Surveillance of Surgical Site Infections following Caesarean Section at Two Central Hospitals in Harare, Zimbabwe

By

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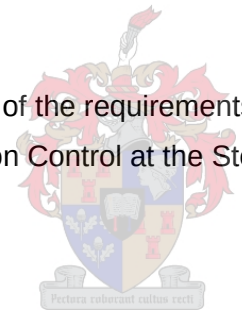

Thesis presented in partial fulfilment of the requirements for the degree of Master of Science in Infection Prevention Control at the Stellenbosch University

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DECLARATION

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ABSTRACT

Background

Caesarean section deliveries are the most common procedures performed by obstetricians in Zimbabwe. Surgical site infections (SSI) following caesarean section delivery result in increased hospital stay, treatment, cost, hospital readmission rates and related maternal morbidity and mortality.

There is no national surveillance system for SSIs in Zimbabwe, however, information is available on number of cases of post-operative wound infection after caesarean section, but the denominator and definition used is not consistent. The objective of this study were develop and strengthen the surveillance system in Zimbabwe, to establish a clinical-based system in a setting with limited microbiological access, to measure post-operative SSI after caesarean section and to describe the associated risk factors and to determine whether feedback of SSI data has any effect on the surgical site infection incidence rate.

Methodology

This was a before and after study with two rolling cohort periods conducted at two Central hospitals in Harare, Zimbabwe. An Infection Prevention and Control (IPC) intervention was conducted in-between. During the pre-intervention period, baseline demographic and clinical data were collected using a structured questionnaire, and during the post-intervention period the impact of the interventions was measured. Convenience sampling was employed.

Results

A total of 290 women consented to participate in the study in the pre intervention period, 86.9% (n= 252) completed the 30-days post-operative follow-up and the incidence rate of SSI was 29.0% (n=73, 95% CI:23.4-35.0)

Interventions developed included: training in Infection Prevention and Control for health workers; implementation of a protocol for cleaning surgical instruments; dissemination of information on post-operative wound management for the women.

After implementation of the intervention, 314 women were recruited for the post-intervention, 92.3%(n= 290) completed the 30-day follow-up and there was a significant ($p<0.001$) reduction in the incidence rate of SSIs to 12.1 % (n=35, 95% CI: 8.3 -15.8) during this period.

Development of SSI after caesarean section was found to be significantly associated with emergency surgery ($p<0.001$), surgical wound class IV ($p=0.001$) and shaving at home ($p<0.001$) at both pre- intervention and post-intervention periods.

Conclusion

This study shows that caesarean section can be performed with low incidence of SSI if appropriate interventions such as training in IPC, adequate cleaning of equipment and education in wound-care for the mother are adhered to. It also demonstrated a simple surveillance data collection tool can be used on a wide scale in resource limited countries to assist policy makers with monitoring and evaluation of SSI rates as well as assessment of risk factors.

Opsomming

Agtergrond

Keisersnitte is die mees algemene prosedure wat uitgevoer word deur obstetriese dokters in Zimbabwe. Chirurgiese wond infeksies wat op keisersnitte volg lei tot verlengde hospitaal verblyf, behandeling, koste, heropname koerse en verwante moederlike morbiditeit en mortaliteit.

Alhoewel daar geen nasionale waaktoesig sisteem vir chirurgiese wondinfeksies is nie, is informasie beskikbaar vir ‘n aantal gevalle wat post-operatiewe wondinfeksie na ‘n keisersnit onwikkel het, maar die noemer en definisie word inkonsekwent gebruik. Die doel van hierdie studie was om die waaktoesig sisteem in Zimbabwe te ontwikkel en te versterk, om ‘n klinies-gebasseerde sisteem te vestig in ‘n opset met beprekte mikrobiologiese toegang, om postoperatiewe chirurgiese wond infeksies na keisersnitte te meet en om die geassosieerde risikofaktore te beskryf en om vas te stel of terugvoering van chirurgiese wondinfeksie data enige effek op die infeksiekoerse na keisersnitverlossings gehad het.

Metodologie

Hierdie was ‘n voor-en-na studie met twee kohort periodes uitgevoer by twee sentrale hospitale in Harare, Zimbabwe. ‘n Infeksievoorkoming en –beheer intervensie was tussenin uitgevoer. Tydens die pre-intervensie periode was basislyn demografiese en kliniese data ingesamel deur middel van ‘n gestruktureerde vraeboog, en gedurende die post-intervensie fase was die impak van die intervensies gemeet. Gerieflikheidsteekproefneming was geimplementeer.

Resultate

‘n Totaal van 290 vroue het toestemming verleen om aan die studie deel te neem in die pre-intervensie periode, waarvan 86.9% (n=252) die 30 day post-operatiewe opvolg voltooi het en die insidensiekoers van chirurgiese wondinfeksies was 29.0% (n=73, 95% CI:23.4-35.0)

Intervensies wat onwikkel was het ingesluit: opleiding in Infeksie Voorkoming en -Beheer vir gesondheidswerkers; die implementering van ‘n protokol om chirurgiese instrumente skoon te maak; disseminering van informasie oor post-operatiewe wondhantering vir vroue.

Na die implimentering van die intervensie was 314 vroue gewerf in die post-intervensie fase, waarvan 92.3% (n=290) die 30 dae opvolg voltooi het. Daar was ‘n beduidende ($p<0.001$) verlaging in die insidensiekoers van chirurgiese wondinfeksies na 12.1% (n=35, 95% CI: 8.3-15.8) gedurende hierdie periode.

Daar was bevind dat chirurgiese wondinfeksies beduidend geassosieer was met noodchirurgie ($p<0.001$), chirurgiese wondklassifikasie IV ($p=0.001$) en skeer van hare by die huis ($p<0.001$) by beide die pre-intervensie en post-intervensie periodes.

Gevolgtrekking

Hierdie studie wys dat keisersnitte uitgevoer kan word met ‘n lae insidensie van chirurgiese wondinfeksies indien toepaslike intervensies, soos opleiding in infeksievoorkoming en beheer, voldoende skoonmaak van toerusting en opvoeding in wondsorg vir die moeders. Dit het ook aangedui dat ‘n eenvoudige data-insameling instrument op ‘n wye basis gebruik kan word in beperkte-hulpbron lande om beleidmakers te help met monitering en evaluering van chirurgiese wondinfeksie koerse, asook die assessering van risikofaktore.

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List of Abbreviations

A &E	Accident and Emergency
ANC	Ante Natal Care
ART	Antiretroviral Treatment
C- Section	Caesarean Section
CDC	Centres for Disease Control
CI	Confidence Interval
CSSD	Central Sterile Services Department
ECDC	European Centre for Disease Control
GMO	Government Medical Officer
HAI	Healthcare Associated Infections
HIV	Human Immunodeficiency Virus
IPC	Infection Prevention and Control
IQR	Interquartile range
JRMO	Junior Resident Medical Officer
LSCS	Lower Segment Caesarean Section
NHSN	National Health System Network
NNIS	National Nosocomial Infection System
NVD	Normal Vaginal Delivery
OR	Odds Ratio
PPH	Postpartum Haemorrhage
SHO	Senior Houseman
SRMO	Senior Resident Medical Officer
SSI	Surgical Site Infections
ZIPCOP	Zimbabwe Infection Prevention and Control Project

Glossary of Terms

1. Surveillance is the on-going, systematic collection, analysis, and interpretation of health data essential to the planning, implementation and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know.(Goutrrup et al., 2005),(Condon et al., 1983)
2. A Healthcare Associated Infection (HAI) is an infection occurring in a patient during the process of care in a hospital or other health-care facility which was not present or incubating at the time of admission. Infections acquired in the hospital, including those appearing after discharge and occupational infections among health workers are considered as health care associated infections. (Goutrrup et al., 2005)
3. A surgical site infection is a type of healthcare associated infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure, or within 90 days if a prosthetic device is implanted at surgery according to CDC NHSN SSI guidelines 2014 (CDC NHSN SSI Definition, 2014). In this study surgical site infection was defined as per CDC NHSN SSI guidelines based on the clinical presentation of the patient as outlined below:
    i. Superficial SSI: An infection occurring within 30 days after the operation involving only skin or subcutaneous tissue of the incision with at least one of the following clinical signs and symptoms: Purulent discharge from superficial incision AND any of the infection symptoms; pain or tenderness, localised swelling heat redness and fever (>38°C), or diagnosis of superficial incisional surgical site infection was made by the surgeon or clinicians;
    ii. Deep SSI: An infection occurring within 30 days after the operation involving deep soft tissue e.g. fascial and muscle layers) of the incision with at least one of the following clinical signs and symptoms: Purulent drainage from the deep incision or deep incision that spontaneously dehisced or was deliberately opened by a surgeon AND any of the infection symptoms; pain or tenderness, localised swelling, heat, redness and fever (>38°C) or diagnosis of a deep incisional SSI by a surgeon or clinician; and
    iii. Organ Space: An infection occurring within 30 days after the operation involving any part of the body deeper than the fascial/muscle layers that was opened or manipulated during the operative procedure e.g. endometritis with at least one of the following signs and symptoms: organisms cultured from endometrial fluid or tissue (including amniotic fluid). Patient has at least two of the following signs or symptoms: fever (>38.0°C), pain or tenderness (uterine or abdominal), or purulent drainage from uterus.

N.B: Stitch abscesses (minimal inflammation and discharge confined to the points of suture penetration) are not considered as SSI.

4. Elective caesarean section is a planned procedure, performed when scheduled whereas all other instances of caesarean section are defined as emergency procedures**.**
5. Caesarean section deliveries were classified as: Class I if there was no rupture of membranes or labour, Class II if there was less than 2 hours of rupture of membranes without labour or labour of any length, Class III for rupture of membranes greater than 2 hours, and Class IV for purulent amniotic fluid. according to the modified wound classification (Emmons et al., 1988)
6. Caesarean delivery (also called caesarean section and caesarean birth) refers to the delivery of a baby through surgical incisions in the abdomen and uterus. Caesarean deliveries are categorized as either primary (i.e., first caesarean delivery) or repeat (i.e., after a previous caesarean birth)
7. Referrals were women referred from other hospitals or clinics and non-referrals were women who had Ante Natal Care (ANC) at the hospital's ANC clinic.

Chapter One: Introduction

Caesarean section delivery is one of the most common procedures performed by obstetricians. Recovery after caesarean section can be stressful for women from low income settings who develop a surgical site infection (SSI), especially after early hospital discharge. These women often have very little practical experience on wound management and have to cope on their own at home. SSIs are associated with substantial morbidity and mortality, prolonged hospital stay, and increased cost(Goutrrup et al., 2005). Infectious morbidity after caesarean section can have a remarkable effect on the postpartum woman's return to normal function and her ability to care for her baby(Hillan, 1995). Surveillance is an essential system of measuring SSIs and provides data upon which interventions to improve patient safety can be based(Aiken et al., 2013). SSIs are recognized as a significant form of Healthcare Associated Infections (HAIs) and SSI surveillance is widely recognized as being central to efforts to identify and control SSI risk. Surveillance is common in high-income countries for a wide-range of surgical procedures but in sub-Saharan Africa very few studies have been done on SSI surveillance systems(Aiken et al., 2013).

In Zimbabwe there is no published data on the prevalence or incidence of SSIs following caesarean section. Elsewhere prevalence reports have shown SSIs to be the second most common complication to urinary tract infections in hospitalized patients following caesarean section among female patients who are usually deemed to be young and healthy(Sykes et al., 2005). Surveillance of Healthcare Associated Infections (HAI) in Zimbabwe, whether in patients or among health workers is also very rarely done and if it does exist, it is inadequately documented. Some information is available from infection control reports on the number of SSI cases but the definitions and methods used to identify the SSIs are not consistent. This therefore necessitates the development and strengthening of SSI surveillance system in Zimbabwe.

The aim of this study was to establish a clinical-based SSI surveillance system in a setting with limited microbiological support. The SSI surveillance system was developed to contribute to the assessment of compliance with infection prevention and control (IPC) practices and to measure the impact of these IPC interventions.

Prevalence or incidence of HAI is used world-wide to determine the effectiveness of IPC programmes.(Haley et al., 1985) Surveillance, followed by action for improvement, can have a substantial influence on rates of HAIs.(Allegranzi et al.) A clinical based SSI surveillance model can also be adapted to other SSIs following different types of surgeries and implemented in other health facilities where microbiological diagnostic facilities are restricted or inadequate.

