hospitalized patients experience preventable postoperative complications. Considering a 3% risk of acquiring postoperative complication globally, more than seven million patients who had undergone surgery will suffer from any form of postoperative complication and about one million of whom die within the immediate postoperative period (4).

Postoperative complications following surgery can be infections or noninfectious and several predisposing factors have been suggested for their development after elective or emergency surgeries. Surgical Site Infections (SSI) are one of the most frequent types of infectious postoperative complication and account for 14-16% of hospital-acquired infectious complications (5).

Any type of surgical procedure could possibly be complicated with SSIs and poses a great risk on patients undergoing surgery. SSIs are among the easily preventable infections; however, they still contribute to the major portion of the burden in morbidity and mortality and additional costs to health systems worldwide (1).

The rate of SSIs is higher in middle and low-income countries. However, despite advances in perioperative and postoperative care, developed nations are still facing challenges. In the United States of America (USA) in 2010, an estimated 16 million surgical procedures were performed in acute care hospitals and the rate of SSI was 1.9% and SSI is considered as the hospital-acquired infection (HAI) with the largest range of annual costs (US$ 3.2–8.6 billion and US$ 3.5–10 billion) (1,4). The European point prevalence survey of HAIs and antimicrobial also showed that SSIs are the second most frequent HAI in hospitals. The cumulative incidence of patients with SSI was the highest in colon surgery with 9.5% (episodes per 100 operations), followed by 3.5% for coronary artery bypass graft) (1, 4).

In developing countries, the magnitude of the problem remains largely underestimated. The WHO's systematic review of data from low and middle-income countries (LMICs) showed that the pooled SSI rate was 11.8 per 100 surgical patients. Studies done in Iran and India showed that the incidence of SSIs was 14-17% especially in dirty wounds (6-8).

Africa is also facing a huge challenge in tackling morbidities related to surgical site infection. The number of surgical operations is increasing due to the increment of trauma associated illnesses and also the change in the lifestyle of Africans. In Uganda, the overall SSI incidence was 16.4% where 5.9% of SSIs is superficial and 47.1% deep and organ space SSIs each whereas studies in Tanzania showed that SSI incidence was 19- 24% where superficial infections are common (9, 10).

Regardless of how surgeons are gifted and capable, surgical infections still create difficulty in operative treatment of patients. In order to alleviate the problem, advances have been made in surgical procedures, anti-septic techniques, and instrument sterilization and infection prevention strategies. Despite those advances, SSI is still the main cause of hospital-acquired infection. Reports have shown that rates of SSIs are increasing in hospitals where there is a standard protocol for perioperative patient follow up and antibiotic prophylaxis (11)(12).

## 1.2 Statement of the Problem

Due to the epidemiologic transition of diseases from primarily infectious to more chronic conditions which need surgical intervention, surgical diseases have become among the leading problems worldwide where more than two billion people have no access to basic surgical care (13).

For more than a century, surgery has become an essential component of public health and developed into a leading discipline that not only provides opportunities for curing certain diseases but fulfills a special role in preventing and mitigating a disability. However, the vast majority (90%) of the world's population receives only 10% of the surgical care delivered. Data from 56 countries showed that in 2004 the annual volume of major surgery was estimated ranging from 187 to 281 million operations, or approximately one operation annually for every 25 human beings alive. Population surveys in the African sub-Saharan region have also shown that more than 120 million people living in the sub-Saharan region have unmet basic surgical care (4, 13)**.**

Surgical site infections are among the commonest surgical complications and are responsible for considerable morbidity and mortality. Globally, SSI rates are found to be 2.5% to 41.9%. WHO's a systematic review of data from LMICs has shown that SSI incidence was 11.8 per 100 surgical patients undergoing surgical procedures (6). In 2018 the Global Surgery Network's observational cohort study showed that the incidence of SSI in low-income countries in 2014 (14-20%) was two times higher than that of middle and high-income countries (**7.4%) (12)** . Studies conducted in Hawassa University Referral Hospital and Tikur Anbesa Hospital also showed that the rate of postoperative surgical site infection to be 14-19%. However, researches in Ethiopia regarding postoperative surgical site infections are still rare (14, 15).

Lots of major surgeries have been performed at Debre Tabor General Hospital. Currently, however apart from the routine service provided there is no any empirical evidence indicating the burden of postoperative surgical site infections. This study is therefore intended to give an insight into the incidence of postoperative surgical site infections and finally put forward suggestions on the future handling of the problem.

## 1.3 Significance of the Study

Studying postoperative surgical site infections has public health implications as it allows identification of potential risk factors for the disease as well as the consequences and better preventive strategies to the groups facing high risk.

Postoperative surgical site infections impose substantial costs on surgery patients, increase the length of hospital stay and have adverse effects on patient outcomes. Hence, this study will help hospitals to identify the burden of postoperative surgical site infections and devise strategies to decrease the impact. This, in turn, will increase the quality of service provided by decreasing mortality, length of hospital stay, and patient cost.

Moreover, the WHO guideline on safe surgery also indicated that there is paucity data related to the volume of surgery and their adverse outcomes in Low and Middle-income countries due to poor surveillance practices. Therefore, this study will fill in the data shortage, serve as a baseline study for further studies and also helps to generate effective prevention strategies. It will also give an insight for the academics and researchers to initiate further research on the subject and for policymakers to give due consideration to the health service.

## 2. Literature Review

According to Center for Disease Control (CDC), Surgical Site Infection (SSI) is an infection that develops within 30 days after an operation or within one year if an implant was placed, and the infection appears to be related to the surgery. However, CDC reports indicated that symptoms required to diagnose SSI usually occur within a seven to ten days timeframe with no more than 2-3 days between the manifestations (16).

SSIs are potential complications associated with any type of surgical procedure and are infections of the tissues and organs exposed during surgery (17). Due to the invasiveness of surgical procedures and the immunosuppressive effect of surgical illnesses (e.g., trauma, burns, malignant tumors), surgical patients are prone to develop infections (13). Although SSIs are among the most preventable HAIs, they still represent a significant burden in terms of patient morbidity and mortality. SSI is both the most frequently studied and the leading HAI reported hospital-wide in LMICs (18).

Surgical site infections play a pivotal role in determining the rate of patient survival after surgery. They also impose an additional cost to surgical patients, health systems and service payers worldwide by doubling the length of time a patient stays in hospital, costing extra nursing care and interventions and repeat admissions following discharge (6, 7).

The global rate of postoperative surgical site infections has been increasing with the increment of surgical operations. In Africa due to injuries, perforations, obstructions, and strangulations, abdominal surgeries are frequent and patients are prone to develop postoperative infectious complications. Among surgical complications, Surgical Site Infections (SSIs) are one of the most frequent types of hospital-acquired infections (5, 8).

SSIs are classified into incisional and organ/space infections, and the former are further sub-classified into superficial (limited to skin and subcutaneous tissue) and deep incisional categories (16). Several predisposing factors have been suggested for their development after elective or emergency surgeries (13).

The development of SSIs is related to three factors: the degree of microbial contamination of the wound during surgery, surgery-related factors and host factors.

### A. The degree of microbial contamination of the wound during surgery

The wound's bacterial load at the time of surgery is used as a reference to determine the degree of microbial contamination of the wound. Based on the level of contamination surgical wounds are classified into clean, clean-contaminated, contaminated and dirty wounds (16).

Clean (class I) wound are wounds in which no infection is present; only skin microflora potentially contaminates the wound, and no hollow viscus that contains microbes is entered. Clean wound has 1-2% risk of being infected. Clean-contaminated (class II) wounds are wounds in which hollow viscus is entered under controlled circumstance. These types of wounds have 2-10% risk of infection. On the other hand, contaminated and dirty wounds are open wounds with extensive bacterial contamination and spillage of viscous contents. However, dirty wounds designate delayed intervention and have characteristic purulent discharge. Contaminated and dirty wounds have 3.4%–13.2% and 3.1%–12.8% risk of being infected (13).

As the level of wound contamination increases the risk of developing SSI also increases. A prospective study on 50 patients who had laparotomy in India had shown that all patients with contaminated or dirty wounds developed wound infections in the postoperative period (19). Studies showed that there is no much difference in the incidence of SSIs between developed and developing countries. A study in Uganda showed that the risk of SSI was twenty times higher in dirty and contaminated wounds compared to clean and clean contaminated wounds. This finding is comparable with a Serbian study where dirty wounds have ten times more risk of being infected (20). Other Studies done in Iran and India also showed that the incidence of SSIs was 14-17% especially in dirty wounds (7, 8).

### B. Surgery-related Factors,

The level of wound contamination, surgery-related factors like duration of operation, duration of preoperative hospital stay, mode of surgery, type and site of surgery, and prophylactic antibiotic administration before operation have been incriminated as a potential factor for the development of surgical site infections (15).

The duration of surgical procedures differs based on the type of procedure performed. Many studies used different cut points to define the duration of surgery. Despite the difference in the cut point, procedures which took longer duration had a higher rate of SSI. Evidence show, for every 15 minutes, 30 minutes, 60 minutes increment in the duration of surgery; there was a 13%, 17% and 37% increased likelihood of contracting SSIs (21). This finding was also evidenced in Hawassa University Referral Hospital where patients with duration of operation greater than 1hour were 8.01 times more likely to develop SSIs compared with patients whose operation was completed within 1 hour AOR = 8.01(95% CI:1.562-,41. 099) (15) .

Patients who are admitted for elective surgery usually spend days in hospital until their date of surgery. It is presumed that patients having longer preoperative hospital stay have increased the chance of getting SSI. Though it lacks standard cut off point for the duration of preoperative hospital stay, studies in Iran, India and Ethiopia showed a positive correlation between the duration of preoperative hospital stay and rate of SSIs where patients who stayed longer had higher incidences of SSI (7, 8, 15).

In order to prevent SSIs WHO's surgical safety checklist recommends antibiotics to be given within one hour before skin incision is made. A study done in Ethiopia showed patients who were given antimicrobial prophylaxis before one hour of skin incision developed SSI compared to those who had the prophylaxis within one of skin incision (4, 15) .