Chapter Two: Literature Review

2.1 Burden of Healthcare Associated Infections Worldwide

Healthcare-associated infections constitute an essential health challenge worldwide and pose a major threat to patient safety. Risks for developing infections during health care delivery have improved radically with advances in diagnostic and treatment procedures. In the developing world this challenge is greater because infection prevention and control policies are often non-existent, poorly designed or inadequately funded by governments. The risk of infection in developing countries is two to twenty times higher and the proportion of patients infected can exceed 25%(Pittet et al., 2008). Estimates of the global burden of healthcare-associated infections are hampered by the limited availability of reliable data. (Allegranzi and Pittet 2008) According to a literature review of national and multicentre studies published between 1995 to 2008, the overall prevalence of healthcare-associated infections in high income countries varies between 5.1% and 11.6% and approximately the same proportion of hospitalized patients acquire at least one healthcare-associated infection (World Health Organisation, 2010). Surveillance systems such as the National Healthcare Safety Network of the United States of America or the German hospital infection surveillance system exist in most developed countries and provide regular reports on national trends of endemic HAI. (Pittet et al., 2005) The European Centre for Disease Prevention and Control (ECDC) reported an average prevalence of 7.1% in European countries. The ECDC reported that 13/28 (46%) European high-income countries had national surveillance systems in place in 2008 to monitor either ICU-acquired infections, SSI, or both, and were regularly reporting to the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) network(Annual Epidemiological Report on Communicable Diseases in Europe, 2008). The estimated incidence rate in the United States of America was 4.5% in 2002, corresponding to 9.3 infections per 1000 patient-days and 1.7 million affected patients(Klevens et al 2007).

Multi-centre studies conducted in health care settings in developing countries (Albania, Brazil, Mexico, Tanzania and Thailand) report hospital-wide rates of health care-associated infections markedly greater than 15% with a range from 6% to 27%) than those in developed countries(World Health Organisation, 2010).

According to the World Health Organization (WHO) summary on burden of HAI adults in critical care and neonates are at a much higher risk of developing HAI with device-associated infection rates several-fold higher in developed countries. Device-associated infections (e.g., bloodstream infection and ventilator-associated pneumonia), incidence densities can be up to 19 times higher than in developed countries. Neonatal infection rates in developing countries are 3-20 times higher than in developed countries. SSI represents the most measured and most common type of infection in developing countries with incidences ranging from 1.2 to 23.6 per 100 surgical procedures (World Health Organisation, 2010). This level of risk is significantly higher than in developed countries where SSI rates average around 2-3%. Even though HAI global estimates are not yet available, it is clear that hundreds of millions of patients are affected by HAI every year around the world. This has been shown by integrating data from studies conducted in both developed and developing countries, and it is evident that the burden of disease in low- and middle-income countries is much higher than in developed countries

2.2 Burden of Healthcare Associated Infections in Africa

The real burden of HAI in Africa has been noted to be more pronounced in countries with weaker infection control infrastructures and fewer resources(Allegranzi 2011). There is a significant need to ascertain and devise possible and sustainable approaches to strengthen HAI prevention, surveillance and control in Africa. In developing countries because of limited resources in healthcare systems, the enormity of the problem remains underrated and unidentified largely because HAI diagnosis is multifaceted and surveillance activities to guide interventions require expertise and resources. The lack of infection control policies and

guidelines, inadequate trained personnel, overcrowding and understaffing in these resource-limited settings compounds the problem (Allegranzi 2011).

A systematic review of nineteen studies from ten African countries with several from the same country were published in a systematic review showing the status of HAI epidemiology in healthcare settings in Africa(Nejad et al., 2011). HAI prevalence ranged between 2.5% and 14.8%, up to twice that of the average European prevalence of 7.1% reported by the European Centre for Disease Prevention and Control. Eight of the nineteen studies were from middle income countries whereas eleven were from low income countries. The CDC definition of HAI was used in four of the studies, modified in two studies and not used at all in eleven studies with great variations in study designs. Seventeen out of the nineteen studies were of low quality and this makes comparison with other studies from the developed countries difficult. The criteria used by the authors to assess the quality of the studies were whether study was a prospective design, usage of standardized definitions (i.e. according to those of the NNIS/NHSN system of the US Centres for Disease Control and Prevention), identification of at least four major infections on HAI studies and whether the study was published in a peer-review journal.

The insignificant amount of papers published is evidence that there is limited research on epidemiology of HAI in Africa. Prevalence of SSI at three public hospitals in Cameroon was 9.16% which is similar to studies done in Nigeria but still much higher than those found in developing countries(Ntsama et al., 2013),(Jido and Garba 2012). The high prevalence of SSI in Cameroon was attributed to poor preventive strategies at the three hospitals. The authors concluded that vigorous strategies were needed to improve infection prevention control in order to decrease SSI infection rates to acceptable levels. Recognising how the epidemiological data such as rates of HAI are collected is crucial to allow interpretation of information and comparison of results from different studies .

2.3. Defining Surgical Site Infections (SSI's)

There are three types of SSIs, depending on the depth of infection penetration into the wound. They are superficial incisional, deep incisional and organ/space (Figure 1 below). Evidence of incisional pus, cellulitis, deliberate incision and drainage of surgical site and/or diagnosis of SSI by physician are also required for conformance with the definition.

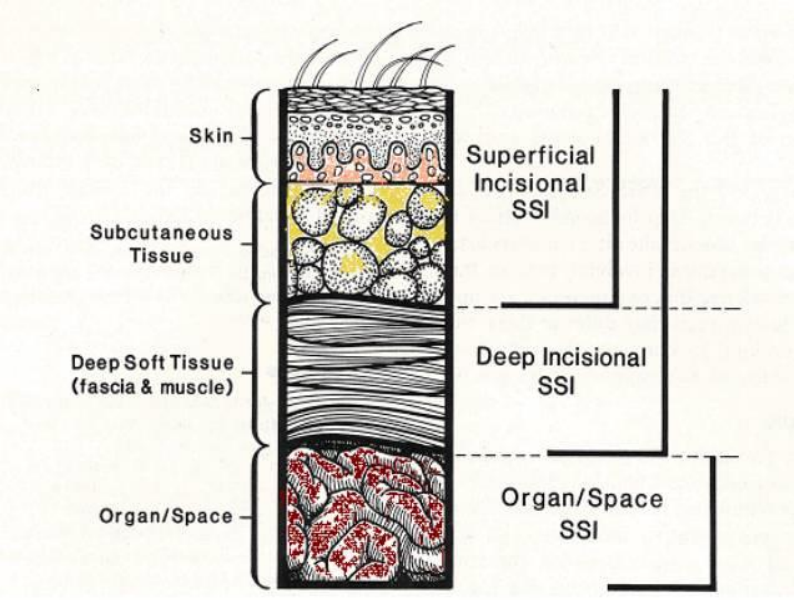


Figure 1:Shows cross-section of abdominal wall depicting CDC classifications of surgical site infections (from Horan et al, 1992)

The development of an SSI after a surgical procedure may be due to multiple factors, with damage to host barrier mechanisms induced by the trauma of a surgical incision being the major risk factor (Horan et al, 1992). For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera. However, contamination may also occur from an exogenous source such as surgical personnel, the operating environment, instruments, and materials brought to the sterile field during an operation(Mangram et al, 1999).

2.4 Burden of SSI following Caesarean section delivery.

It has been shown that women who undergo caesarean section are five times more likely to develop a postpartum infection compared with women who undergo vaginal delivery (Villar et al., 2007). Prevalence surveys have indicated that SSIs are the third most recurrent type of healthcare associated infection accounting for approximately 15% of HAI. The 15% reported rate from these surveys is considered an underestimate as most infections occur in the post discharge period. A multi-centre collaborative study of SSI following caesarean section in the UK reported overall SSI of 8.9% (Ward et al., 2008). The authors prospectively studied caesarean wound infection, including the use of post-discharge surveillance. The reported incidence of SSI following caesarean section varies widely, ranging from 0.3% in Turkey to 17% in Australia.(Ward et al., 2008) The variation in incidence rates was found to be dependent on the definition accepted for SSI, the intensity of surveillance, the prevalence of risk factors for SSI in the patients' group being audited, and whether the survey contained data on post-discharge follow up. Among hospitals reporting to the National Nosocomial Infections Surveillance (NNIS) System, the rate of SSI after caesarean section was noted to be 2.8% to 6.7% depending on the risk index category (National Nosocomial Infections Surveillance (NNIS) System Report, 2002).

Following caesarean section most patients are discharged home early and studies have reported that over 50% of surgical site infections manifest post-discharge(Creedy et al, 2002; de Oliveira et al, 2007). Another study estimated that between 12% and 84% of SSIs are detected after patients are discharged from hospital(Kent et al, 2001). Literature advocates the utilization of post-discharge surveillance for more accurate data collection and better monitoring of SSI, but the ideal method of conducting post discharge surveillance still needs to be ascertained(Mitt et al, 2005). A study done in Kuwait showed that 45% of the SSIs post caesarean section were detected post discharge demonstrating that inpatient surveillance only is not efficient and will result in underestimates of SSI(Aly Nya et al). A similar study showed the incidence of SSI in caesarean section detected by both in-patient and post

discharge surveillance to be 9.6%(Coutto et al, 1998). The results of the study showed that most of the SSI's following caesarean section were detected only after patients were discharged from the hospital and indicates that failure to perform follow-up evaluation of these patients could result in significant miscalculation of accurate SSIs rates. The authors concluded post-discharge surveillance data should be incorporated to accurately estimate the actual rates of SSI in obstetric patients and to sanction the implementation of measures to reduce post-partum infection.

In Africa, there is limited information on burden of SSI following caesarean section delivery because of the paucity of studies and the diversity of methods used. The limited data on SSI in these low income countries, and information obtained from higher income countries such as the US cannot be generalized to the target population in Africa. Based on a recent systematic review, infection rates following C-sections in Africa range between 15 and 25%(Nejad et al., 2011). The SSI incidence following caesarean section vary generally depending on the intensity of surveillance, criteria used to define SSI, postoperative hospital stays, antibiotic prophylaxis, the prevalence of risk factors for SSI in the patient group being audited, and whether the survey contains post discharge data (Mitt et al., 2005).

A study done in Tanzanian district hospital reported the SSI rate following caesarean section and hysterectomy to be 24% and 36% respectively, including those identified post discharge (Fehr et al., 2006). The cumulative incidence of surgical site infection after caesarean section was 19% at a district hospital in central Kenya. (Koigi-Kamau R, et al, 2005) SSI incidence among patients undergoing caesarean in a recent study in Tanzania was 10.9% which is lower than previously reported (Mpongoro et al, 2014). In Nigeria the prevalence of SSI following caesarean section in a case control study was 9.1%. The study was limited to those patients whose SSI was detected before discharge and those that came back because of the complications.(Shija J.K, 1976). The investigators recommended that timely

interventions needed to be put in place in order to reduce the caesarean wound infection rate.

In Zimbabwe a study on abdominal surgical site infections reported the SSI rate to be 23% among general surgery and 38% among gynaecology patients. (Muchiwetu D and Jonsson, 2013) According to the 2007 Zimbabwe Maternal and Perinatal Mortality Study, 0.3% of the 364 notified maternal deaths were caesarean section related which shows the extent of complications following caesarean section delivery.(Munjanja PS, 2007) These studies clearly indicate that SSI is a common post-operative complication which results in morbidity and increased hospital costs and therefore the need to implement effective surveillance systems.

2.5. Risk factors associated with SSI development

The risk of SSI is stratified according to three major factors by the Centres for Disease Control and Prevention's (CDC) National Nosocomial Infection Surveillance System (NNIS). The three factors are the: The American Society of Anaesthesiologists' (ASA) score which reflects the patient's state of health before surgery, wound classification reflects the degree of contamination of the wound and the duration of the operation reflects the technical aspects of surgery. Infection rate has been noted to increase with increasing risk index score(Culver et al, 1991). The process of identifying risk factors for SSI within the literature is restricted by the various methods of data collection and varying data definitions for SSI. Recognising high-risk patients who require intensive postoperative care is crucial in order to lower the incidence of SSIs.

The risk factors for SSI in relation to caesarean section that have been identified in the literature can be categorized as:

2.5.1 Patient Related factors

a) The American Society of Anaesthesiologists (ASA) physical status classification is widely used as a measure for intrinsic host susceptibility, with a higher score indicating an increased infection risk. Some studies though have found no association of this risk index in caesarean section (Aiken et al., 2013),(Johnson et al., 2006)

b) The various pre-existing medical conditions like HIV and AIDS and diabetes mellitus are associated with lowered immunity to infections and therefore are strong factors predisposing to SSI. Diabetes is associated with hyperglycaemia, in case of unsatisfactory glucose control. Hyperglycaemia during the immediate postoperative period is a significant risk factor for development of SSI, because of a direct effect of elevated glucose on immune mechanisms. Hypertensive disorder of pregnancy is also a risk factor for SSI and could be explained by the chronic alteration of peripheral blood supply due to the increased vascular resistance. A significant proportion of infections associated with obese women following caesarean section surgery has been reported. Obesity is associated with a poor tissue oxygenation which results in the subcutaneous adipose tissue poorly supplied with blood vessels and it may be difficult to reduce bleeding when the wound is closed if the patient is overweight increasing the risk of infection.(Moir-Bussy B et al., 1984),(Pelle H et al., 1986)

c) Nulliparity and the socio economic status of the woman have also been noted to contribute to development of SSI though the precise mechanism is unknown.

2.5.2 Microbiological Factors

a) Evidence that removing hair can reduce SSI is uncertain though it has been shown to increase the risk of SSI compared to removing hair with clippers. Shaving causes micro-abrasions in the skin, increasing the surface area that can be contaminated by bacteria(Alexander et al, 1983).

b) The most significant risk factor for the development of SSI has been categorically highlighted to be bacterial load at time of surgery and has formed the basis of wound classification which was later adopted by CDC (Culver et al, 1991). Surgical wound class is an assessment of the degree of contamination of a surgical wound at the time of the operation. The risk of developing an SSI is influenced by the degree of microbial contamination of the operative site. Wound class has been found to be an independent predictor of SSI (Culver et al, 1991).

c) Prophylactic antibiotic is the use of antibiotics before, during, or after a diagnostic, therapeutic, or surgical procedure to prevent infectious complications. For all operations involving entry into a hollow organ antibiotic prophylaxis has been recommended. Adequate concentration of antibiotic within the serum and tissues reduces the risk of resident bacteria overcoming the immune system during the immediate postoperative period. This has been shown in several studies to reduce the risk of SSI (Albers et al, 1994, Cruse and Foord 1980)A review of 15 of mixed design studies in 2009 concluded that the use of either cefazolin alone before surgical incision or an extended spectrum regimen after cord clamping was associated with a reduction in post-caesarean maternal infection.(Tita AT, et al, 2009) This review included an earlier meta-analysis of three that found that preoperative administration of cefazolin significantly reduced the risk of postpartum endometritis without affecting neonatal outcomes.(Constantine M et al 2008).

2.5.3. Operation Factors

a) Good surgical skill play a crucial role in the prevention of surgical site infections Operations carried out by an intern or junior doctor as well as prolonged duration of the surgical procedure (lasting longer than 60 minutes) have been reported to be independent factors which increase the risk of SSI(Shija 1976), (Mpongoro et al., 2014).

b) The length of an operation indicates the amount of time tissues are exposed to potential sources of contamination. Longer operations are usually associated with higher rates of SSI.(Amoran et al., 2013),(Leong et al., 2006).

c) Patients undergoing emergency caesarean are at higher risk of infections than those having elective surgery and this has been attributed to inadequate preparation time owing to maternal or foetal threat(Beattie et al., 1994). Some studies though have found no conclusive evidence to associate emergency procedures with a greater incidence of infection.(Tran et al., 2000).

d) There is contradictory evidence regarding the ideal method of skin closure following abdominal surgery. Surgeons' preference and experience and patient's clinical presentation to surgery determine the choice of skin closure material. Literature has demonstrated that the method of skin closure following abdominal surgery is determined by the cost, postoperative pain and cosmetic appearance rather than risk of developing an SSI. Several studies also have shown that the choice of subcuticular suture rather than staples to close the surgical site post caesarean section is associated with a considerably lower incidence of infection.(Johnson et al., 2006),(Gould 2007).

2.5.4 Labour related factors

a) An association between prolonged rupture of the membranes and an increased risk of SSI has been reported. When the membranes rupture, the amniotic fluid is no longer sterile and this may act as a transport medium by which bacteria may come into contact with the uterine and skin incisions thereby leading to risk of developing SSI.

b) The relationship between duration of labour and development of SSI may be expounded by the increased vulnerable time where infection can be acquired. As duration of labour increases, the number of vaginal examinations also increase and the likelihood of progression to an emergency procedure also rise. Multiple vaginal examinations have been noted be strong predictors of SSI (Salim et al., 2012). It has been noted that when the operation time is shorter, the risk of developing SSI is also lower (Ezechi et al., 2009).

c) Blood loss is associated with poor control of bleeding and increased tissue damage from prolonged retraction and manipulation thereby increasing risk of developing infection

2.5.5. Institutional Factors

a) Ventilation in Theatres is critical. Operating room air may contain microbial-laden dust, lint, skin squames, or respiratory droplets. Movement of people in the operating room has been noted to increase the number of airborne particles due to friction of the skin against clothing which can then settle in the wound. Efforts to minimize personnel traffic during operations have been recommended(Ayliffe 1991). Outbreaks of SSIs caused by Group A beta-haemolytic streptococci have been traced to airborne transmission of the organism from colonized operating room personnel to patients(Berkelman et al., 1982, Gryska et al, 1970, Staam et al., 1978).

b) Inadequate sterilization of surgical instruments has been reported to result in SSI outbreaks. In a Tanzanian study, a high SSI rate was linked to unavailability of sterile equipment and the authors concluded that pathogens may have been introduced by contaminated instruments into deeper layers during surgical intervention. Appropriate instrument sterilization management has been shown to reduce SSI rates in patients undergoing caesarean section among other Interventions which were implemented (Salim et al., 2012)**,** (Rauk et al , 2010)**.**

2.6 Surveillance of Surgical Site Infections

Surveillance of SSIs is an important infection control activity. Surveillance of SSI is an important way of monitoring and maintaining quality of care and clinical outcomes. Conducting SSI surveillance routinely in resource poor settings as described for high income countries is not possible due to multifarious constraints such as economic, financial, shortages of staff and laboratory support, so a practical clinical based SSI surveillance methodology is required.

The impact of SSI surveillance was analysed in a 10-year study of surveillance of epidemiology of SSI in North America. The study demonstrated key factors that influence the risk of SSI and that the significant reductions are associated with feedback to surgeons(Cruse and Foord 1980). The Centres for Disease Control (CDC) conducted a multicentre study SENIC (Study on the Efficacy of Nosocomial Infection Control) to explore the burden of HAI in hospitals and the effectiveness of surveillance and control programs in reducing risk of infection. More than 6000 hospitals were involved and a random stratified sample of 338 hospitals was used to estimate the impact of surveillance and control on rate of HAI. The study demonstrated that hospitals with the most effective surveillance and control programme reduced their HAI rate by 32% and indicated that the SSI rate was reduced to 38% where surveillance and feedback to surgeons was in place. The importance

of Infection control and the need for prevention efforts were not evident to physicians, nurses or administrators until they were given feedback of the surveillance data. Surveillance of these SSIs has been proven to be effective in reducing the healthcare associated infections.

Successful implementation of a SSI surveillance programme includes use of a standard definition, good surveillance methods and stratification of the SSI rates according to risk factors associated with the development of SSI(Gaynes et al, 2001). Literature has demonstrated reduction of SSI rates after caesarean section through continuous surveillance in single institutions(Evaldson G et al., 1992). After intensive SSI surveillance in Saudi Arabia a 50% reduction was reported through implementation of concerted infection control practices(Balkhy et al., 2003).Continuous SSI surveillance in France for five years included 30 day post discharge and a 40% reduction in SSI after C- section was achieved. Surveillance led to increased awareness of infectious problems among health workers and noted improvements in evaluation of health procedures(Barbut et al., 2004). If the true burden of SSIs is to be determined there is need for high quality post discharge surveillance with dedicated surveillance staff.(Leaper et al, 2013).

The rates of SSI resulting from a well implemented surveillance system can be used to evaluate the quality of infection control practices related to surgical procedures. This SSI data can be used to increase awareness of SSI risk and encourage surgical teams to take appropriate action if rates are noted to be increasing (Allegranzi 2011). There is limited research from sub-Saharan Africa on interventions to reduce the incidence of SSI and this lack of research studies on post-operative SSI surveillance has been highlighted as an area for future work in Africa(Aiken et al., 2012). From the limited information from sub Saharan Africa analysed through a WHO systematic review, health facilities with the capacity to conduct surveillance studies and publish results had better resources to implement infection prevention and control programmes than those who did not collect or publish data (Nejad et al., 2011). In these low resource settings microbiological and diagnostic support services are

limited and SSI diagnosis often relies upon individual doctor's judgment and variations in how these definitions are interpreted is inevitable. Minimizing these differences is a challenge in these settings and requires a dedicated surveillance system. Most of the studies analysed in a systematic review failed to explain clearly the extent of wound contamination, variation in SSI definition were noted as well as inconsistent methods used to identify SSIs and follow up patients. The authors found that none of the studies used pre-operative checklists or used surveillance as a method of reducing SSIs and highlighted these areas as important for future research (Aiken et al., 2012). In Tanzania, wound infection rate was noted to be increasing over time from 6% in 1973 to 12% by year 2000 and to 15.6% by 2001 (Shija 1976) (Ussiri et al 2005). The actual reason for this rise in SSI was not reviewed but the researcher concluded that there was no routine surveillance scheme in place to monitor and control these infections. The introduction of facility based infection prevention and control programme in Algeria reduced the overall hospital-wide prevalence of HAI over five consecutive years(Atif et al., 2009). After the implementation of a standardized protocol for surgical wound management in Uganda there was a significant reduction in surgical site infection rate after caesarean section (Hodges et al, 1997). In Nigeria at a teaching hospital the HAI rate significantly dropped from 5.8% in 2003 to 2.8% in 2006 after the implementation of an infection control programme (Abubakar 2007). Several studies have also shown that a series of evidence-based interventions incorporated as a single bundle significantly decrease overall SSI rates (Bryce et al., 2011).

A bundle is a structured way of improving processes of care and patient outcomes. It consists of a set of evidence based practices which when performed collectively, reliably and consistently have been proven to improve patient outcomes. The four key elements of an SSI bundle include appropriate use of prophylactic antibiotics, appropriate hair removal, maintenance of post-operative glucose control and maintenance of post op normothermia. The effectiveness of the bundle of care has been measured and was associated with improved compliance over time from 10% in 2009 to 60% in 2011 resulting in a 36%

reduction of the SSI rate. This study concluded that the implementation of the bundle is an important instrument to improve patient safety (Crolla et al., 2012).

2.7 Problem Statement

In Zimbabwe through the Zimbabwe Infection Prevention and Control Project (ZIPCOP) the strengthening of IPC programs in health facilities was started in 2012 to ensure that health facilities have functional IPC committees and annual IPC plans. The IPC committees have been tasked set up effective mechanisms to produce appropriate evidence-based IPC recommendations which ensure clinicians take responsibility and adhere to recommended evidence-based practices. One such mechanism is a surveillance system for surgical site infections. Setting up the surveillance system will aid in monitoring and improving IPC practices. The incidence of surgical site infection after caesarean section is not known either at Parirenyatwa or Harare hospital. The knowledge of incidence and associated risk factors of SSI after caesarean section will help to increase the awareness among the health care professionals in the prevention of this problem in both hospitals.

Observation of a high number of surgical site infections following caesarean section delivery at Parirenyatwa and Harare Hospitals through routine infection control reports led to an investigation and consideration for initiating SSI surveillance through this study. There is some information available on a number of cases who develop post-operative wound infection after caesarean section but the denominator and definition used is inconsistent. Thus, there was a need to develop and strengthen the surveillance system in Zimbabwe to generate data on SSI. The data will then be used to facilitate, strengthen and monitor the effectiveness of the IPC interventions being implemented in the various health facilities. Given the importance of these infections, and the lack of any existing national surveillance system in Zimbabwe, the study was developed to comprehensively evaluate the SSI rate following caesarean section by identifying SSIs during the initial inpatient stay and through

telephone contact after discharge. The study also collected data on potential risk factors for these infections. This research then focused on implementing a clinical based surveillance system in order to identify SSIs among caesarean sections and determine effective interventions to reduce the incidence of SSI.

2.8 Research question

1. What is the incidence of surgical site infection following caesarean section surgery at Parirenyatwa and Harare Hospitals?
2. What are the risk factors that predispose caesarean patients to surgical site infection at the two hospitals?
3. Will the introduction of interventions following the determination of baseline SSI rates reduce the SSI incidence rate following caesarean section?

2.9 Research aim

The aim of this study was to determine whether surveillance and feedback of SSI data has an effect on the surgical site infection incidence rate following caesarean section delivery.

2.10 Research Objectives

1. To develop a clinical SSI surveillance system to monitor SSI rates at Harare and Parirenyatwa Hospitals.
2. To identify risk factors for developing SSI following caesarean section at Parirenyatwa and Harare Hospitals.
3. To determine whether specific interventions would reduce the risk of SSI following Caesarean Section.

Chapter Three: Methodology

3.1Study Design

This was a before and after study with two rolling cohort periods. There was a pre-intervention period in which baseline data was collected, an intervention phase to develop and implement interventions and post- intervention phase when the impact of the interventions was determined. Women who consented to participate in the study were recruited following caesarean section. Data was collected from every patient regarding the various risk factors and demographic details by means of a detailed questionnaire. Surgical site infection was defined as per CDC NHSN SSI guidelines based on the clinical presentation of the patient as outlined previously in the definitions(CDC NHSN SSI Definition 2014).

3.2 Duration of study

The study was conducted between April 2014 and October 2014. The pre intervention period was from April to May (2 months), intervention period was June to July (2 months) and post intervention period August to September 2014 (a further two months).

3.3 Site of the study

The study was conducted at Parirenyatwa and Harare Central Hospitals. Both Hospitals are affiliated to the University of Zimbabwe College of Health Sciences. Parirenyatwa Group of Hospitals is the biggest specialist referral hospital in Zimbabwe with a bed capacity of 1100. It's designated as the biggest hospital because it offers all specialist services which include cardio thoracic, oncology, general surgery, paediatrics, orthopaedics, neurology, urology, radiology, radiotherapy, obstetrics and gynaecology even though its bed capacity is less than that of Harare Hospital. There is a separate maternity hospital with a bed capacity of

87. Two of the thirteen theatres are based in the maternity hospital. Parirenyatwa hospital has a Central Sterile Services Department (CSSD) department which caters for the whole hospital.