The rate of surgical site infections also varies based on the site where the incision is made. Abdominal surgeries have higher SSI rate compared to other surgeries. It is estimated that SSIs affect 25- 40% of patients after midline laparotomy and also accounts for the death of one-third of postoperative patients following gastrointestinal surgeries (14).

### C. Host factors

Patients with co-morbid conditions such as hypertension, diabetes, malnutrition, anemia, obesity, immune suppression, and a number of other underlying disease states are prone to develop surgical infections especially SSI (22, 23). A study done in Uganda showed that the odds of developing SSI were higher among patients with low serum albumin compared to those with normal levels (10). On the other hand, patients who are obese have a 21% increased risk of developing a surgical site infection (24). Moreover, smoking cigarette has also been incriminated as having a triple rate of risk as compared to nonsmokers (15, 25)**.**

Potential risk factors of surgical site infection can be summarized in the conceptual framework as shown in figure 1.

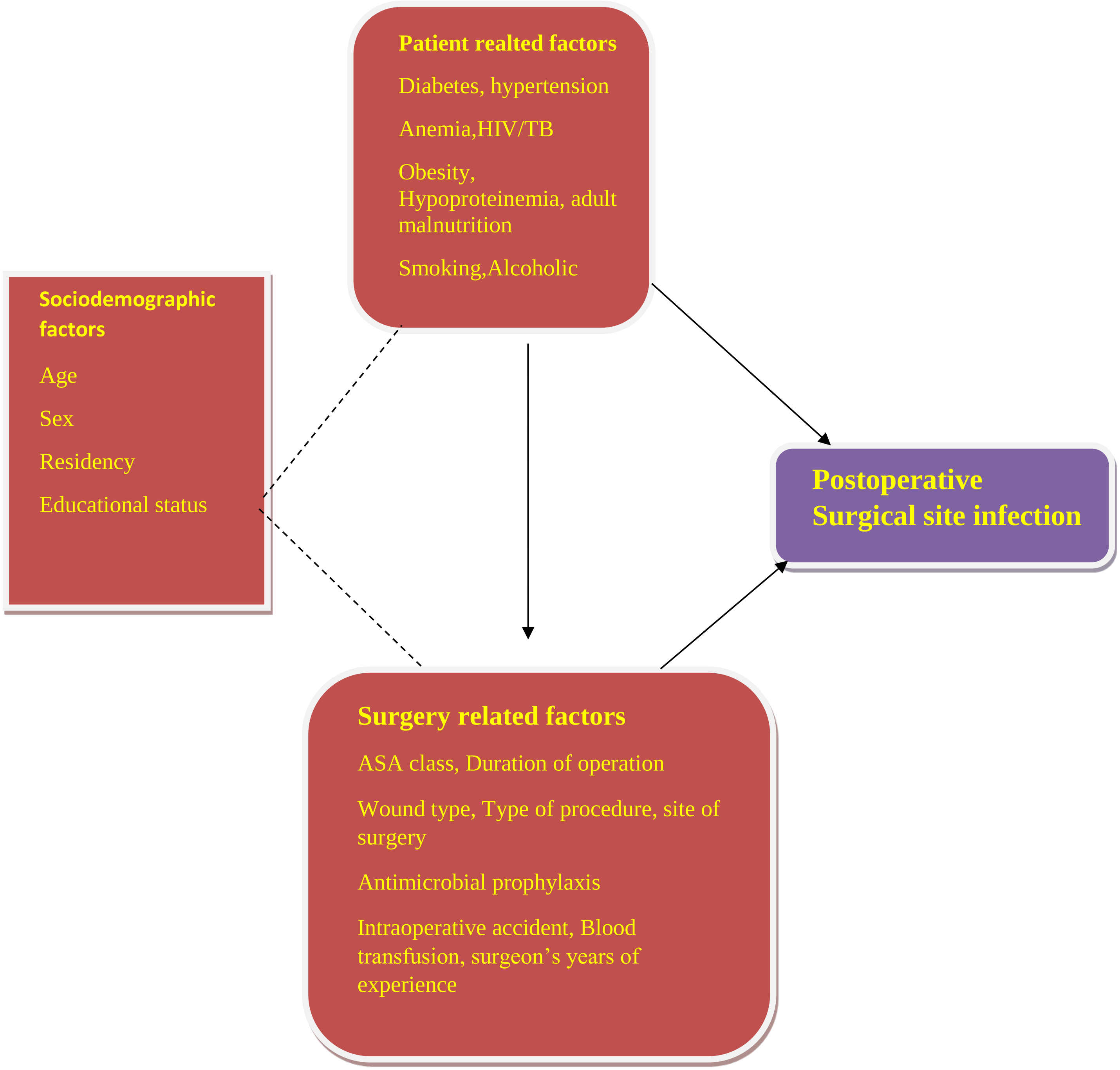


**Figure 1. Conceptual framework for the development of postoperative surgical site infection**

# 3. Objectives of the Study

## 3.1. General Objective

1. To assess the incidence and predictors of postoperative surgical site infections after major surgeries at Debre Tabor General Hospital.

## 3.2. Specific Objectives

1. To estimate the incidence of postoperative surgical site infections after major surgeries at Debre Tabor General Hospital.
2. To estimate the time to the development of surgical site infections after major surgeries at Debre Tabor General Hospital.
3. To identify the predictors of postoperative surgical site infections after major surgeries at Debre Tabor General Hospital.

# 4. Research Methods and Materials

## 4.1 Study Design and Period

A hospital-based prospective cohort study was conducted from 10$^{th}$ June 2018 to 10$^{th}$ December 2018 on postoperative patients who had undergone major surgery at Debre Tabor General Hospital.

## 4.2 Study Area/ Setting

The study was conducted at Debre Tabor General Hospital found in Debre Tabor city and which provides clinical services for a catchment population of 1.5 million. The hospital is organized into emergency, outpatient and inpatient departments on the four major fields (Internal Medicine, Surgery, Gynecology and Obstetrics, and Pediatrics). Daily on average more than 50 patients (new cases & patients on follow up) are seen.

Major surgical procedures are performed in surgical and gynecology departments. The surgical department of the hospital is comprised of four qualified surgeons, six general practitioners, and 10 surgical nurses. The gynecology department is also working with three qualified gynecologists, five general practitioners, and 12 nurses (26).

Monthly, more than 50 emergency and elective major surgeries are performed. Patients who had undergone surgery are admitted and followed. After being discharged they get consecutive follow-ups in the outpatients' clinic.

The hospital has separate wards for each major department. The surgical ward is found at the western part of the old hospital buildings and has a total of 31 beds for adolescents and adults (age $\geq$14) and five pediatric (age<14) beds in the pediatric ward. The gynecology ward is found in the new building and has 15 beds. In the wards, patients stay in a room where there are three to four beds. Each room has its own ventilating window. Physicians perform daily rounds every morning in both wards and see the condition of the wound and patient status daily until the patient is discharged.

The hospital has a major operation theater which is built in a separate building from the hospital wards. It has two operating tables where two surgeries can be done simultaneously. Each of the operating tables is in separate rooms having its own anesthesia machine. The Operation Theater has also a washing facility, where the surgeons wash their hands before the surgery, and a room for the staffs to change their clothes.

Preoperatively anesthetists evaluate patients whether they are fit or unfit for surgery. During surgery, before the surgeon makes skin incision the surgical incision site will be cleaned with iodine/alcohol, depending on the site of incision, and the body will then be covered with a sterile dressing (drape). Then the surgery is conducted using sterilized instruments. The surgeon and the assistant scrub nurse wear sterilized gown and gloves throughout the procedure. After completing the surgery, the surgical wound is dressed/covered using sterile gauze and clean plaster. The patient then is transferred to the post-anesthesia recovery room and stay there until he/she is fully awake and stable. Later the patient is transferred to the surgical or gynecologic ward. The rooms in the wards measure 12 to 16-meter squares and three to four patients are kept in a room.

The hospital has no standard protocol for surgical wound care. Surgical dressings aren't changed daily. Surgical dressings are usually removed 48 hours post-surgery by the attending ward physician. If patients develop SSI or wound dehiscence, they receive wound care daily in the wards and are discharged when they improve.

## 4.3 Source and Study Population

**Source Population**- All postoperative patients who had undergone elective or emergency surgeries at Debre Tabor General Hospital

**Study Population**- All postoperative patients who had undergone elective or emergency major surgeries surgery from 10$^{th}$ June 2018 to 10$^{th}$ December 2018.

## 4.4 Eligibility Criteria

### 4.4.1. Inclusion Criteria

- All postoperative patients who had undergone major surgery (emergency and elective) from 10 June 2018 to 10 December 2018.
- All postoperative patients whose ages are greater than or equal to 1

#### 4.4.2. Exclusion Criteria

- Mothers who had undergone cesarean section
- Patients who had undergone simple hernia repair at minor OR
- Patients with previously infected wound prior to surgery

## 4.5 Study Variables

### 4.5.1. Dependent Variable

1) Postoperative surgical site infection

### 4.5.2. Independent Variables

1) **Sociodemographic characteristics** (age, sex, Educational status, Residency)
2) **Patient-related factors** (hypertension, Diabetes, Asthma, anemia, malnutrition, cigarette smoking, alcoholic)
3) **Surgery related factors** (Type of surgery, ASA classification, wound type, blood transfusion, surgeon's year of experience)

## 4.6 Operational Definitions

**Postoperative Surgical site infection** - Surgical site infection (SSI) is an infection that develops within 10 days after an operation with no implant.

**Superficial infection- is** Infection occurring on the surgical wound within 10 days after surgery and involves skin and subcutaneous tissue only, having purulent discharge and diagnosis confirmed by a trained general practitioner (GP).

**Deep Incisional infection- is** Infection occurring on the surgical wound within 10 days after surgery with no implant and soft tissue involvement; involves deep soft tissues (fascia and muscle), and diagnosis confirmed by a trained general practitioner (GP) or radiologic examination or on reoperation.

**Organ Space infection-** is Infection occurring on the surgical wound within 10 days after surgery with no implant; involves any part of the operation opened or manipulated, and diagnosis confirmed by a trained general practitioner (GP) or radiologic examination or on reoperation

**Major surgery**- is a surgical procedure which is done under general anesthesia and which involves body cavity like abdomen, pelvis, and skull.