Harare Hospital is the second biggest referral hospital with a bed capacity of 1524. The hospital offers specialist services similar to Parirenyatwa except oncology, neurology and cardiothoracic. There is a separate maternity hospital with a bed capacity of 180, two theatres dedicated for caesarean sections and a CSSD department separate from the main one which is responsible for reprocessing maternity medical devices only. Harare Hospital houses the country's National Reference Laboratory and also the National Tuberculosis (TB) Reference Laboratory.

Microbiological support is available for both hospitals. On average, 250 caesarean sections are performed monthly at each of the hospitals. Surgical instruments are reprocessed in a steam autoclave and dry heat autoclave with monitoring by use of an external chemical indicator. Both hospitals offer midwifery training for nurses. There are Infection Prevention and Control (IPC) committees at both hospitals with Harare Hospital's IPC committee being chaired by a physician and Parirenyatwa Hospital's IPC team is chaired by a microbiologist. At Parirenyatwa Hospital the Infection Control Team is responsible for ensuring the operation of the Infection Control Programme in the hospital. There is one full-time infection control nurse for the whole hospital at Parirenyatwa Hospital while Harare Hospital has five full time infection control nurses (two for the main hospital, one for the paediatric hospital, one for the psychiatric unit and one for the maternity hospital). Surveillance of healthcare associated infections is done, though the method and definitions used are not consistent.

3.4 Recruitment Procedures.

The recruitment began in maternity ward. Women who came in for delivery and designated for caesarean section were informed of the study. Informed consent was obtained and those that agreed to participate were required to sign the consent form.

3.5 Eligibility criteria

The women that were eligible for study are those that were included as follows:

Inclusion criteria

i. Women undergoing caesarean section who could be contacted by phone during follow up at the two central hospitals during the study period were included.

ii. Women gave written consent which included consent for telephonic contact after discharge from hospital. (See Appendix 3)

Exclusion criteria:

i. Patients readmitted with SSI following caesarean section delivery who did not give consent when the initial caesarean section was done.

ii. Patients who had their index operation at a hospital other than Parirenyatwa or Harare Hospitals.

3.6 Sample size

Sample size calculated was based on the difference between two proportions formulae in order to detect a difference in incidence rates between the pre- and post-intervention groups. The study enrolled 290 women in the pre intervention period and 314 in the post intervention period. To detect an effect size of 5% using power of 80% and 95% significance level and an estimated SSI incidence of 7.3%, the estimated sample size was 286 women in each group. (pre and post intervention). This was based on a similar study done in Kenya which had an SSI rate of 7.3% post caesarean section during hospital stay, readmissions and follow up to

post discharge(Aiken et al., 2013). Assistance was given by statistician Dr. Justin Harvey from the Centre for Statistical Consultation at Stellenbosch University.

3.7 Sampling frame and Sampling method

Women indicated for caesarean section at Parirenyatwa and Harare hospitals as either elective or emergency cases. Convenience sampling method was used. Women who have had caesarean section and were are available and eligible to participate in the research study were recruited. This was because of limited time as recruitment of both pre intervention and post intervention periods had to be done in six months.

3.8 Data Collection

Data was collected using a standardized questionnaire (SSI data Collection tool shown in Appendix 1) in the pre-intervention and post-intervention period. The questionnaire was pretested and modified before use. The data collected during the pre-test was not included in the analysis. Each patient was given a unique identification number and patient names did not appear on the data collection form to preserve confidentiality. A facility assessment questionnaire (see Appendix 2) was used to collect information on the process of decontaminating medical devices and status of theatres in terms of infection prevention and control. Data collected among the women included characteristics such as age in years, height in centimetres, weight in kilograms, co-morbidities such as diabetes mellitus, hypertension, HIV status and whether woman was on ART. Pre-operative data such as a history of previous caesarean section, gestational age at delivery, level of doctor who performed caesarean, duration of operation in minutes and type of anaesthesia used (whether general anaesthetic or spinal), Data on duration of labour included whether the woman had been in labour and if so the duration of labour in hours. The length of time membranes ruptured prior to caesarean section was also noted. Duration of rupture of membranes in hours was defined as the interval between the recorded timing of rupture of

membranes and surgical incision. Data collected on antibiotic prophylaxis included type and time antibiotic prophylaxis was given.

Infections that met the standard case definitions were identified through active follow up by healthcare staff during the hospital stay, on return to hospital and during post discharge through telephone contact. During inpatient stay, data was collected from patient's clinical notes, as well as from theatre registers using the SSI data tool (Appendix 1). Postoperative readmissions of patients recruited in the study were actively sought through checking admissions registers in the gynaecology ward and casualty department registers. The following measures were used to ensure that the women who were included in the surveillance were identified after readmission:

1. Wards most likely to receive patients for readmission post caesarean section were the gynaecology wards. These wards were contacted regularly to enquire about patients readmitted with SSI. The ward staff were made aware of the surveillance through training, and asked to document clinical signs of SSI and report them to designated surveillance personnel.
2. The staff working in A&E were made aware of the surveillance project and asked to document clinical signs of SSI and report them to the designated surveillance personnel. Reminder notices were placed in the wards to remind staff to report any possible SSI to the surveillance team.

3.9 Examination and Classification of Caesarean section surgical wounds

Surgical wounds were inspected by the doctor on Day 3 before discharge and documented in the patient's notes, and then on Day 7 by the nurse when patient attended their nearest local clinic for routine check-up. Thereafter follow-up telephone calls were made every week up to Day 30 to gather wound- related information and confirm diagnosis of SSI using the structured questionnaire (Appendix 1). The women were asked to answer brief questions

regarding their general health, fever, and other potential symptoms of infection together with antibiotic use and visits to an emergency department or clinic.

Patients were advised to contact the surveillance team, return to hospital or to visit the nearest health facility if they experienced pain or tenderness, fever, localized swelling, redness, heat or purulent discharge from operation site. The signs and symptoms of SSI were described on the patient's consent form (see Appendix 3). To make clinical diagnosis of SSI simpler a matrix was used to assign whether the patient developed SSI or not (see appendix 4) Caesarean section deliveries were classified as Class I, Class II, Class III and Class IV, depending on length of time membrane ruptured. Surgical site infection was defined as per CDC NHSN SSI guidelines based on the clinical presentation of the patient as outlined previously in the definitions.("CDC NHSN SSI Definition," 2014). The identification of SSIs that met the definitions of infection based on clinical assessment was facilitated by encouraging the clinicians to clearly document the presenting clinical signs and symptoms of SSI and the diagnosis of SSI in the patient's clinical notes.

3.10 Pre assessment and Training

Briefing meetings with the doctors, matrons and staff of both maternity hospitals were done and objectives of the study outlined and discussed. Training sessions were conducted before the study began for the sister in charge of ante natal ward, post-natal ward, infection control nurse, sisters in charge of gynaecology wards and the theatre charge nurse on methods of data collection and on the SSI definitions. Data collected from the pre intervention period was used to obtain baseline SSI incidence rates.

3.11 Assessment of support services

An assessment using a structured questionnaire was done in the CSSD on how the surgical instruments were cleaned and reprocessed, maintenance of sterilizers, types of tests done to check if sterilizers are working properly. The theatres were inspected using a structured

questionnaire as well for type of ventilation, number of air changes in the operating theatres, staff establishment and average number of people at any given time during caesarean section deliveries. Weekly visits to the wards, theatre and CSSD were done to check on adherence to IPC practices.

3.12 Development of interventions

The baseline data in the pre intervention period was discussed among the doctors and the nurses during ward visits and possible interventions which could be implemented were identified and agreed upon. In order to develop interventions, the nursing staff and senior obstetricians in the maternity wards of both hospitals were provided with regular feedback on the surveillance findings. This outcome led to the review of IPC practices and to debates at local level at each hospital on possible interventions to reduce SSIs. Through these series of verbal discussions by attending doctors' rounds and meetings with the nurses, possible interventions to reduce risk of SSI and improve IPC practices were recommended. Observations noted by attending ward rounds were that patients were not given enough information on wound care post operatively. It was observed that most doctors and nurses were not adhering to IPC practices such as aseptic technique and hand hygiene during ward rounds. Majority of the health workers had not received training in IPC for over five years.

3.13 Ethical considerations

Approval to conduct the study was obtained from Health Research Ethics Committee (HREC) at Stellenbosch University(S13/10/214), the Ethics Committee at Harare Hospital, the Joint Parirenyatwa and College of Health Sciences Ethical Committee (JREC/19/14) and the Medical Research Council of Zimbabwe (MRCZ project number MRCZ/B/627). An informed consent document was included with the project proposal. It included details about the study, why the study was being done, signs and symptoms of SSI and whom to contact if patient developed any of the infection symptoms. The informed consent form was in both English and Shona languages (see appendix 3**)**

3.14 Informed consent process

The participant would first have the study explained to them. Understanding would be confirmed and then she would sign the agreement to participate before any information was collected from her clinical notes. The participant was asked to sign two duplicate consent forms, one which remained with the Principal Investigator for filing and the other she took home.

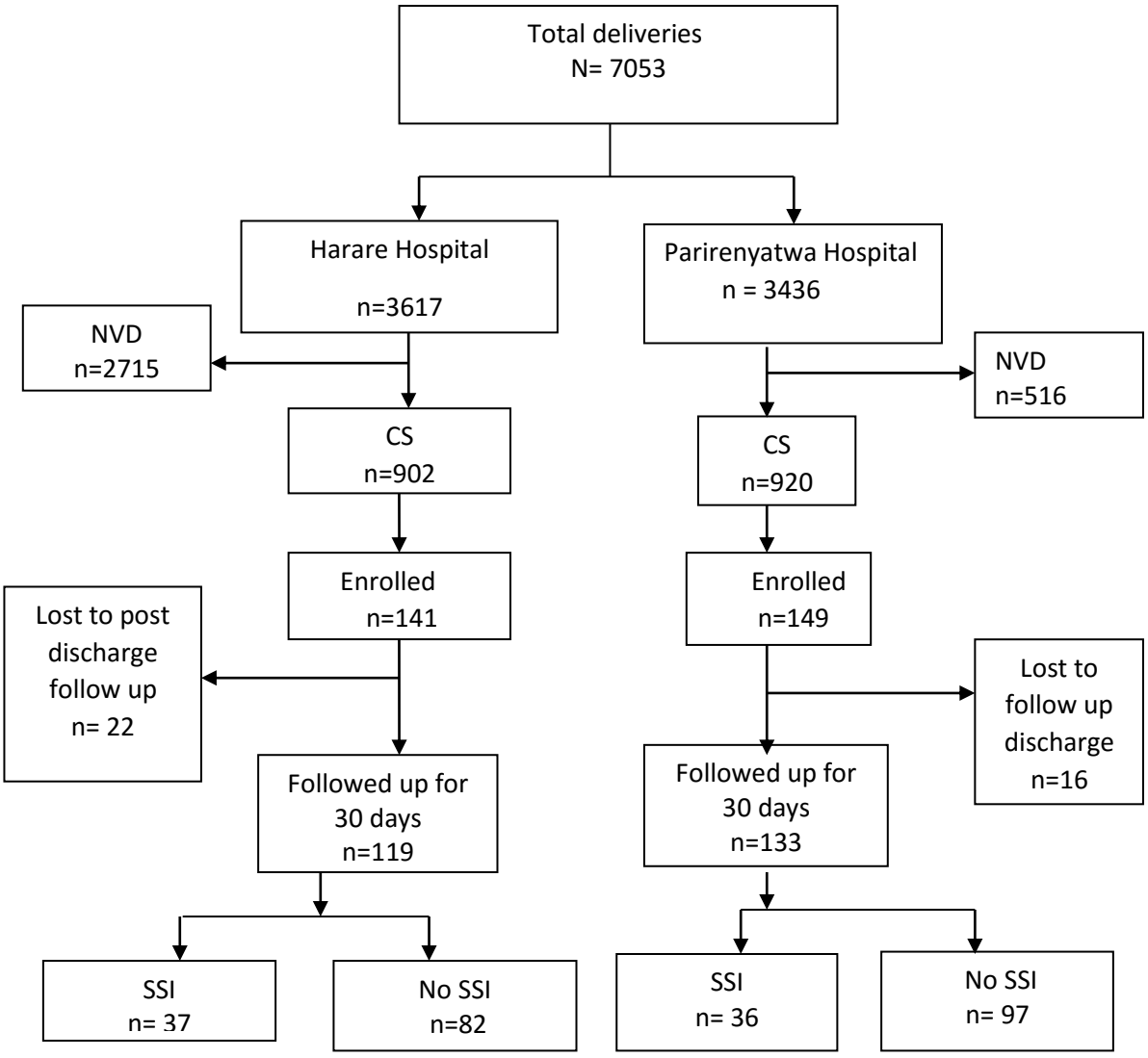
3.15 Data Analysis

Stata, Release 13 (StatCorp, 2007) was used for data analysis. Descriptive statistics were performed for the baseline characteristics. For continuous variables, means and standard deviations (or non-parametric equivalent median and inter-quartile range) were calculated. For categorical variables, frequencies and percentages were determined. The Chi-square test, Fisher's exact test or Mann–Whitney test and Logistic regression were used to assess the association between the variables of interest and the occurrence of SSI as appropriate. Incidence rates during the Pre and Post intervention period were used to describe the differences and the relative risk ratios are reported. In cases where data was missing, analyses were performed using the available data only. No sensitivity analyses were performed. The number and percentages represented by missing data are reported in the tables.

Chapter 4: Results

4.1 Pre intervention Study Participants

During the pre-intervention period April to May 2014, a total of 7053 deliveries were recorded at the two referral hospitals, Parirenyatwa Hospital and Harare Hospital. Harare hospital recoded 3617 and Parirenyatwa hospital 3436. (see Figure 2). Just over a quarter of these deliveries 25.8% (n=1822) were caesarean section deliveries. Two hundred and ninety patients 15.9% consented to participate in the study, 141 at Harare hospital and 149 at Parirenyatwa hospital. These women were followed for 30 days and 86.9 (n=252) completed the follow-up period and 29%(n=73) developed SSI.



Key: CS= Caesarean section, NVD= Normal vaginal delivery, SSI=Surgical Site Infection

Figure 2: Pre-Intervention Participants Flow Chart

4.2 Pre-Intervention Socio-demographic and obstetric characteristics of the women pre-intervention

The socio-demographic and obstetric characteristics of the women recruited during the pre-intervention period are presented in Table 4-1. The majority 67.8% (n=197) of the women were below 31 years, however, there was borderline difference between women recruited from Harare hospital as compared to Parirenyatwa (62.4% vs 73.2%, p=0.050). Their overall median age was 28years (IQR: 23-32years). Only 41.3% (n=120) out of the 290 women recruited had weight recorded in their notes. The median weight was 69kg (IQR: 63-80kgs). The majority 91.4% (n= 265) of the women were referrals from another facility and there was significant different (p=0.010) in referrals from each facility, with 95.7% for Harare hospital as compared to 87.3% for Parirenyatwa Hospital. Diabetes was noted to be in one participant only and there was no record of any of the participants being on TB treatment. Hypertension was recorded in 15.2% (n=44) and there was no significant difference by hospital. Nearly a tenth, 9.3% (n= 27) of the women were HIV positive and all were on ART. The majority of the women, 74.1% (n= 274) had caesarean section done during their 37-40 weeks range gestation period, and there was significant difference in the proportions by hospital with Harare Hospital at 93.6% as compared to Parirenyatwa Hospital with 55.7%. Just over half of the women enrolled had caesarean section after being in labour for less than 24 hours, 54.8% n= 159). Nearly half 42.8% (n=116) of the women had record of membranes ruptured more than two hours indicated in their notes and there was no significant difference by hospital.

Table 0-1: Pre Intervention socio-demographic and obstetric characteristics of the women who had caesarean section from the two participating hospitals

Variable	All N= 290 (%)	Harare n=141 (%)	Parirenyatwa n =149 (%)	p-value
Maternal age				
≤30 years	197(67.9%)	88(62.4%)	109(73.2%)	0.050
>30years	93(32.1%)	53(37.6%)	40(26.9%)	
Median age years (IQR)	28(23-32)	28(24-33)	27(22-31)	0.068
**Median weight kg (IQR)	69(63-80)	73(59-71)	69(63-71)	0.878
Referral from another facility:				
Yes	265(91.4)	135(95.7)	130(87.3)	
No	25(8.6)	6(4.3)	19(12.8)	0.010*
Diabetes Mellitus:				
Yes	1(0.3)	1(0.7)	0(0)	0.303
No	289(99.7)	140(99.3%)	149(100%)	
HIV Status:				
Positive	27(9.3)	15(10.6)	12(8.05)	0.449
Negative	263(90.7)	126(89.4)	137(91.9)	
If HIV positive is patient on ART	27/27(100)	15/15(100)	12/12(100)	-
Hypertension:				
Yes	44(15.2)	17(12)	27(18.1)	0.150
No	246(84.8)	124(87.9)	122(81.9)	
Patients on TB treatment	0(0)	0(0)	0(0)	-
Gestation age:				
>37weeks	39(13.5)	7(5.0)	32(21.5)	<0.001*
37-40 weeks	215(74.1)	132(93.6)	83(55.7)	
<40 weeks	36(12.4)	2(1.4)	34(22.8)	
Time in labour:				
No Labour	115(39.7)	68(48.2)	47(31.5)	0.006*
0-24 hours	159(54.8)	69(48.9)	90(60.4)	
>24 hours	16(5.5)	4(2.8)	12(8.1)	
**Membrane rupture:				
No rupture	135(49.8)	70(47.1)	65(47.1)	0.244
Rupture less than 2 hours	5(1.9)	3(2.3)	2(1.5)	
Rupture more than 2 hours	116(42.8)	50(37.6%)	66(47.8)	
Purulent amniotic fluid	15(5.5)	10(7.5%	5(3.6)	
Missing data	19(6.6%)	8(5.6%)	11(7.4%)	

Key: *****- Statistically significant ****** - Missing data

4.2.1 Pre-Intervention Operation characteristics of the women

The median duration of operation was 50minutes (IQR:40-60minutes). The majority of the operations were emergency 81.7% (n=237), with Parirenyatwa hospital having a significantly (p<0.001) higher proportion of emergency cases 90.6% compared to Harare hospital 72.3%. (see Table 4-2) History of previous caesarean section was noted in 22.4% n= 65) of the women recruited in the study. The most common type of anaesthesia was spinal anaesthesia given to 89.3% (n=259), and Harare Hospital gave this anaesthesia to a significantly higher proportion than Parirenyatwa Hospital (99.3% vs 79.9%, p<0.001). Senior House Officers (SHO) and Registrars performed the majority of the caesarean sections 82.1%(n= 238). However, there was significant (p<0.001) difference by hospital with more Registrars at Harare hospital (51.1%) performing caesarean sections compared to Parirenyatwa hospital (20.9%). Women who had post-partum haemorrhage post caesarean section were 4.5% (n=13) and significantly (p=0.008) more of these were from Harare hospital (7.8%) as compared to Parirenyatwa hospital (1.3%). Interrupted skin sutures were used on 1% of the women and 99% had continuous skin suturing.

Table 0-2: Pre Intervention operation characteristics

Variable	All N =290 (%)	Harare n=141 (%)	Parirenyatwa n =149 (%)	p-value
Median duration of operation (IQR) minutes	50(40-60)	50(40-60)	50(40-55)	0.067
Type of operation:				
Emergency	237(81.7)	102(72.3)	135(90.6)	<0.001*
Elective	53(18.3)	39(27.3)	14 (9.4)	
Previous Caesarean section:				
Yes	65(22.4)	25(17.7)	40(26.8)	0.060
No	225(77.6)	116(82.3)	109(73.2)	
Type of anaesthetic:				
General	31(10.7)	1(0.7)	30(20.1)	**<0.001***
Spinal	259(89.3)	140(99.3)	119(79.9)	
Surgeon grade:				
Consultant	11(3.8)	1(0.7)	10(6.8)	<0.001*
Registrar	103(35.5)	72(51.1)	31(20.9)	
SHO	135(46.6)	52(36.9)	83(56.1)	
GMO	4(1.4)	4(2.8)	0(0)	
SRMO	29(10)	4(2.8)	25(16.8)	
JRMO	8(2.8)	8(5.7)	0(0)	
Post-partum haemorrhage:				
Yes	13(4.5)	11(7.8)	2(1.3)	0.008*
No	277(95.5)	130(92.2)	147(98.7)	

*Antibiotic prophylaxis given: Yes No Record	237(81.7) 53(18.3)	139(98.6) 2(1.42)	98(65.8) 51(34.2)	<0.001*
Median time prophylactic antibiotic given (IQR) minutes Missing data*	60(30-115) 120(41.4)*	60(35-120) 14(9.4)*	45(25-105) 106(75.1)*	0.070
Surgical hand scrub: Anti-microbial soap Plain soap	 113(39) 177(61)	 0(0) 141(100)	 113(75.8) 36(24.2)	<0.001*
Skin preparation: Aqueous betadine	290(100)	141(100)	140(100)	-
Shaving: Operating room Anaesthetic room Ward Home	 84(29) 55(19) 132(45.5) 19(6.5)	 1(0.7) 0(0) 129(91.9) 11(7.4)	 83(55.7) 55(36.9) 3(2) 8(5.4)	<0.001*
Type of suturing: Continuous Interrupted	 287(99) 3(1.0)	 138(97.9) 3(2.1)	 149(100) 0(0)	0.070
Surgical wound classification: Class I Class II Class III Class IV	 135(46.6) 5(1.7) 116(40.3) 15(5.2)	 70(49.6) 3(2.1) 50(35.5) 10(7.1)	 65(43.6) 2(1.3) 66(44.3) 5(3.4)	0.244

Key: *****- Statistically significant

4.2.2 Pre-Intervention Pre-Operative Antibiotic Prophylaxis

Women who had a record of having received antibiotic prophylaxis were 81.7% (n=237). A significantly ($p<0.001$) higher proportion of women at Harare Hospital (98.6% n= 139) had antibiotic prophylaxis record indicated in their clinical notes compared as compared 65.8% (n=98) at Parirenyatwa Hospital (see Table 4-3); Harare hospital mainly used three antibiotics whilst Parirenyatwa hospital used seven types. Ceftriaxone was the main prophylactic antibiotic for just over half the women 51.9% (n=123) although a significantly ($p<0.001$) higher proportion of the women at Harare Hospital, 69.8% compared with 26.0 % at Parirenyatwa hospital used it.

Table 0-3: Pre Intervention Type of antibiotic used

Type of Antibiotic	All N=237(%)	Harare n=139(%)	Parirenyatwa n=98(%)
Ceftriaxone	123(51.9)	97(69.8)	26(26.5)
Chloramphenicol & Benzyl penicillin	44(18.6)	38(27.3)	6(6.1)
Metronidazole &Ceftriaxone	31(13.1)	0(0)	30(30.6)
Ampicillin & Chloramphenicol	28(11.8)	0(0)	28(28.6)
Metronidazole & Chloramphenicol	1(0.4)	0(0)	1(1.0)
Ceftriaxone & Chloramphenicol	4(1.7)	0(0)	4(4.1)
Metronidazole	1(0.4)	0(0)	1(1.0)
Chloramphenicol	2(0.8)	1(0.7)	1(1.0)
Benzyl penicillin	3(1.3)	3(2.2)	0(0)

4.2.3 Pre-Intervention Antisepsis and Skin preparation

Plain soap was used as surgical hand scrub by the surgical team for all the cases at Harare hospital while at Parirenyatwa hospital plain soap and an antimicrobial soap (Betadine surgical scrub) was used on 24.2%(n= 36) and 75.8%(n= 113) of the cases. Aqueous betadine was the agent used as preoperative skin preparation for all cases at both hospitals.

Shaving of the operation site was done at different times prior to caesarean section with 46.6% (n= 135) being shaved on the ward, 1.7%(n= 5) in the operating room, 40.3% (n=116) on the anaesthetic table and 5.2% (n= 15) who shaved themselves at home.

4.3 Pre-Intervention SSI Incidence rate

The follow-up period was thirty days from date of operation with day of operation being the first day. Post discharge surveillance detected 86.9% (n= 252) of the enrolled women who completed their 30-day follow-up period (Figure 1). Women who were lost to post discharge follow-up were 13.1% n= 38).

The 30-day overall SSI Incidence rate across both hospitals was 29.0% (95% CI:23.4-35.0). There was no significant (p=0.482) difference between the SSI incidence rate detected

between the two hospitals with Harare recording 27.1% (95% CI:19.7-35.4) and Parirenyatwa hospital 31.1% (95% CI: 22.9-40.2. The overall median time to onset infection in the pre intervention period was 14 days (IQR 10-19). There was significant (p<0.001) difference in median time to onset of infection with Harare hospital having a longer median time to infection of 17days(IQR:13-22) as compared to Parirenyatwa with median time to infection of 11days(IQR:8-15), which is shown in the Kaplan Meier plot (Figure 3).