**Abdominal surgery**- is a surgical procedure which involves the abdominal cavity. It includes hepatobiliary surgery, colorectal surgery, urological surgery, gastrointestinal surgery, inguinal hernia repair

**Gynecologic surgery**- is a surgical procedure which involves the pelvic cavity and is related to female reproductive organs. It includes oophorectomy, hysterectomy (other than obstetric indication), and myomectomy

## 4.7 Sample Size and Sampling Procedure

### 4.7.1 Sample Size Determination

The sample size for incidence was calculated using the value of p as 0.19 (taken from related literature done at Hawassa Referal Hospital) (15). In most scientific researches the desired level of significance is 95%, that is $\alpha$ =5% and this was adopted for this research. From the normal distribution table $Z\alpha/2$=1.96 and margin of error was 0.05, accordingly, the sample size[n] of the study was calculated as:

Where

n=initial sample size

nf=final sample size after correction

d= margin of error

P=proportion

$\alpha$=degree of accuracy

n= ((1.96)2 0.19(1-0.19))/ (0.05)2 = **237**

For risk factors, sample size was calculated using open-Epi sample calculator by incorporating exposure variables from a study done on SSI at Hawassa University Referral Hospital. Exposures which were statistically significant in the study (age, cigarette smoking, preoperative hospital stay and duration of surgery) were taken into consideration. Using 95% confidence level and 80% power the total sample size calculated for the study was 237 patients (table 1) and was set at 250 patients after adjusting for loss to follow up.

**Table 1- sample size determination variables and corresponding sample size of postoperative patients**

| Exposure | OR | Ratio of unexposed to exposed | %of unexposed with the outcome | Sample size |
|---|---|---|---|---|
| Age | 4.71 | 2.08 | 11.6 | 104 |
| **Cigarette smoking** | **2.84** | **2.75** | **14.3** | **237** |
| Preoperative hospital stay | 12.92 | 2.89 | 7.7 | 47 |
| Duration of surgery | 4.97 | 1.23 | 8.6 | 109 |

### 4.7.2 Sampling Procedures and Cohort Recruitment

To conduct the study a total of 250 patients were required. Since the hospital has limited beds, all 250 patients required for the study couldn't be enrolled at the same time. Therefore, patients were serially enrolled until the sample size was reached. The patients' recruitment started on10 June 2018 and ended on 30 November 2018. Surgical patients were screened for legibility of the study after they were admitted to the Surgical or Gynecology ward. Legible patients (patients who fulfilled inclusion criteria) who gave consent were enrolled in the study. Follow up began in the first postoperative day. Patients who had similar operation day were considered as a cohort.

## 4.8 Data Collection Instruments and Techniques

Data were collected using postoperative complication assessment checklist which was developed through referring published researches done Worldwide on a similar problem. The format was commented and approved by respective advisors before data collection.

Data were collected by the investigator and also physicians who were working at the hospital other than surgical and Gynecology ward and surgical and Gynecology outpatient department. Data collectors were given orientation and training on the data collection tools and also how to carry out the data collection. Then data collection tool was pretested on 5% of patients to check for consistency and reliability of the data collection tool.

Data were collected from patients through an interview, medical record review and direct observations of patients' wound using the checklist prepared. Surgical Patients' wound condition was followed every day until the patients were discharged and continued until the tenth postoperative day. Upon discharge, all patients were appointed to come after a week for stitch removal. The patients were followed up by phone call till their date of appointment. On the day of the appointment, the physicians took a brief history of whether the patient had developed symptoms of SSI and treated for it before the date of appointment or not. The physical exam had also been performed and the patient was either declared as SSI positive or Negative.

## 4.9 Data Quality Assurance

The data collection checklist consent form was translated into Amharic language and was tested on 5 % of the sample (13 patients) before beginning the actual data collection in order to identify any missing components and difficulties during implementation. During data collection days the postoperative complication assessment checklist was checked for its completeness by the principal investigator. Errors or omissions were communicated with the data collectors for corrections immediately on receiving.

## 4.10 Data Management and Analysis

The collected data were checked for completeness and variables were coded in SPSS 23.0 in the variable view prior to entering. Later on, data were entered and cleaned before analysis. Then data were exported to STATA 14.0 and proportional hazard assumption test was done to check if assumptions for Cox-regression were fulfilled and the test yielded that proportional hazard assumption was not fulfilled (global test P-value 0.014). Descriptive statistics were carried out to describe the sociodemographic, patient factor and surgical related data. The survival analysis was carried out since this study considered the time to event data. Incidence density was calculated to determine the magnitude. Kaplan Meier's curve with Log-rank test was done to compare the survival of different covariates. Weibull's regression was used for analysis to identify independent risk factors since Cox proportional hazard assumption wasn't fulfilled (see result section). Variables having p-values <0.05 in the regression were considered as significantly and independently associated factors.

## 4.11 Ethical Considerations

Ethical clearance was obtained from Bahir Dar University, College of Medicine and Health Sciences Institutional Review Board and permission letter were received form Amhara Public Health Institute and Debre Tabor General Hospital. Patient consent was taken before starting collecting individual data. Consent of patients with age below 18 was taken from parents/ guardian. The patients' data were recorded only by the data collectors and the final combined data were accessible only to the principal investigator and advisors. The information summarized is not discussed referring to the patient's name. The collected data will be disposed of after the paper gets approval for publication.

# 5. Results

A total of 365 major surgeries were performed during the study period. Among these 108 surgeries were gynecologic surgeries. Patients with emergency abdominal surgeries were predominant during the study period and large bowel obstruction (62%) was the frequent indication for surgery. After admission to the wards, surgical patients were scrutinized for legibility of the study and of the total 365 patients 250 patients fulfilled the inclusion criteria and were enrolled into the study and followed for ten consecutive days after surgery. Two hundred seventeen patients completed the ten days follow up. This section illustrates the characteristics of the study participants, description of variables and the determinants of the outcome.

## 5.1 Sociodemographic Characteristics of the Cohort

More than half (55.6%) of the patients enrolled in the study were male and the majority of the patients were in the age group of between 25 and 45 years with a median age of 39 years. The majority (61.2%) of the participants were from the rural areas and 47.2% of them can't read and write (Table 2).

**Table 2. Socio-demographic characteristics of the postoperative patients, who had undergone major surgery at Debre Tabor General Hospital, 10 June 2018 to 10 December 2018**

| Variables | | Frequency | Percentage |
|---|---|---|---|
| **Age (in years)** | 0-14 | 15 | 6.0 |
| | 15-24 | 37 | 14.8 |
| | 25-34 | 53 | 21.2 |
| | 35-44 | 50 | 20.0 |
| | 45-54 | 37 | 14.8 |
| | 55-64 | 34 | 13.6 |
| | 65+ | 24 | 9.6 |
| **Sex** | Male | 139 | 55.6 |
| | Female | 111 | 44.4 |
| **Residency** | Rural | 153 | 61.2 |
| | Urban | 97 | 31.8 |
| **Level of education** | unable to read and write | 118 | 47.2 |
| | can read and write | 49 | 19.6 |
| | primary school | 42 | 16.8 |
| | secondary school | 31 | 12.4 |
| | preparatory school | 4 | 1.6 |
| | above 12th grade | 6 | 2.4 |

## 5.2 Factors Related To the Development of Surgical Site Infection

Factors which are presumed to be contributors to surgical site infection can be categorized into patient-related factors and surgery-related factors.

**Patient-related factors**

Patient related factors like patients physical status (ASA score), having comorbid illnesses, cigarette smoking and abusing alcohol were assessed. Smoking status was determined by asking if the patient is currently smoking or ceased smoking within the past six months. Most of the participants were from rural areas where dinking is socially accepted. A patient was considered as alcoholic if he fulfilled the CAGE criteria (Annex). Moreover, nutritional status of the patients was assessed using BMI for patients with the age of 16 and above and mid upper arm circumference (MUAC) for those below age 16.

The majority (82.8%) of the patients were having ASA class I and also most of the participants had no associated co-morbid illnesses. Cigarette smoking and alcohol dependence were also low although most of the participants were social drinkers. Moreover, most of the participants had a normal BMI (Table 3). All participants didn't have tuberculosis or Asthma.

**Table 3. Patent-related factors of postoperative patients, who had undergone major surgery at Debre Tabor General Hospital, 10 June 2018 to 10 December 2018**

| Variables | | Frequency | Percentage |
|---|---|---|---|
| **ASA class** | Class I | 207 | 82.8 |
| | Class II | 37 | 14.8 |
| | Class III | 6 | 2.4 |
| **Hypertension** | Yes | 13 | 5.2 |
| | No | 237 | 94.8 |
| **Diabetes** | Yes | 5 | 2 |
| | No | 245 | 98 |
| **Malignancy** | Yes | 12 | 4.8 |
| | No | 238 | 95.2 |
| **Anemia** | Yes | 29 | 11.6 |
| | No | 221 | 88.4 |
| **Smoking Habit** | Yes | 5 | 2 |
| | No | 245 | 98 |
| **Alcoholic** | Yes | 16 | 6.4 |
| | No | 234 | 93.6 |
| **BMI** | Normal | 214 | 85.6 |
| | Underweight/malnourished | 23 | 9.2 |
| | Overweight/Obese | 13 | 5.2 |

## Surgery Related Factors

Surgical procedure-related factors had also been assessed during the study. Majority of the surgeries were abdominal surgeries. Most of the admission were emergency and more than two-thirds of the surgeries took more than one hour to complete. Patients who were planned for elective surgery stayed in the ward preoperatively. The mean preoperative hospital stay was 3.3 ± 1.4 days.