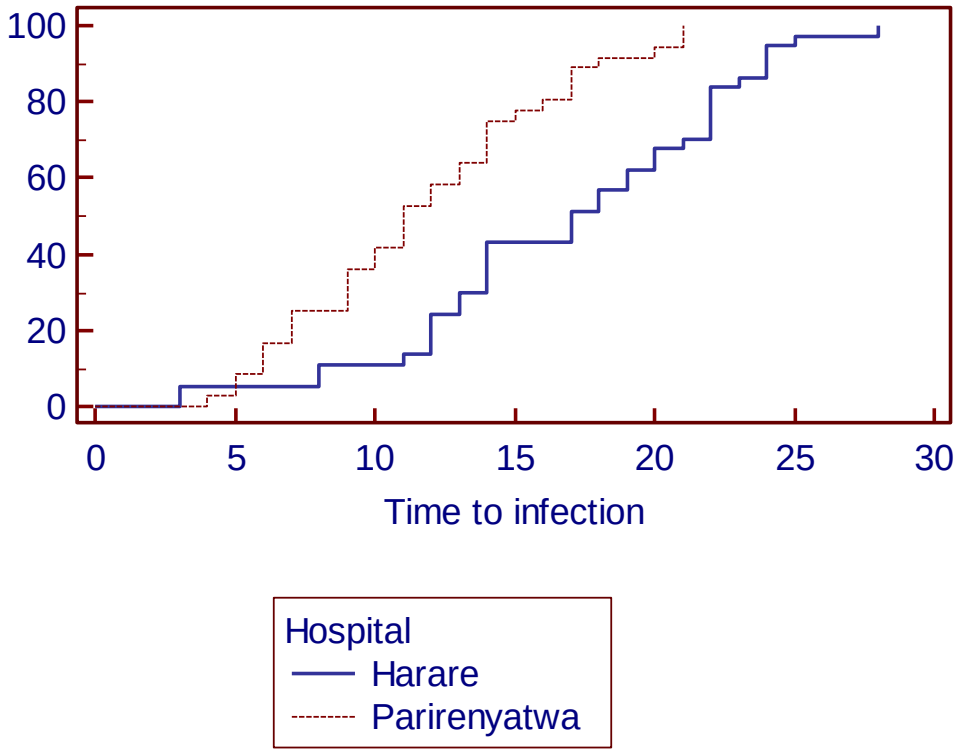


Figure 3: Pre Intervention Kaplan-Meier Plot of Time to Infection

4.3.1 Type of SSIs

The majority, 72.6% (n= 53) of SSIs were Superficial SSIs. (see Figure 4) However, there was no significant (p=0.100) difference by hospital although Parirenyatwa hospital recorded the highest proportion of deep incisional SSIs of 36.1% (n=13) compared to 18.9% n =7) at Harare Hospital.

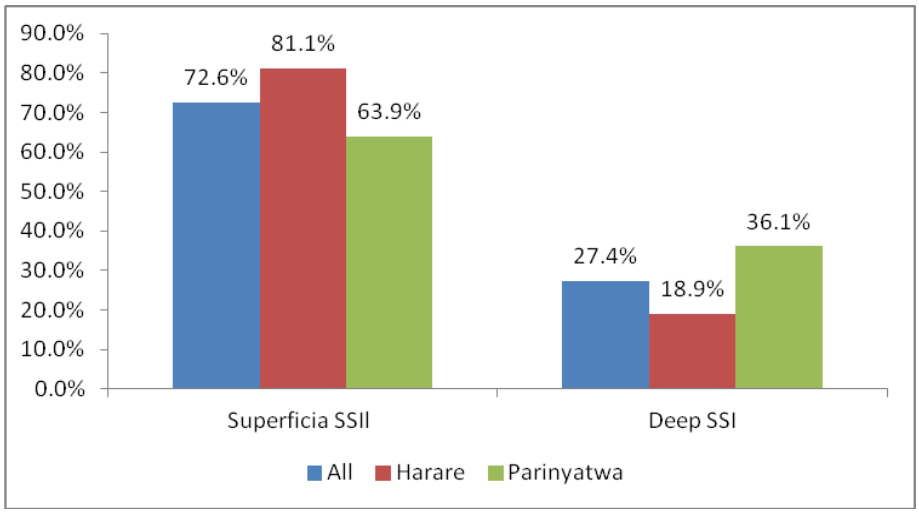


Figure 4: Pre-Intervention Type of SSIs detected

4.4 Pre-Intervention Risk factors for SSI

The analysis was based only on women who were followed up for 30 days as the outcome of those lost to follow up discharge could not be determined. Chi-squared test and univariate logistic regression was used to determine factors associated with SSI (see Table 4-4). There was no significant ($p>0.05$) association found between the following factors and development of SSI: maternal age, being a referral, HIV status, gestational age at delivery, duration of operation, history of previous caesarean section, type of anaesthesia used, type of surgical hand scrub, whether antibiotic prophylaxis was given and timing of antibiotic prophylaxis. Weight could not be analysed as determinate for SSI as there was 93.1% missing data. However, the following factors were significantly ($p<0.05$) associated with development of SSI:

- duration of labour
- surgical would classification
- type of operation
- surgeon grade
- when patient was shaved.

Table 0-4: Determination of risk factors associated with SSI (Pre intervention)

Variables	With SSI n=73(%)	Without SSI n=179(%)	Odds ratio (95% CI)	X^2 p- value
Hospital				
Parirenyatwa	36(49.3)	97(54.2)	1.0 (Reference)	0.482
Harare	37(50.7)	82(45.8)	1.2(0.7-2.1)	
Maternal Age(years)				
≤30	43(58.9)	127(70.9)	1.0 (Reference)	0.065
>30	30(41.0)	52(29.1)	1.7(0.9-3.0)	
Referral from another facility:				
No	6(8.2)	15(8.4)	1.0 (Reference)	0.854
Yes	67(91.8)	164(91.6)	1.1(0.4-2.9)	
Hypertension:				
No	12(16.4)	26(14.5)	1.0 (Reference)	0.700
Yes	61(83.6)	153(85.5)	1.2(0.5-2.4	
Diabetes Mellitus:				
No	73(100.0)	178(99.4)	-	0.522
Yes	0(0.0)	1(0.6)		
HIV Status				
Negative	66(90.4)	161(89.9)	1.0 (Reference)	0.910
Positive	7(9.6)	18(10.1)	0.9(0.4-2.4)	
Gestation period:				
<37weeks	12(16.4)	23(12.9)	1.0 (Reference)	
37-40 weeks	53(72.6)	132(73.7)	0.8(0.4-1.7)	
>40 weeks	8(11)	24(13.4)	0.6(0.2-1.8)	0.692
Duration of operation (mins)				
≤60	54(74.0)	150(83.8)	1.0 (Reference)	0.072
>60	19(26.0)	29(16.2)	1.8(0.9-3.5)	
History of previous CS:				
No	57(78.1)	140(78.2)	1.0 (Reference)	
Yes	16(21.9)	39(21.8)	1.0(0.52-1.94)	0.982
Type of anaesthetic:				
Spinal	65(89.0)	160(89.4)	1.0 (Reference)	
General	8(11.0)	19(10.6)	1.0(0.4-2.3)	0.936
Time antibiotic prophylaxis given				
≤ 60 minutes	22(55.0)	60(58.3)	1.0 (Reference)	0.724
>60 minutes	18(45.0)	43(41.7)	1.1(0.5-2.4)	
*Missing data 120(41.4)				
Skin closure:				
Interrupted	72(98.6)	177(98.9)	1.0 (Reference)	
Continuous	1(1.4)	2(1.1)	0.8(0.7-9.1)	0.867
Postpartum haemorrhage:				
No	69(94.5)	170(95.0)	1.0 (Reference)	0.883
Yes	4(5.5)	9(5.0)	0.9(0.27-3.06)	
Duration of labour:				
No Labour	20(27.4)	78(43.6)		
0-24 hours	43(58.9)	95(53.1)	Reference	
>24 hours	10(13.7)	6(3.3)	1.2(0.9-3.2)	0.002*
Surgical wound classification:				
Class I	27(23.4)	89(53.9)	1.0 (Reference)	
Class II	0(0.0)	4(2.4)	-	0.028*
Class III	36(35.3)	66(40.0)	1.7(0.99-3.24)	
Class IV	7(53.9)	6(3.6)	3.8(1.19-12.4)	

Type of operation:				
Elective	2(2.7)	42(23.5)	1.0 (Reference)	
Emergency	71(97.3)	137(76.5)	0.9(0.2-.03)	0.001*
Surgeon grade				
Senior	17(26.0)	77(43.0)	1.0 (Reference)	
Junior	54(74.0)	102(57.0)	2.1(1.2 -3.9)	0.012
Where patient was shaved:				
Operating room				
Anaesthetic	20(27.4)	56(31.2)	1.0 (Reference)	<0.001*
Room	9(12.3)	39(21.8)	0.6(0.3-1.5)	
Ward	30(41.1)	83(46.4)	1.0(05-1.9)	
Home	14(19.2)	1(0.6)	38.7(4.9-307.3)	

Key: *****- Statistically significant

The risk factors with a p-value <0.2 were included in the multivariate analysis. According to this analysis, the duration of labour >24hrs, emergency operation, Junior Surgeon Grade and being shaved at home were independent risk factors for SSI ($p<0.05$) (see Table 4-5 below). There was almost borderline association with Class IV surgical wound.

Table 0-5: Multivariate Pre-Intervention investigation of risk factors associated with SSI

Variables	Adjusted Odds ratio (95% CI)	p- value
Maternal Age(years)		
≤30	1.0 (Reference)	
>30	1.7(0.8-3.6)	0.158
Duration of operation (mins)		
≤60	1.0 (Reference)	
>60	2.3(0.9- 5.8)	0.079
Duration of labour:		
No Labour	1.0 (Reference)	
0-24 hours	1.8(0.6 -5.6)	0.273
>24 hours	8.2(1.6 – 39.5)	**0.009***
Surgical wound classification:		
Class I	1.0 (Reference)	
Class II	-	
Class III	0.9(0.3-2.5)	0.816
Class IV	5.3(0.9-31.8)	0.059
Type of operation:		
Elective	1.0 (Reference)	
Emergency	26.2(3.2 -214.2)	**0.002***
Surgeon grade		
Senior	Reference	
Junior	3.1(1.4-6,5)	**0.004***
Where patient was shaved:		
Operating room	1.0 (Reference)	
Anaesthetic Room	0.5(0.2-1.3)	0.187
Ward	1.8(0.7-3.3)	0.187
Home	26.7(2.9-250.0)	0.004*

Key: *****- Statistically significant

4.5 Interventions

The feedback of surveillance data through departmental meetings led to the development of interventions. The following interventions were agreed upon by the matrons and doctors of the maternity department of both hospitals in order to improve better patient outcomes.

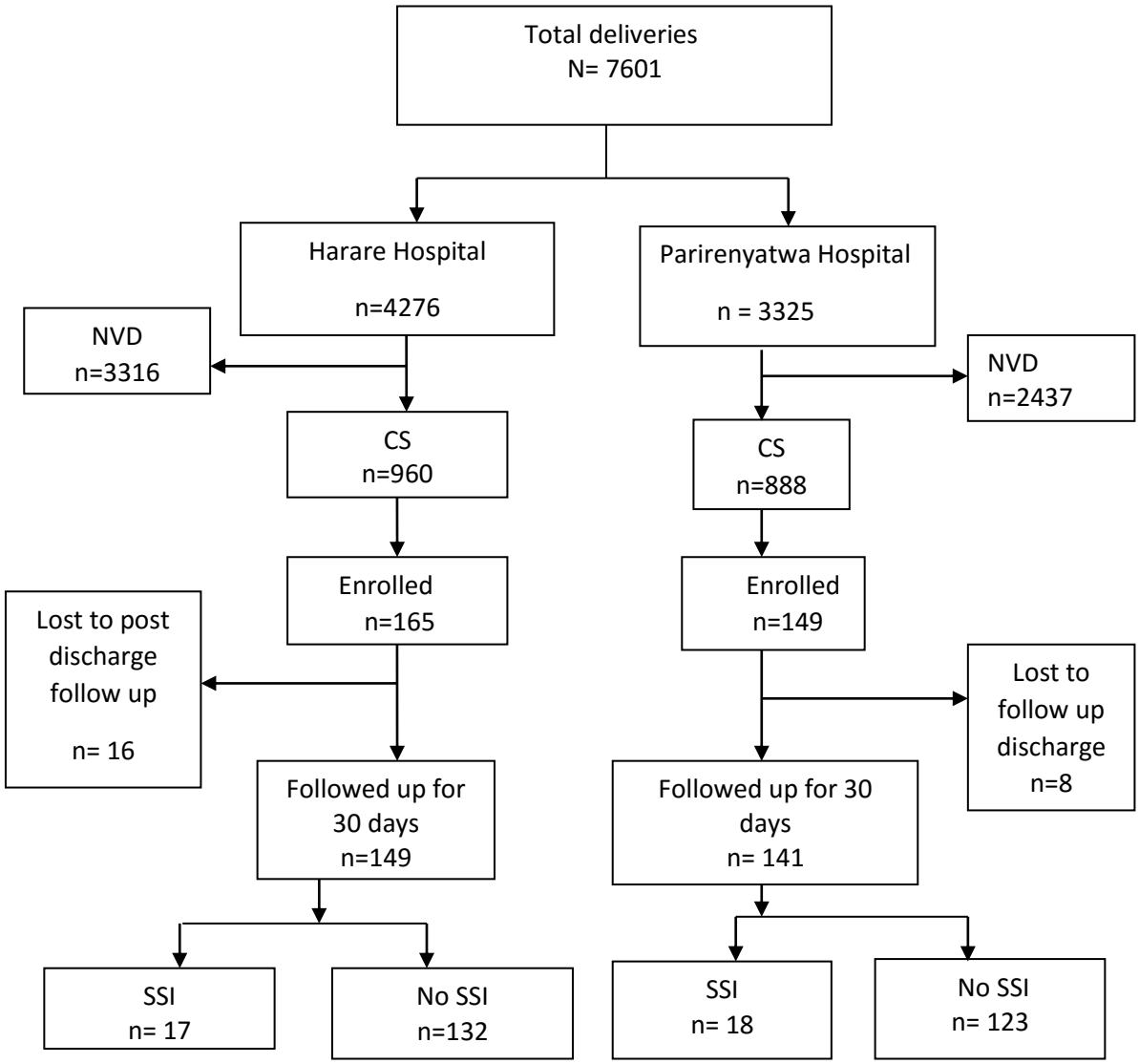
1. IPC Training
2. Standard operating procedure on cleaning of surgical instruments
3. Post-operative wound management fact sheet for the patient

Shaving however was not considered for inclusion in the interventions as there were disagreements among the nurses and the various consultant firms with others arguing basing on personal opinion rather than scientific evidence. To improve on IPC practices, training was conducted before the beginning of the post intervention period for the nursing team, which included nurses from CSSD department, theatre, gynaecology ward, casualty and maternity department. For topics taught see Appendix 5**.** The training was conducted over three weeks with different topics being taught weekly at Parirenyatwa Hospital and at Harare it was conducted over a two-day workshop. A standard operating procedure on cleaning of medical devices was introduced for the CSSD in consultation with the infection control nurses and the CSSD staff (see Appendix 6). A fact sheet on post-operative wound management was developed and this information was disseminated both verbally and in written form to the woman in the post-natal period and upon discharge by the nursing team (see Appendix 7). Several ad hoc meetings with the nursing department were conducted weekly to evaluate impact of training and implementation of interventions. In addition, participation in the doctors' ward round was done to emphasise the importance IPC practices.