An Hour before skin incision is made antibiotics will be given for the patients. During the study, almost 90% of the patients had received antimicrobial prophylaxis. Depending on the type of surgical procedure the type of anesthesia given also differs. Ninety one percent of the patients' surgery was performed under general anesthesia. About 6.4 % the patients required a transfusion during surgery. (Table 4)

**Table 4. Frequency of site of surgery, duration of surgery, nature of admission and antimicrobial prophylaxis of postoperative patients at Debre Tabor General Hospital, from June 10 to Dec 10, 2018**

| Variables | | Frequency | Percentage |
|---|---|---|---|
| **Site of surgery** | Abdomen | 200 | 80.0 |
| | Head and Neck | 41 | 16.4 |
| | Thorax | 4 | 1.6 |
| | Extremities | 5 | 2.0 |
| **Duration of surgery** | Less than one hour | 75 | 30.0 |
| | More than one hour | 175 | 70.0 |
| **Nature of admission** | Emergency | 132 | 52.8 |
| | Elective | 118 | 47.2 |
| **Antimicrobial prophylaxis** | Yes | 224 | 89.6 |
| | No | 26 | 10.4 |
| **Type of Anesthesia** | General | 228 | 91.2 |
| | Regional | 22 | 8.8 |
| **Blood Transfusion** | Yes | 16 | 6.2 |
| | No | 234 | 93.6 |

During the study period, there were four general surgeons and three gynecologist and obstetricians who performed surgeries. Their mean year of experience was 3.96 with a standard deviation of 1.09. Upon completion of the surgery, the surgeons classify the level of contamination of the patients' wound. Of the 250 patients, 53.6% had a clean-contaminated wound, 18% clean wound, 17.6% contaminated and 10.8 % dirty wounds (Figure 2).

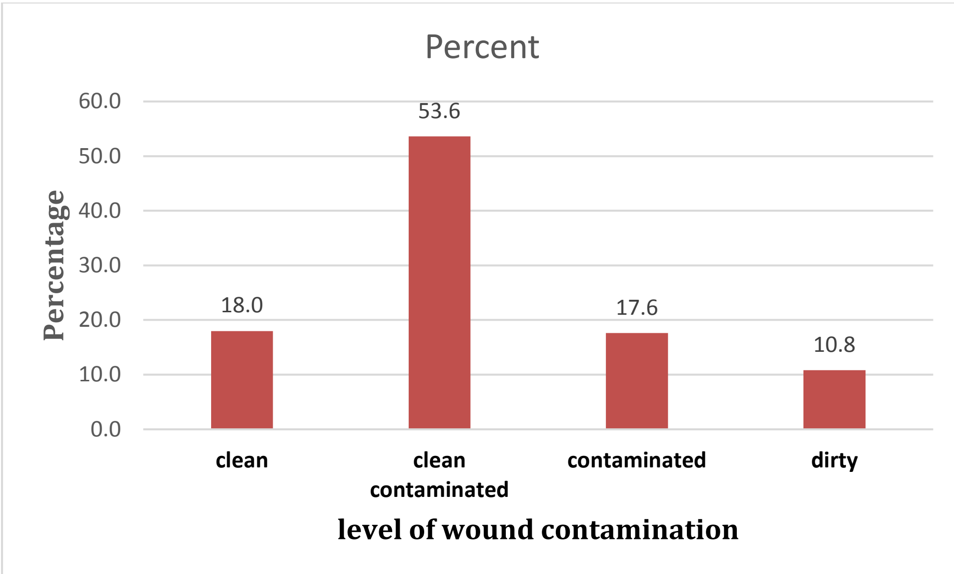


**Figure 2- Frequency of level of wound contamination of postoperative patients, who had undergone major surgery at Debre Tabor General Hospital, 10 June 2018 to 10 December 2018**

## 5.3 Follow Up Results of The Cohort

A total of 250 patients were serially selected and enrolled in the study. Patients who were operated on the same day were considered as a cohort and have similar days of follow up. Among the 250 study participants, 33 patients didn't complete the follow up (five deaths and 28 loss to follow-ups). The patients were followed for ten consecutive days after their operation. The average days of follow up were 8.2 ± 2.8 days and the total person-time observation was 2041 days. Forty-nine patients developed SSI.

### Survival Analysis

In order to see the probability of surviving or the probability of not acquiring surgical site infection life table and survival plot was done. The cumulative probability of surviving without developing surgical site infection at the end of the 3$^{rd}$ day, 5$^{th}$ day, 7$^{th}$ day, and at the end of the follow up was 0.98, 0.87, 0.8 and 0.76 respectively indicating that 76 percent of the patients didn't develop SSI until the end of the tenth day (Table 5) (figure 3).

**Table 5- life table calculation for Surgical site infection among patients who undergone general surgery at Debretabor General Hospital from June 10 – Dec 10, 2018**

| | Beg. | . | | | |
|---|---|---|---|---|---|
| Interval | Total | Deaths | Lost | Survival | [95% Conf. Int.] |
| | | | | | |
| 3 - 4 | 217 | 4 | 2 | 0.98 | 0.95, 0.99 |
| 4 - 5 | 211 | 12 | 1 | 0.93 | 0.88, 0.95 |
| 5 - 6 | 198 | 12 | 0 | 0.87 | 0.82, 0.91 |
| 6 - 7 | 186 | 11 | 1 | 0.81 | 0.76, 0.86 |
| 7 - 8 | 174 | 3 | 0 | 0.80 | 0.74, 0.85 |
| 8 - 9 | 171 | 3 | 0 | 0.79 | 0.73, 0.84 |
| 9 - 10 | 168 | 1 | 0 | 0.79 | 0.72, 0.83 |
| 10 - 11 | 167 | 3 | 164 | 0.76 | 0.69, 0.81 |
| | | | | | |
| | | | | | |

Median survival time 10.0

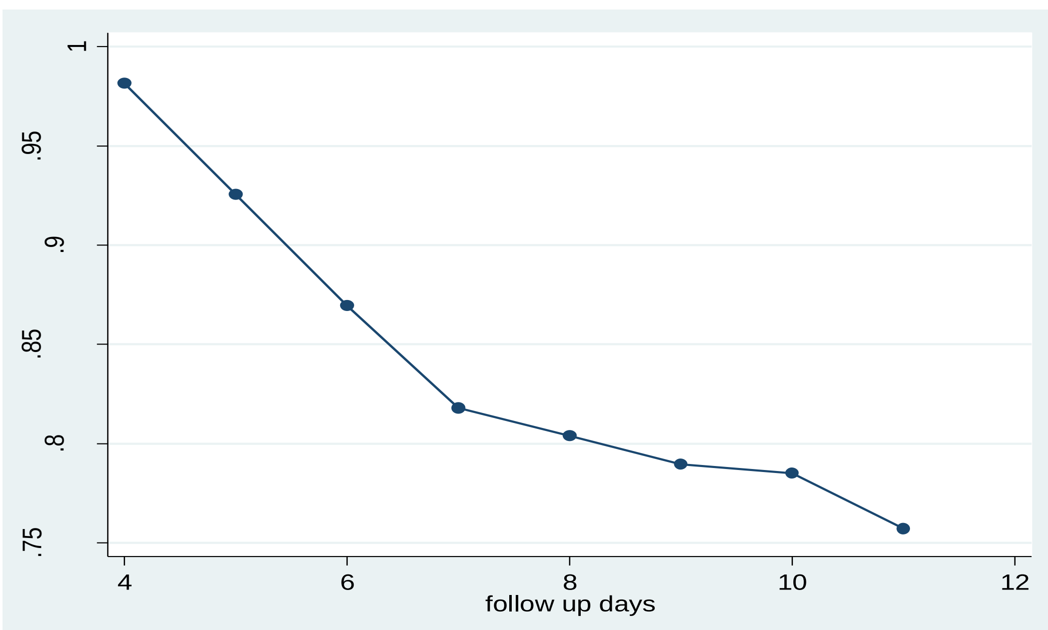


Figure 3- **Survival function curves for time to development of surgical site infection among postoperative patients who had undergone general surgery at Debre Tabor General Hospital 10 June 2018 to 10 December 2018**

## 5.4 The incidence rate of surgical site infections

A total of 250 patients were enrolled in the cohort and produced a total of 2041 patient days of observation. Forty-nine patients (19.6%) developed surgical site infection. The mean time of development of SSI was 5.39 ± 1.61 days. Of those who developed the infection 77.6% of the patients had a superficial surgical site infection (Figure 4).

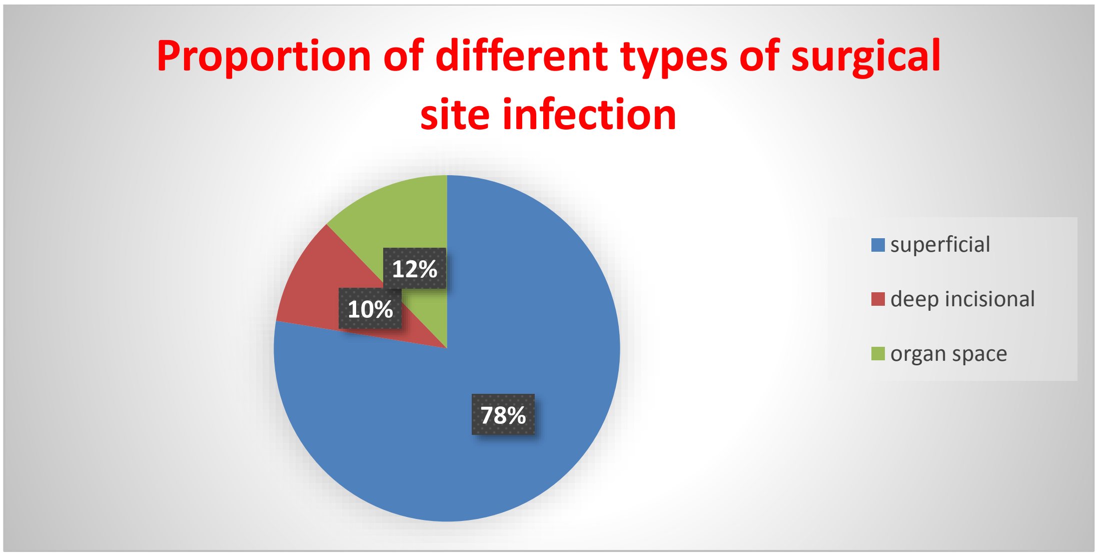


Figure 4- **Frequency of SSI type among surgical patients who developed SSI at Debre Tabor General Hospital**

Since all patients have person time observation incidence density was calculated rather than cumulative incidence. The total person-time observation was 2041 days making the incidence density of 24 cases per 100 patient-days of observation (95% CI: 0.018, 0.032).

**Kaplan-Meier Survival Curves**

In order to investigate associations between the different covariates, the timing of surgical site infection and the difference in survival rate, Kaplan Meier survival curves with log-rank test was done. Antimicrobial prophylaxis had a significant effect on the timing of developing surgical site infection (log-rank test = <0.001 ) and the probability of surviving without developing SSI was higher in patients who were given antibiotic prophylaxis compared to those who didn't (Figure 5).

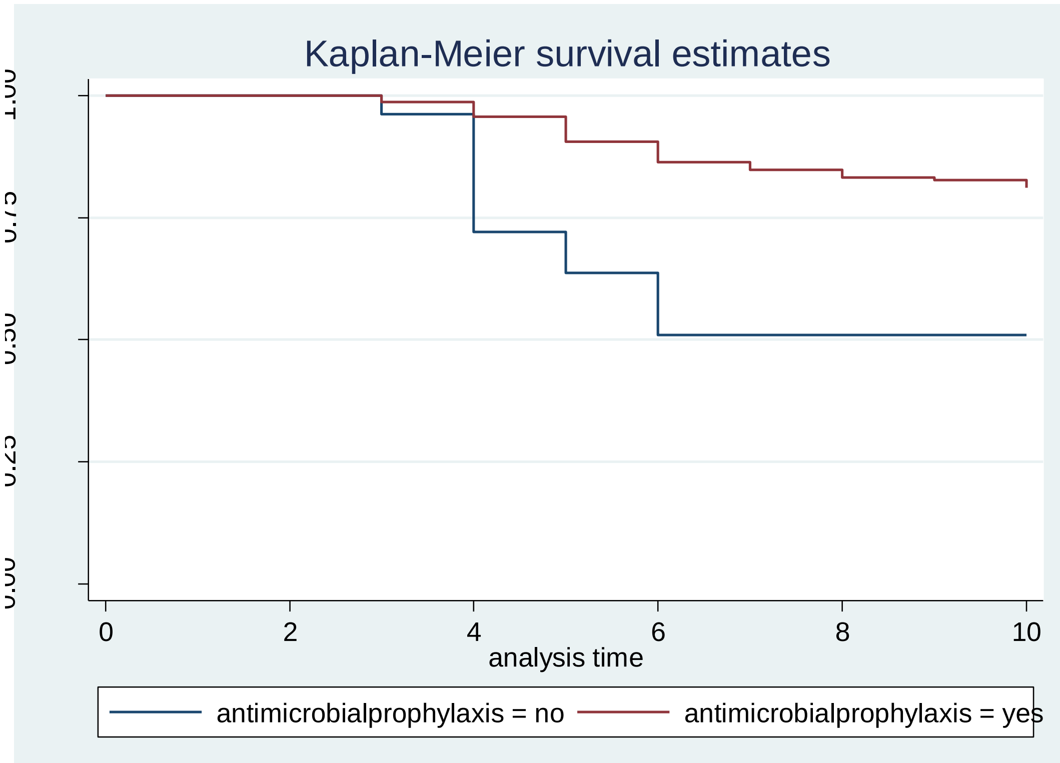


**Figure 5- Kaplan-Meier plot for time to development of SSI among surgical patients who had undergone major surgery, Debre Tabor General Hospital, 10 June 2018 to 10 December 2018, classified by antimicrobial prophylaxis status**

Kaplan-Meier plot for level wound contaminations showed that it had a significant effect on the timing of developing surgical site infection (log-rank test = <0.001 ) and the probability of surviving without developing SSI was lower in patients having dirty wounds. However, there is no much difference in survival among patients with contaminated and dirty wounds (Figure 6).

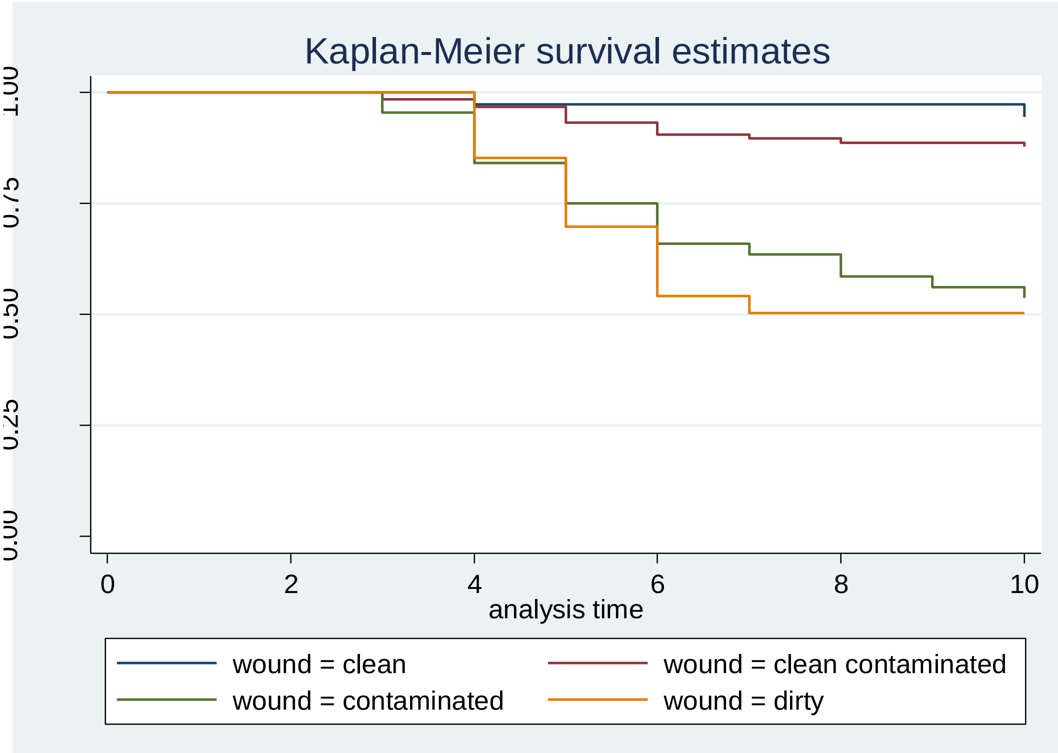


**Figure- 6 Kaplan Meier plot for time to development of SSI among surgical patients who had undergone major surgery, Debre Tabor General Hospital, 10 June 2018 to 10 December 2018, classified by wound class**

Kaplan Meier plot for type of anesthesia (Log rank test =0.38) and smoking status (Log rank test = 0.12) showed that there is no significant effect on the timing of developing surgical site infection between groups. (Figure 7 and 8) .

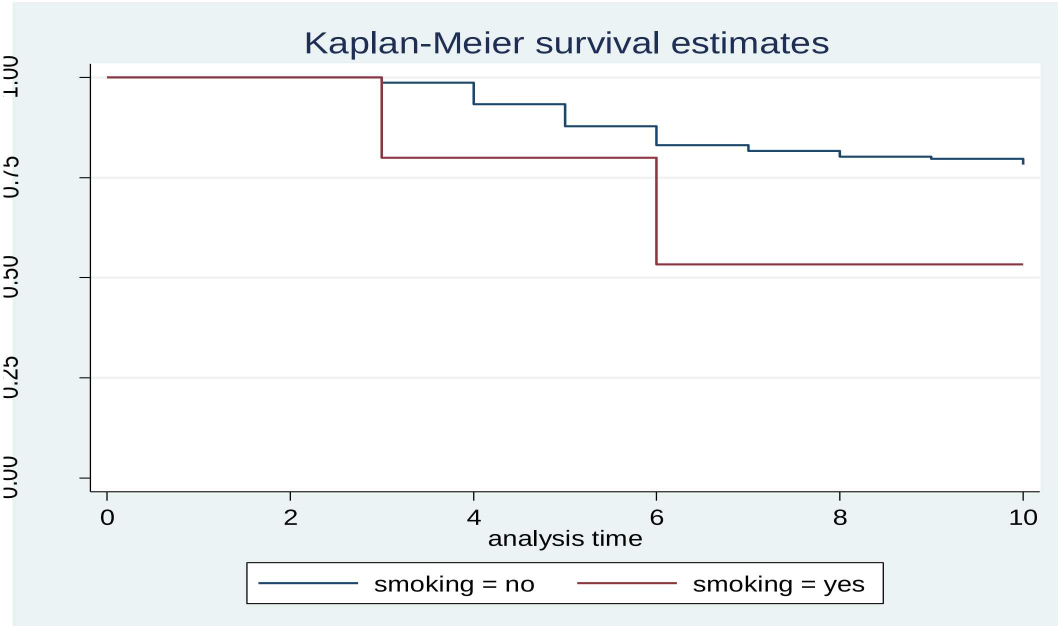


**Figure- 7 Kaplan Meier plot for time to development of SSI among surgical patients who had undergone major surgery, Debre Tabor General Hospital, 10 June 2018 to 10 December 2018, classified by smoking status**