4.6 Post intervention Study Participants

A total of 3325 deliveries were conducted at Parirenyatwa hospital and 4276 at Harare Hospital. Of the 3325 deliveries at Parirenyatwa hospital, 2437 were normal deliveries and

888 were caesarean section deliveries. At Harare hospital out of the 4276 deliveries, 3316 were normal deliveries and 960 were caesarean section deliveries. In the post intervention period 314 women were recruited, 149 at Parirenyatwa hospital and 165 at Harare Hospital. Women were followed up for 30 days' post operatively were 149 and 141 at Harare and Parirenyatwa Hospital respectively. Those lost to post discharge follow up were (9.7%(n= 16) and 5.3% (n= 8) for Harare and Parirenyatwa hospital, respectively. The flow chart below (Figure 5) shows the number of deliveries conducted at both hospitals, the number of women recruited in the study and the number followed up.



Key: CS= Caesarean section, NVD= Normal vaginal delivery, SSI=Surgical Site Infection

Figure 5: Post-Intervention Participants Flow Chart

The socio-demographic and obstetric characteristics of the women recruited during the post-intervention period are presented in Table 4-6. Their overall median age was 28years (IQR: 23-32years). Only 40.4% (n=127) out of the 314 women recruited had weight recorded in their notes. The median weight was 69kg (IQR: 63-80kgs). The majority 95.2% (n= 299) of the women were referrals from another facility and there was significant different (p= <0.000) in referrals from each facility, with 100%(n= 165 for Harare hospital as compared to 89.3%(n=134) for Parirenyatwa Hospital. Diabetes was noted to be in 1.9%(n=6) and there were 0.6% (n=2) women noted to be on TB treatment. Hypertension was recorded in 20.4% (n=64) and there was no significant difference by hospital. In the post intervention period 14.3% (n= 45) of the women were HIV positive and all were on ART. Just over half of the women enrolled had caesarean section after being in labour for less than 24 hours, 53.5% n= 168). There was 7.3% (n= 23) missing data on records of when membranes ruptured in the clinical notes.

Table 0-6: Post Intervention socio-demographic and obstetric characteristics of the women who had caesarean section from the two participating hospitals

Variable	All N= 290 (%)	Harare n=141 (%)	Parirenyatwa n =149 (%)	p-value
Maternal age				
≤30 years	(%)	88(62.4%)	109(73.2%)	0.014
>30years	(%)	53(37.6%)	40(26.9%)	
Median age years (IQR)	28(23-32)	28(24-33)	27(22-31)	
**Median weight kg (IQR)	69(63-80)	73(59-71)	69(63-71)	<0.001
Missing data	127(40.4)	58(35.2)	69(46.3)	
Referral from another facility:				
Yes	299(95.2)	165(100.0)	134(89.3)	<0.001
No	15(4.8)	0(0.0)	15(10.1)	
Diabetes Mellitus:				
Yes	6(1.9)	2(1.2)	4(2.7)	0.341
No	308(98.1)	163(98.8)	145(97.3)	
HIV Status:				
Positive	45(14.3)	19(11.5)	26(17.5)	0.134
Negative	269(85.7)	146(85.5)	123(82.5)	
If HIV positive is patient				
on ART	45/45(100)	19/19(100)	26/26(100)	-
Hypertension:				
No	250(79.6)	131(79.4)	119(79.1)	0.917
Yes	64(20.4)	34(20.6)	30(20.1)	

Patients on TB treatment No Yes	 312(99.4) 2(0.6)	 163(98.8) 2(1.2)	 149(100.0) 0(0)	0.178
Gestation age: >37weeks 37-40 weeks >40 weeks	 251(79.9) 34(10.9) 29(9.2)	 146(88.5) 8(4.9) 11(6.6)	 105(70.5) 26(17.5) 18(12.0)	<0.001
Time in labour: No Labour 0-24 hours >24 hours	 114(36.3) 168(53.5) 32(10.2)	 52(31.5) 99(60.0) 14(8.5)	 62(41.6) 69(46.3) 18(12.1)	0.051
**Membrane rupture: No rupture Rupture less than 2 hours Rupture more than 2 hours Purulent amniotic fluid Missing data	 126(43.3) 18(6.2) 120(41.2) 27(9.3) 23(7.3)	 51(34.5) 12(8.1) 69(46.6) 16(10.8) 17(10.3)	 75(52.5) 6(4.2) 51(35.7) 11(7.7) 6(4.0%)	0.018

Caesarean section deliveries performed as emergency cases were 74.8%(n=235) compared to 25.2%(n=79) elective cases. The median time the caesarean section took was 55 minutes (IQR 45,65). History of previous caesarean section was noted in 34.1% (n= 107) of the women. Women who had no record of duration of operation indicated in their clinical notes were 1.8%(n=3). General anaesthetic was given to 10.5%(n=33)) and Spinal anaesthesia to 281(89.5%). Consultants performed 2.2%(n= 7) of the caesarean sections while Registrars performed 36.3%(n=114), SHOs 29.9% (n=94), GMOs 0.7%(n=2), SRMOs 23.6% (n=74). and JRMOs 7.3% (n=23). Registrars performed most of the caesarean section deliveries followed by SHOs and lastly by SRMOs. Women who developed post-partum haemorrhage were 11.6%(n=.36)

Table 0-7: Post Intervention operation characteristics

Variable	**All N =290 (%)**	**Harare n=141 (%)**	**Parirenyatwa n =149 (%)**	**p-value**
Median duration of operation (IQR) minutes	55(45-65)	55(45-65)	55(45-65)	0.808
Type of operation: Elective Emergency	 79(25.2) 235(74.8)	 50(30.3) 115(69.7)	 29 (19.5) 120(80.5)	0.027
Previous Caesarean section: No Yes	 207(65.9) 107(34.1)	 94(57.0) 71(43.0)	 113(75.8) 36(24.2)	<0.001
Type of anaesthetic: Spinal General	 280(89.2) 34(10.8)	 153(92.7) 12(7.3)	 127(85.2) 22(14.8)	0.033
Surgeon grade: Consultant Registrar	 7(2.2) 114(36.3)	 6(3.6) 95(57.6)	 1(0.7) 19(12.8)	<0.001

SHO GMO SRMO JRMO	94(29.9) 2(0.7) 74(23.6) 23(7.3)	49(29.7) 0(0.0) 14(8.5) 1(0.6)	45(30.2) 2(1.3) 60(40.3) 22(14.7)	
Post-partum haemorrhage: No Yes	278(88.5) 36((11.5)	130(78.8) 35(21.2)	148(99.3) 1(0.7)	<0.001
*Antibiotic prophylaxis given: Yes No Record	280(89.2) 34(10.8)	159(96.4) 6(3.6)	121(81.2) 28(18.8)	<0.001
Median time prophylactic antibiotic given (IQR) minutes *Missing data	60(40,103) *124(39.5)	55(40,90) 12(7.3)	80(40,169) 112(75.2)	0.124
Surgical hand scrub: Anti-microbial soap Plain soap	149(47.5) 165(52.5)	0(0.0) 165(100.0)	149(100.0) 0(0.0)	<0.001
Skin preparation: Aqueous betadine	314(100.0)	165(100.0)	149(100.0)	-
Shaving: Operating room Anaesthetic room Ward Home	51(16.2) 18(5.7) 209(66.7) 36(11.4)	0(0.0) 0(0.0) 148(89.7) 17(10.3)	51(34.2) 18(12.1) 61(40.9) 19(12.7)	<0.001
Type of suturing: Continuous Interrupted	307(97.8) 7(2.2)	161(97.6) 4(2.4)	146(98.0) 3(2.0)	0.806
Surgical wound classification: Class I Class II Class III Class IV *Missing data	126(43.3) 18(6.2) 120(41.2) 27(9.3) 23(7.3)	51(34.5) 12(8.11) 69(46.6) 16(10.8) 17(10.3)	75(52.5) 6(4.2) 51(35.7) 11(7.6) 6(4.0)	0.018

Key: *- Statistically significant ** Missing data

4.7.1 Post –Intervention Antibiotic Prophylaxis

Women who had record indicated in their clinical of having received antibiotic prophylaxis were 89.2%(n=280) and 10.8%(n=34) did not have a record. The median time antibiotic prophylaxis was given was 60 minutes (IQR 40, 103). The type of prophylaxis antibiotic given among those women who had record indicated was 98.2% whereas 1.8% did not have a record. notes. There was missing data on time prophylactic antibiotic was given among 39.5% (n= 124) of the clinical notes

Table 0-8: Post-Intervention type of prophylaxis antibiotic given

Type of Antibiotic	Harare Hospital n=159(%)	Parirenyatwa Hospital n =116(%)
Ceftriaxone	133(83.7)	8(6.9)
Chloramphenicol & Benzyl penicillin	25(15.7)	84(72.4)
Metronidazole &Ceftriaxone	0(0.0)	20(17.4)
Ampicillin & Chloramphenicol	0(0.0)	1(0.9)
Metronidazole & Chloramphenicol	0(0.0)	1(0.9)
Ceftriaxone & Chloramphenicol	0(0.0)	1(0.9)
Benzyl penicillin and Metronidazole	0(0.0)	1(0.9)
Metronidazole	0(0.0)	1(0.9)
Chloramphenicol	1(0.6)	0(0.0)
Missing data		

4.7.2 Post-Intervention Antisepsis and Skin preparation

Plain soap was used as surgical hand scrub by the surgical team for all the cases at Harare hospital while at Parirenyatwa hospital an antimicrobial soap (Betadine surgical scrub) was used for all the cases. There was no change in preoperative skin preparation. Aqueous betadine was the agent used as for all cases at both hospitals. Women who were shaved on the ward were 66.7%(n= 209), in the anaesthetic room 5.7%(n=18) and on the operating table from 16.2%(n=51) and those who shaved themselves were 11.4%(n=36). Interrupted skin closure was used only on 2.2%(n=7) of the women compared to 97.8%(n=307) who had continuous suturing.

4.8 Post-Intervention SSI Incidence rate

The overall SSI Incidence rate across both hospitals in the post intervention period was 12.1%(n= 35 CI 8.3 -15.8). There is no significant difference between the SSI incidence rate detected between the two hospitals with Harare recording 11.4 %(n=17 CI 6.3 -16.5)) and Parirenyatwa hospital 12.8 % (n=18 CI 7.3 -18.3) with a p=0.723. Women who were lost to post discharge follow up were 9.7%(n=16) for Harare Hospital and 9.7%(n=8) for Parirenyatwa Hospital. The follow up period was thirty days from date of operation with day

of operation being the first day. Post discharge surveillance detected 85.7% (n=30) of the cases while 14.3%(n=5) were noted during initial admission

4.8.1 Post-Intervention Type of SSIs

Superficial SSIs accounted for a total of 74.3%(n=26) of the SSIs detected and the rest 25.7%(n=9) were deep incisional SSIs. There was not much difference in the type of SSIs between the two hospitals. Parirenyatwa recorded a total of 51.4%(n=18) while Harare hospital had 48.6%(n=17).

4.8.2 Time onset of infection

The overall median onset of infection in the pre intervention period was 12 days (IQR 10,19) as shown in Figure 6 below.