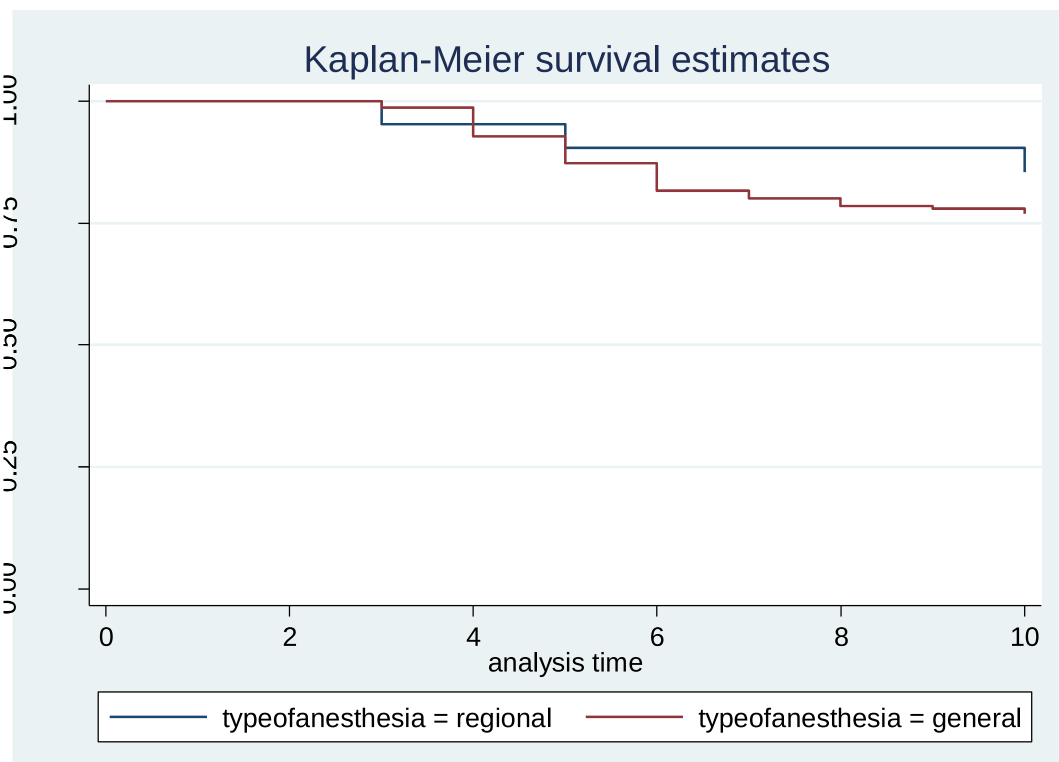


**Figure- 8 Kaplan Meier plot for time to development of SSI among surgical patients who had undergone major surgery, Debretabor General Hospital, 10 June 2018 to 10 December 2018, classified by type of anesthesia**

## 5.5 Model Fitness Test

**PH Assumption Test**

Since the data generated is a survival data the Cox proportional hazard assumption test was done prior to performing cox regression. The main assumption of the Cox proportional hazards model is proportionality of hazards i.e. the hazard function is constant over time. The Cox proportional hazard assumptions were checked by both statistical test and graphical method.

**A. Graphical Method**

In order to check the PH assumption, plots of scaled Schoenfeld residuals of the covariates (blood transfusion, surgeons' year of experience, ASA class, and site of surgery) against time was done. The Schoenfeld residuals will be distributed in symmetrical pattern making the slope zero if the covariate fulfills the PH assumption. However, the plot for the covariates showed that the slope was not zero or near zero and it indicated that the covariates do not satisfy the proportional hazard assumption (Figure 9).

**A. Statistical Method**

Graphical methods are subjective for interpretation. Therefore, it is necessary to do a statistical test in order to confirm whether the Proportional hazard assumption is fulfilled or not. In this study, the global fitness test was done. The global test assumes that the correlation between the covariates and time is zero and $p\text{-value} < 0.05$ indicates the violation of the assumption. Type of admission, ASA class, malignancy, surgeon's year of experience, and preoperative hospital stay don't fulfill the proportional hazard assumptions. Moreover, the global test also showed that the proportional hazard assumption is not fulfilled (Table 6).

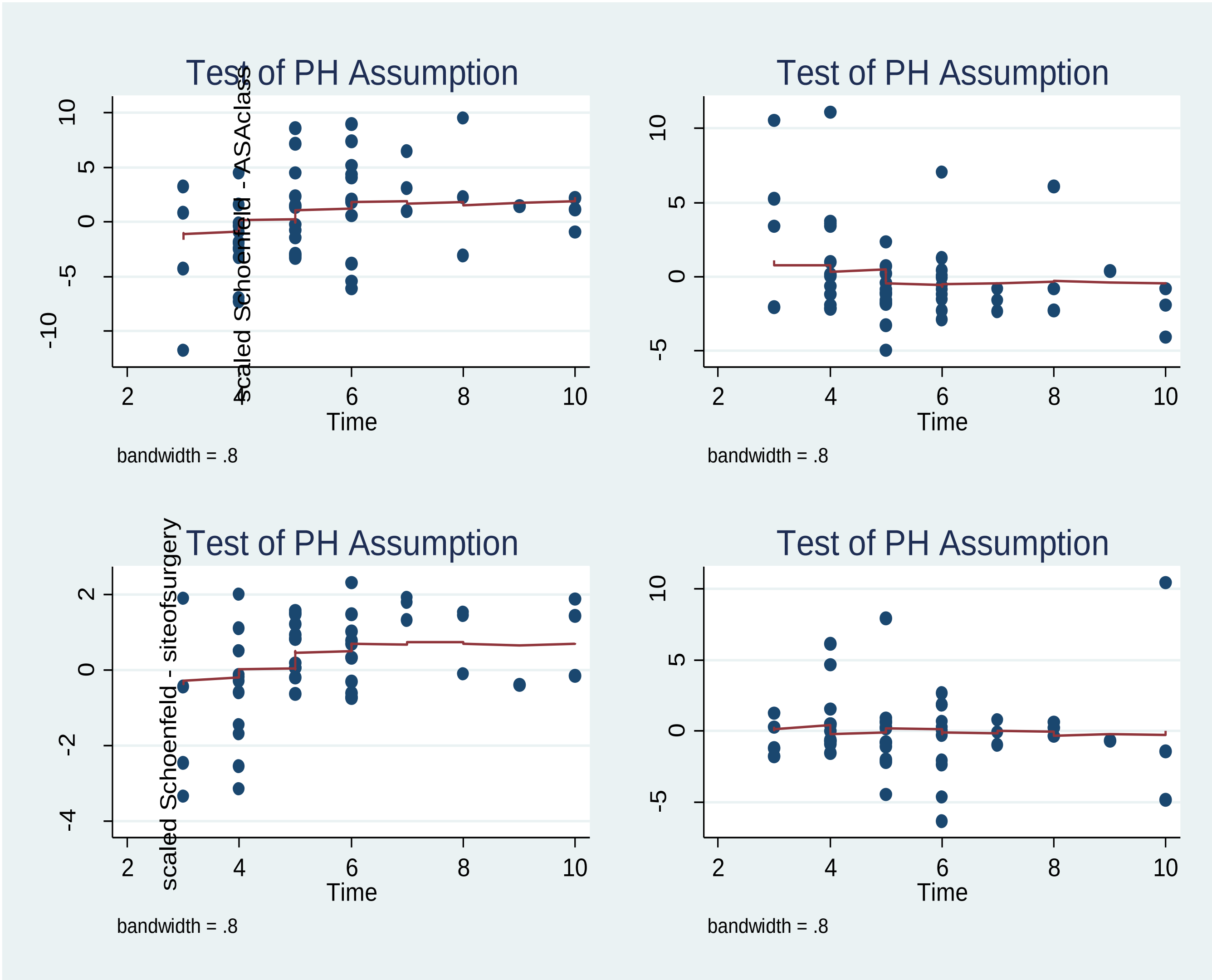


**Figure 9- Scaled Schoenfeld residuals test of proportional hazard assumption among surgical patients who had undergone major surgery, Debre Tabor General Hospital, 10 June 2018 to 10 December 2018,**

**Table 6- Global test of proportional hazards assumption for covariates of Surgical site infection among patients who undergone general surgery at Debre Tabor General Hospital from June 10 – Dec 10, 2018**

| | rho | chi2 | df | Prob>chi2 |
|---|---|---|---|---|
| **age** | -0.13387 | 1.15 | 1 | 0.2833 |
| **Sex** | -0.04519 | 2.35 | 1 | 0.448 |
| **residency** | -0.18635 | 1.87 | 1 | 0.1711 |
| **Level of education** | -0.07619 | 0.29 | 1 | 0.5911 |
| **Type Of Admission** | -0.38824 | 10.14 | 1 | 0.0015* |
| **ASA class** | -0.24968 | 4.71 | 1 | 0.0299* |
| **Type Of Anesthesia** | 0.06432 | 0.29 | 1 | 0.5879 |
| **Duration of Operation** | 0.09704 | 0.53 | 1 | 0.4684 |
| **Level of wound contamination** | -0.00099 | 0.00 | 1 | 0.9953 |
| **Site of surgery** | 0.01243 | 0.01 | 1 | 0.9239 |
| **Surgeons' year of experience** | 0.39 | 8.1 | 1 | 0.0045* |
| **Antimicrobial prophylaxis** | 0.19 | 2.17 | 1 | 0.1405 |
| **Transfusion** | 0.176 | 1.79 | 1 | 0.1812 |
| **Preoperative hospital stay** | 0.363 | 11.8 | 1 | 0.0006* |
| **hypertension** | -0.0352 | 0.06 | 1 | 0.811 |
| **diabetes** | 0.134 | 1.15 | 1 | 0.285 |
| **malignancy** | 0.35047 | 5.00 | 1 | 0.0253* |
| **RVI** | 0.22364 | 2.56 | 1 | 0.1099 |
| **anemia** | -0.18176 | 2.25 | 1 | 0.1334 |
| **BMI** | -0.03325 | 0.07 | 1 | 0.7905 |
| **alcoholic** | -0.01527 | 0.02 | 1 | 0.9022 |
| **smoking** | 0.14772 | 1.99 | 1 | 0.1578 |
| **global test** | | **45.72** | **21** | **0.0014** |

* Covariates which don't satisfy proportional hazard assumption

## Parametric Regression Models

Since the proportional hazard assumption is not met parametric regression model (accelerated failure time model) is applied. Among the many parametric regression models, the exponential and the Weibull regressions were done. In order to select the best model, the likelihood ratio, Akaike's information criterion (AIC) and Bayesian information criterion (BIC) of the models were compared. The model with the lowest AIC and BIC was considered as the best model (table 7).

**Table 7- selection of the best fitting model for covariates of Surgical site infection among patients who undergone general surgery at Debre Tabor General Hospital from June 10 – Dec 10, 2018**

| Model | Obs | Ll (null) | ll(model) | df | AIC | BIC |
|---|---|---|---|---|---|---|
| | | | | | | |
| Exponential | 250 | -150.5057 | -106.7163 | 35 | 283.4326 | 406.6838 |
| **Weibull** | **250** | **-142.9839** | **-93.5372** | **35** | **257.0744** | **380.3255** |

**Weibull regression analysis**

This study employed a longitudinal prospective study design. Cox regression was planned to be done but since the PH assumption was not fulfilled the Accelerated Failure- Time Weibull's regression model was selected. The event was surgical site infection and the survival status of patients (dead, alive or loss to follow up) is considered as censored variables. The survival time (follow up time) was put into a regression with possible influential variables that affect the development of surgical site infection.

With multivariate Weibull's regression duration of operation, level of wound contamination, having cancer and being anemic were found to be independent risk factors which have a significant association with surgical site infection (Table 8).

The hazard ratio of the duration of operation is 4.07 (95% CI: 1.07, 15.46). Surgical procedures which took more than one hour have 4.07 times higher hazards of acquiring surgical site infection compared to those procedures which took less than an hour.

Level of contamination of wound had also significant association. Patients with contaminated and dirty wounds had nearly thirteen (HR= 13.83, 95% (CI): 2.51, 76.35) and twenty-five (HR= 25.06 95% (CI): 4.46, 140.79) times higher hazards of developing SSI compared with clean surgical wounds respectively. However, there was no difference in the hazards between patients having clean and clean contaminated wounds.

Moreover, patients with cancer were 10.89 (95% CI: 2.47, 48.14) as likely to acquire SSI compared with those who don't have. Anemic patients also had 3 times higher hazards of (AHR= 3.29 95% (CI): 1.52, 7.12) developing SSI (Table 8).

**Table-8 Multivariate Weibull regression analysis between different predictor variable of postoperative SSI among surgical patients who had major surgery at Debre Tabor General Hospital, 10 June 2018 to 10 December 2018**

| Variables | | Hazard Ratio | z | P>z | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| **Sex** | **Male** | 1 | - | - | - | - |
| | **Female** | 0.53 | -1.51 | 0.13 | 0.24 | 1.21 |
| **Residency** | **Rural** | 1 | | | | |
| | **Urban** | 1.83 | 1.40 | 0.16 | 0.78 | 4.26 |
| **Level of education** | | | | | | |
| | **can read and write** | 0.94 | -0.14 | 0.89 | 0.396 | 2.23 |
| | **primary school** | 0.84 | -0.30 | 0.76 | 0.273 | 2.59 |
| | **secondary school** | 0.19 | -1.80 | 0.07 | 0.034 | 1.16 |
| | **preparatory school** | 3.40e-07 | -0.01 | 0.99 | 0 | . |
| | **above 12th grade** | 0.2 | -1.26 | 0.21 | 0.017 | 2.43 |
| **Duration of operation** | | | - | - | - | - |
| **Less than or equal to one hour** | | 1 | | | | |
| | **more than one hour** | 4.07 | 2.06 | 0.04 | 1.069 | 15.46 |
| **Wound** | **Clean** | 1 | - | - | - | - |
| | **clean contaminated** | 3.55 | 1.44 | 0.15 | 0.63 | 19.9 |
| | **contaminated** | 13.83 | 3.01 | 0.003 | 2.51 | 76.35 |
| | **dirty** | 25.06 | 3.66 | <0.001 | 4.46 | 140.79 |
| **Antimicrobial prophylaxis** | | | - | - | - | - |
| | **NO** | 1 | | | | |
| | **Yes** | 0.55 | -1.45 | 0.15 | 0.24 | 1.24 |
| **Hypertension** | **NO** | 1 | - | - | - | - |
| | **Yes** | 3.73 | 1.95 | 0.051 | 0.99 | 14.01 |
| **Diabetes** | **NO** | 1 | - | - | - | - |
| | **Yes** | 2.07 | 0.86 | 0.391 | 0.39 | 10.98 |
| **Cancer patient** | **NO** | 1 | - | - | - | - |
| | **Yes** | 10.895 | 3.15 | 0.002 | 2.47 | 48.14 |
| **RVI** | **NO** | 1 | - | - | - | - |
| | **Yes** | 2.43 | 1.33 | 0.19 | 0.65 | 9.04 |
| **Preoperative Anemia** | | | | | | |
| | **NO** | | | | | |
| | **Yes** | 3.29 | 3.03 | 0.002 | 1.52 | 7.12 |
| **BMI** | | 1 | - | - | - | - |
| **Malnourished/underweight** | | | | | | |
| **Normal** | | 1.41 | 0.62 | 0.54 | 0.47 | 4.19 |
| **Obese/overweight** | | 3.93 | 1.47 | 0.14 | 0.64 | 24.35 |
| **Surgeons' years of experience** | | 1 | - | - | - | - |
| | **3 years** | 0.37 | -1.16 | 0.248 | .066 | 2.01 |
| | **4 years** | 0.91 | -0.16 | 0.876 | .261 | 3.13 |
| | **5 years** | 1.41 | 0.58 | 0.562 | .436 | 4.60 |
| **Age** | | 0.98 | -1.13 | 0.258 | 0.96 | 1.01 |

## 6. Discussion

Surgical site infection still forms a large health problem and contribute substantially to patient morbidity, mortality, prolonged hospital stays, expensive hospitalization, and prolonged therapy.

In this study, 250 patients were enrolled in the follow-up and 217 completed the study. Forty nine patients (19.6%) developed SSI. The incidence of SSI differs from place to place to place due to the methodological difference especially duration of follow up and the inclusion criteria used. The cumulative incidence in this study is 19.6%. This result is comparable with the study conducted in Ethiopia where, Hawassa University referral hospital (19.6%), and Black Lion hospital(14.8%) (14, 15). SSI incidence studies in Uganda (16.4%) and Cameroon (20.1%,) were also congruent with the current study (10, 27). However, it is much higher compared to the study conducted at Felege Hiwot Referral Hospital (10.2%). This discrepancy could be due to the involvement of contaminated and dirty wounds in the current study which were excluded in the study done at Bahir Dar (28). The incidence rate of this study is 24 cases per 100 patient days which is much higher from a study done in Serbia s(4.5 cases per 1000 patient days) (20). This variation could be associated with the difference in surgical techniques, patient care, medication and hospital set up.

For the development of SSI, many risk factors have been attributed. These factors were categorized mainly into patient-related factors and surgical procedure-related factors. This study has found that duration of surgery, level of wound contamination/ wound class, having a co-morbid illness like anemia and cancer as an independent predictor of SSI. However, smoking and BMI were not found as an independent predictor for SSIs in contradiction to other researches (24, 29). This discrepancy could be due to the difference in the study participants. Most of them were from rural and religious areas where smoking is considered as a taboo. They are also physically active since they are farmers.

Depending on the surgical procedure, the time it takes to complete the procedure differs. This study showed that surgical procedures which took more than one hour have 4.07 times risk compared to those procedures which took less than an hour. This finding is similar to the finding of the study done in Ethiopia (8 times the risk of developing SSI) (15). Literature also supports this finding. A meta-analysis on 81 kinds of literature showed that surgical procedures which had taken more than one hour were 2.33 likely to develop SSI (25). Despite the absence of standard cut-off for the duration of surgery, studies in India and Iran have also shown that prolonged durations have increased rate of SSI, since prolonged operative time puts patients on anesthetic drugs longer; which in turn leads to tissue hypoperfusion and increased blood loss (7, 8).

Level of wound contamination/ class of wound is found to be an independent risk factor in this study. Patients with contaminated and dirty wounds had thirteen and twenty-five times risk of developing SSI respectively. Surgical Wounds with high bacterial load are at high risk of SSI and findings from Uganda, Iran and India support this scientific knowledge (7, 8, 10).

Preoperative hemoglobin level was measured to check for the presence of anemia. Results of this study indicated that anemic patients had three times risk of developing SSI compared with non-anemic patients. Studies in Uganda, India and, USA supported this finding where anemic patients had increased risk of acquiring SSI. This is because low hemoglobin level interferes with the delivery of adequate oxygen to the tissues leading to hypoxia. Hypoxia eventually impairs wound healing and leads to the development of SSI (7, 10, 30).

Patients with cancer are prone to have defective immunity due to the infiltration of the bone marrow with cancer cells. This leads to poor wound healing and increases the chance of infection. This study revealed that patients having cancer were having ten times higher hazards of acquiring SSI. This result is supported by a study done by Kamboj, M., et. al. which showed patients with disseminated cancer had a higher chance of developing SSI(31).

## 7. Strength/Limitations of The Study

In this study, possible predictor variables were incorporated through review of related literature and consistent data collection methods were employed. However, due to feasibility issues specific surgical procedure related factors like suturing techniques and the suture material used is not included. Moreover, the hospital's instrument handling and sterilization process, antiseptics used for patient preparation and microbial study were not done. These factors could contribute to the development of SSI. Despite having these limitations, the study delivered relevant information regarding the incidence and predictors of SSI at Debre Tabor General Hospital.

## 8. Conclusions

The aim of this study was to investigate the incidence and the most important predictors associated with the development of SSIs. The incidence rate of SSIs in Debre Tabor General Hospital was 24 cases per 100 patient days of observations which indicates high burden of surgical site infection in the hospital. Most patients developed SSI in the $5^{th}$ postoperative day. About 76% of the patients survived for ten days without developing an infection.

Level of wound contamination, anemia, cancer and long duration of surgery were positively associated independent predictors of surgical sites infection. Age, sex, ASA class, surgeons' years of experience were not found to have an impact on the development of surgical site infection. Moreover, contrary to some researches, the current study showed smoking and BMI were not independent predictors for SSIs.

## 9. Recommendations

Surgical site infections pose a great impact on morbidity and mortality of patients and the quality of the health care provided. This study indicated that the rate of surgical site infection is higher (24 cases per 100 patient-days of observations). Therefore, the hospital should strengthen SSI surveillance and reporting system. The hospital should also provide feedback to the surgical team regularly.

Patients having comorbid illnesses like anemia and cancer should be followed carefully and special wound care should be provided. Surgeons should also try to minimize the duration of the surgical procedure as much as possible.

The hospital has no standard surgical wound care protocol. Thus, the hospital should prepare and implement a standard surgical wound care protocol/guideline.

Finally, further research on sterilization procedures and antiseptic solutions used during surgery should be done. Moreover, the hospital should do culture and sensitivity test for microorganisms from the surgical wound and the surgical ward.

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# 11- Annex

## Annex I- Postoperative complication assessment checklist,

### 11.1 Patient information sheet

I am __________________ working at Debre Tabor University department of medicine. I am conducting research on **INCIDENCE AND PREDICTORS OF POSTOPERATIVE SURGICAL SITE INFECTIONS AFTER MAJOR SURGERIES AT DEBRETABOR GENERAL HOSPITAL.''** The aim of this study is to assess the magnitude and causes of surgical site infection at Debre Tabor general hospital and finally put forward solutions to the problem.

The data will be collected from patients who will undergo major surgery starting from June 10, 2018 by trained physicians who are working in the hospital.

By participating in this study you will not be subjected to any harm and there is no any incentive as well. However, physicians will follow your wound conditions throughout your stay in the hospital which will be advantageous for you.

The information we will get from you will be kept confidential and will only be used for research purposes. Your name, address and health condition will not be discussed with other patients as well.

Your participation in this research is entirely based on your permission. You have full right to refuse and even withdraw during the study once you are enrolled in. Moreover, refusing to participate in the study will not affect the services you will get from the hospital.

## 11.2 Consent form

In undersigning this document, I am giving my consent to participate in the study entitled as '**INCIDENCE AND PREDICTORS OF POSTOPERATIVE SURGICAL SITE INFECTIONS AFTER MAJOR SURGERIES AT DEBRETABOR GENERAL HOSPITAL**." I have been informed about the purpose of this study and understood that participation in this study is entirely voluntarily. I have been told that my answers to the questions will not be given to anyone else and no reports of this study ever identify me in any way. I have also been informed that my participation or non-participation or my refusal to answer questions will have no effect on me. I understood that participation in this study does not involve any risks.

Respondent's signature_________________________________

Investigator,s Name_________________________Signature___________Date____________

## የህሙማን ስለጥናቱ መረጃ መስጫ ቅጽ

እኔ ዶ/ር በእደማሪያም ታደሰ በባህር ዳር ዩኒቨርሲቲ የሁለተኛ አመት የማህበረሰብ ጤና ሳይንስ ተማሪ እና በደብረ ታቦር ዩኒቨርሲቲ የህክምና መምህር ስሆን ለመመረቂያ የሚሆነኝን ጥናታዊ ጽሁፍ በደብረ ታቦር ጠቅላላ ሆስፒታል ከጠቅላላ ቀዶ ህክምና በሁዋላ ስለሚከሰት የቁስል መመርቀዝ መጠንና አጋላጭ ምክንያቶች ላይ እየሰራሁ እገኛለው፡፡ ጥናቱን ለማካሄድም ከ ሰኔ 16 ጀምሮ ጠቅላላ ቀዶ ህክምና የሚደረግላቸው ህሙማን ላይ ስልጠና በወሰዱ ሃኪሞች ከህሙማን መረጃ ይሰበሰባል፡፡ ስለዚህ እርስዎ በዚህ ጥናት ላይ ተሳታፊ ቢሆኑ በእርስዎ ላይ ምንም አይነት ጉዳት አይደርስብዎትም፡፡ ነገር ግን በጥናቱ በመሳተፍዎ ምንም አይነት ክፍያ አይኖረውም፡፡ ይሁን እንጂ ሀኪሞች ለተከታታይ አስር ቀናት የቁስልዎትን ሁኔታ ይከታተላሉ፡፡ ክትትሉም ከሆስፒታል ከወጡ በሁዋላ የሚቀጥል ይሆናል፡፡

በእዚህ ጥናት ላይ የሚኖርዎት ተሳትፎ ሙሉ በሙሉ በእርስዎ ፈቃደኝነት ላይ የተመሰረተ ሲሆን የሚሰጡትም መረጃ መምስጢር የሚያዝ ይሆናል፡፡ በጥናቱ ወቅት በማንኛውም ጊዜ ጥናቱን አቁዋርጦ መውጣት የሚቻል ሲሆን ጥናቱን በማቁዋረጥዎ ከሆስፒታሉ የሚያገኙት አገልግሎት በምንም ሁኔታ አይቁዋረጥም፡፡

**ህሙማን በጥናቱ ለመሳተፍ የሚሰጡት የስምምነት መስጫ ቅጽ**

**የስምምነት መስጫ ቅጽ**

እኔ ከዚህ በታች የምፈርመው ግለሰብ በደብረ ታቦር ጠቅላላ ሆስፒታል ከጠቅላላ ቀዶ ህክምና በሁዋላ ስለሚከሰት የቁስል መመርቀዝ መጠንና አጋላጭ ምክንያቶች ላይ በሚጠናው ጥናት ውስጥ ተሳታፊ እንድሆን መስማማቴን እየገለጽኩ ጥናቱ በፈቃደኝነት ላይ የተመሰረተ መሆኑንም ተረድቻለው፡፡ እነዲሁም በጥናቱ ተሳታፊ መሆኔም አለመሆኔም በህይወቴ ላይ የሚያስከትለው ችግር አለመኖሩን እና ከዚህ ቀጥሎ የምሰጠው መረጃም ሚስጢርነቱ የተጠበቀ አንደሆነ ተነግሮኛል፡፡ በመሆኑም በጥናቱ ለመሳተፍ ፈቃደኝነቴን እገልጻለሁ፡፡

የተሳተፊው ፊርማ________________________________________

የመረጃ ሰብሳቢው ፊርማ____________________________

## 11.3 Questionnaire

**POSTOPERATIVE SURGICAL SITE INFECTIONSASSESSEMENT CHECKLIST I( BASIC INFORMATION)**

| | | | |
|---|---|---|---|
| 1. Socio-demographic characteristics | | | Response |
| | 101 | Age of the patient | ___________ years |
| | 102 | Sex- | 1. Male 2.Female |
| | 103 | Residency- | 1. Urban 2. rural |
| | 104 | Date of admission | ____/_____/______ |
| | 105 | Patient's Level of education | 1. unable to read and write<br>2. can read and write<br>3. primary school (1st -8th grade)<br>4. secondary school ( 9-10)<br>5 preparatory school (11-12)<br>6. above 12th grade |
| 2.Surgery-related factors | 201 | Nature of admission | 1.Elective____ 2.Emergency___ |
| | 202 | ASA class | 1. I 2. II 3. III 4.IV 5. V |
| | 203 | Date of surgery | ____/_____/__E.C |
| | 204 | Type of anesthesia | 1.GENERAL___<br>2. REGIONAL_______ |
| | 205 | Duration of operation(in hr) | __________ hrs |
| | 206 | Wound type | Clean_____ |
| | | | Clean contaminated_______ |
| | | | Contaminated ________ |
| | | | Dirty ___________ |
| | 207 | Site of surgery | 1. abdomen<br>2. Head and Neck<br>3. Thorax<br>4. Extremities<br>5. perineum |
| | 208 | Type of procedure | ___________ |
| | 209 | The surgeons' year of experience | ____________ years |
| | 210 | Is Antimicrobial prophylaxis given within 60 mins? | 1. YES____ 2. NO__ |
| | 211 | Was the patient transfused? | 1.YES_ 2. NO__ |
| | 212 | Intraoperative accidents | 1.YES_ 2. NO__ |
| | 213 | If 'yes' for question 212 what is the Intraoperative accident | 1. contamination,<br>2. hemorrhage/shock |

| | | | |
|---|---|---|---|
| | | | 3. others- specify ________________________________________ |
| | 214 | Days of preoperative Hospitalization | ________________days |
| 3. Co-morbidity ( Check if the patient has any of the following chronic illnesses) | 301 | Hypertension | 1.YES_ 2. NO__ |
| | 302 | Tuberculosis | 1.YES_ 2. NO__ |
| | 303 | RVI | 1.YES_ 2. NO__ |
| | 304 | Diabetes | 1.YES_ 2. NO__ |
| | 305 | Asthma | 1.YES_ 2. NO__ |
| | 306 | Anemia | 1.YES_ 2. NO__ |
| | 307 | Cancer | |
| 4. patient factor | 401 | Smoking Habit | 1.YES_ 2. NO__ |
| | 402 | Alcoholic | 1.YES_ 2. NO__ |
| | 403 | BMI- for adult<br>MUAC- for children | 1. Normal<br>2. overweight/Obese<br>3. underweight/Malnourished |

**Complication assessment checklist**

| | Did the patient develop complication | | If yes Type of SSI | | Day of occurrence of SSI | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Complication** | No | Yes | | | | | | | | | | | | | |
| SURGICAL SITE INFECTION | | | Superficial incisional | | | | | | | | | | | | |
| | | | Deep incisional | | | | | | | | | | | | |
| | | | Organ space | | | | | | | | | | | | |

## 11.4- CAGE Alcohol questionnaire

| Questions | yes | No |
|---|---|---|
| Have you ever felt you needed to **C**ut down on your drinking? | | |
| Have people **A**nnoyed you by criticizing your drinking? | | |
| Have you ever felt **G**uilty about drinking? | | |
| Have you ever felt you needed a drink first thing in the morning (**E**ye-opener) to steady your nerves or to get rid of a hangover? | | |

DECLARATION FORM

Declaration

I, the under signed, declared that this is my original work, has never been presented in this or any other University, and that all the resources and materials used for the research, have been fully acknowledged.

Principal investigator

Name: Dr. BEDEMARIAM TADESSE AMSALU

Signature: ___________________________________________

Date: ___________________________________________

Advisor

Name: Dr. BELAYNEW WASSIE

Signature: ___________________________________________

Date:___________________________________________

Advisor

Name: Mr. MOHAMMED HUSSIEN

Signature: ___________________________________________

Date:___________________________________________

DECLARATION FORM

Declaration

I, the under signed, declared that this is my original work, has never been presented in this or any other University, and that all the resources and materials used for the research, have been fully acknowledged.

Principal investigator

Name: Dr. BEDEMARIAM TADESSE AMSALU

Signature: ___________________________________________

Date: ____________________________________________

INTERNAL EXAMINER

Name: __Dr. ACHENEF MOTBAYNOR

Signature: ___________________________________________

Date:___________________________________________