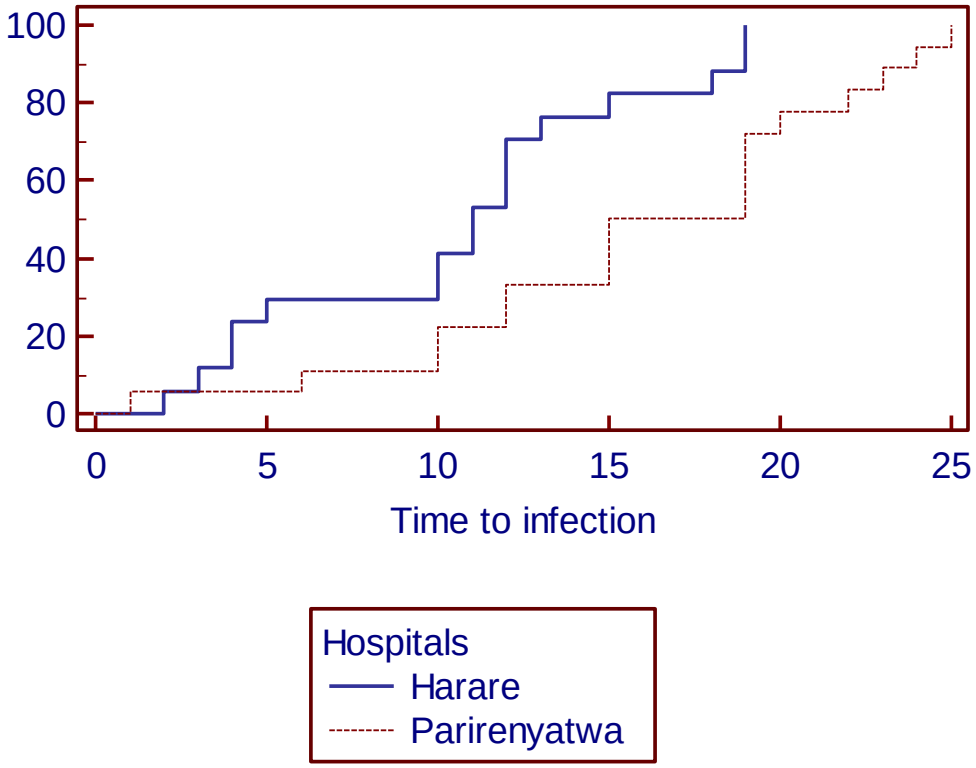


Figure 6: Post Intervention Kaplan-Meier Plot of Time to Infection

4.9 Post-Intervention Determination of risk factors associated with SSI

The chi square test was used to determine associations between risk factors and the outcome for categorical values and the Wilcoxon test was used for numerical values. The Table 4-9 below summarises the variables found to be significantly associated with development of SSI. As highlighted in table 4.9 the following variables were not found to be significantly associated with developing SSI in the post intervention period: being a referral, hypertension, HIV status, gestation age at delivery, length of operation, previous caesarean section, type of anaesthetic, whether antibiotic prophylaxis was given and the time it was given, surgeon grade, solution used as Surgiscrub and post-partum haemorrhage. Since all patients were ART this variable could not be analysed. Shaving could not be evaluated as a risk factor, since all study participants were shaved and thus there was no unexposed group for comparison. SSIs detected in surgical wound class I were 42.4%(n=14) followed by class III with 30.3%(n=10) and lastly by class IV with 27.3%(n=9). No SSIs were recorded among the women in class II. The surgical wound classification was noted to be a significant factor with a p value of 0.001. Among the emergency cases, 97.1%(n=34) developed SSI compared to 2.9%(n=1) of the elective cases. This difference was statistically significant with a p value of 0.001 which demonstrates that the type of operation was significantly associated with SSI development. SSI was detected in 57.1%(n-4) of the women who had interrupted skin sutures and in 11%(n=31) who had continuous skin sutures. There was a statistically significant difference noted between the use of continuous or interrupted skin closure with developing SSI with a p value of <0.001.

Table 0-9: Post-Intervention investigation of risk factors associated with SSI

Variables	Developed SSI n=35(%)	Did not develop SSI n=255(%)	Odds ratio (95% CI)	X^2 p- value
Hospital				
Parirenyatwa	18(12.8)	123(87.2)	1.0 (Reference)	
Harare	17(11.4)	132(88.6)	1.1(0.6=2.3	0.723
Maternal Age(years)				
≤30	30(13.9)	186(86.1)	1.0 (Reference)	
>30	5(6.7)	69(93.2)	0.4(0.1-1.2	0.104
Referral from another facility:				
No	2(5.7)	13(5.1)	1.0 (Reference)	

Yes	33(94.3)	242(94.9)	0.9(0.2-4.1)	0.877
Hypertension:				
No	27(77.1)	206(80.8)	1.0 (Reference)	
Yes	8(22.9)	49919.2)	1.2(0.5-2.9)	0.611
HIV Status:				
Negative	29(82.9)	221(86.7)	1.0 (Reference)	
Positive	6(17.1)	34(13.3)	1.3(0.5-3.4	0.540
Diabetes Mellitus				
No	33(11.6)	251(88.4)	1.0 (Reference)	
Yes	2(33.3)	4(66.7)	3.8(0.7-21.6)	0.106
TB Treatment				
No	35(12.1)	254(87.9)	1.0 (Reference)	
Yes	0(0.0)	1(100.0)	-	0.711
Gestation period:				
<37weeks	28(80.1)	204(80.0)	1.0 (Reference)	
37-40 weeks	2(5.7)	30(11.8)	0.5(0.1-2.1)	
>40 weeks	5(14.3)	21(8.2)	1.7(0.6-5.0)	0.320
Time in labour:				
No Labour	9(25.7)	98(38.4)	1.0 (Reference)	0.343
0-24 hours	22(62.9)	133(52.2)	1.8(0.8-4.1)	
>24 hours	4(11.4)	24(9.4)	1.8(0.5-6.4)	
Duration of operation (mins)				
≤60	25(73.5)	182(71.9)	1.0 (Reference)	
>60	9(26.5)	71(28.1)	0.9(0.4 -2.1)	0.846
*Missing data on 4 women				
History of previous CS:				
No	25(71.4)	164(64.3)	1.0 (Reference)	
Yes	10(28.6)	91(35.7)	0.7(0.3-1.6)	0.407
Type of anaesthetic:				
Spinal	30(85.7))	228(89.4)	1.0 (Reference)	
General	5(14.3)	27(10.6)	1.4(0.5-3.9)	0.513
Surgeon grade				
Senior	14(40.0)	95(37.3)	1.0 (Reference)	
Junior	21(60.0)	160(62.7)	0.9(0.4-1.8)	0.753
Antibiotic prophylaxis given:				
No Record	6(17.1)	26(10.2)	1.0 (Reference)	
Yes	29(82.9)	229(89.8)	1.8(0.7-4.8)	0.219
Time antibiotic prophylaxis				
≤ 60 minutes	12(54.6)	81(54.0)	1.0 (Reference)	
>60 minutes	10(45.4)	69(46.0)	0.98(0.4-2.4)	0.962
*missing data*124(39.5)				
Surgiscrub:				
Antimicrobial soap	18(51.4)	123(48.2)	1.0 (Reference)	0.723
Plain Soap	17(48.6)	132(51.8)	1.1(0.6-2.3)	
Postpartum haemorrhage:				
No	32(91.4)	222(88.6)	1.0 (Reference)	
Yes	3(8.6)	29(11.4)	0.7(0.2-2.5)	0.620
Surgical wound classification:				
Class I	14(42.4)	105(44.2)	1.0 (Reference)	
Class II	0(0.0)	16(6.8)	-	0.001*
Class III	10(30.3)	100(42.2)	0.75(0.3-1.8)	
Class IV	9(27.3)	16(6.8)	4.2(1.5-11.3)	
Type of operation:				
Elective	1(2.9)	74(29.0)	1.0 (Reference)	
Emergency	34(97.1)	181(71.0)	13.9(1.9-103.4)	0.001*
Skin closure:				
Continuous	31(88.6)	252(98.2)	1.0 (Reference)	<0.001*
Interrupted	4(11.4)	3(1.2)	10.8(2.3-50.7)	

Where patient was shaved:				
Operating room	7(20.0)	40(15.7)	1.0 (Reference)	
Anaesthetic Room	2(5.7)	16(5.5)	0.8(0.2-4.4)	<0.001
Ward	4(11.4)	187(73.3)	0.1(0.03-0.4)	
Home	22(62.9)	14(5.5)	9.0(3.2-25.6)	

Key: *****- Statistically significant ** Missing data

The factors with a p-value <0.2 were included in the multivariate analysis. According to this analysis, emergency operation, Junior Surgeon grade and being shaved at home were independent risk factors for SSI (p<0.05) (see Table 4-10). Shaving could not be included in the multivariate analysis as there was no group to compare as all patients in both groups were shaved.

Table 0-10: Multivariate Post-Intervention investigation of risk factors associated with SSI

Variables	Adjusted Odds ratio (95% CI)	p- value
Maternal Age(years)		
≤30	1.0 (Reference)	
>30	0.4(0.1-1.1)	0.085
Diabetes Mellitus		
No	1.0 (Reference)	
Yes	1.7(0.3-10.8)	0.495
Surgical wound classification:		
Class I	1.0 (Reference)	
Class II	-	
Class III	0.5(0.2 -1.3)	0.157
Class IV	2.7(0.9-8.0)	0.058
Type of operation:		
Elective	1.0 (Reference)	
Emergency	13.9(1.7-113.1)	0.015*
Skin closure:		
Continuous	Reference	
Interrupted	12.6(2.1-74.0)	0.005*

Key: * statistically significant

4.10 Comparison of socio-demographic and obstetric characteristics of the women in the Pre-intervention and Post-intervention cohorts

An increase was noted in the proportion of women who had weight recorded in their clinical notes from 41.4% in the pre intervention period to 57.3% in the post intervention period.

High number of referrals still noted in the post intervention period was 95.2%(n=299) compared to 91.4%(n=265) in the pre intervention period. Diabetes Mellitus in pregnancy was noted in 0.7% (n=1) and in 1.9%(n=6) in the pre and post intervention periods respectively. There was no record of any woman on TB treatment in the pre intervention period but there was 0.6%(n=2) in the post intervention period. 64(Women were hypertensive were 20.4% (n=64) in the post intervention period compared to 15.2% (n=44) in the pre intervention period. More women 14.3% (n=45) were noted to be HIV positive in the post intervention period compared to 9.3% (n=27) in the pre intervention period. All the women who were HIV positive were also on ART. Every woman who is admitted to the maternity ward is tested for HIV and if found positive is started on ART irrespective of CD4 count. The majority of the women who had caesarean section laboured between 0-24hours in both periods with 54.8%(n=159) and 58.5%(n=168) in the pre and post intervention periods respectively. There was missing data noted in the women's clinical notes on time membranes ruptured in 6.5% (n=19 and 7.3%(n=23) in the pre and post intervention period respectively.

Table 0-11: Socio demographic characteristics of the women (Pre and Post intervention)

Variable	Pre intervention N=290(%)	After Intervention N=314(%)	p value
Maternal Age (median IQR)	28(23,32)	25(21,30)	0.002
*Weight (median IQR) Missing data	69(63,79.5) 270(93.1)	81(67,91) 127(40.4)	<0.001
Referrals from another facility: No Yes	 265(91.4) 25(8.6)	 299(95.2) 15(4.8)	0.058
HIV Status: Negative Positive	 263(90.7) 27(9.3)	 269(85.7) 45(14.3)	0.06
If HIV positive is patient on ART	27(9.3)	45(14.3)	0.057
Hypertension No Yes	 246(84.5) 44(15.2)	 250(79.6) 64(20.4)	0.09
Diabetes Mellitus No Yes:	 289(99.6) 1(0.3)	 308(98.1) 6(1.9)	0.07
Patients on TB treatment	0(0)	2(0.64)	0.173
Gestation age: <37weeks	 39(13.5)	 29(9.3)	0.186

37-40 weeks	215(74.1)	251(79.9)	
>40 weeks	36(12.4)	34(10.8)	
Time in labour:			
No Labour	115(39.7)	114(36.3)	0.01
0-24 hours	159(54.8)	168(58.5)	
>24 hours	16(5.5)	32(10.2)	
Membranes ruptured:			
No Rupture	135(49.8)	126(43.3)	0.02
Rupture less than 2 hours	5(1.9)	18(6.2)	
Rupture more than 2 hours	116(42.8)	120(41.2)	
Purulent amniotic fluid	15(5.5)	27(9.3)	
*Missing data	19(6.6)	23(7.3)	

4.10.1 Comparison of Operation characteristics in the Pre and Post-Intervention Cohorts

As noted in the pre intervention period most of the cases were also emergency cases 74.8%(n=235). Two women had no record of duration of operation indicated in their clinical notes. There were slightly more cases lasting greater than 45 minutes in the post intervention period 76.9%(n=240) compared to pre intervention period 70.3%(n=204). More cases with previous history of caesarean section were recorded in the post intervention period 34%(n=107) compared to 22.4%(n=65) in the pre intervention period. General anaesthetic was given to 10.5%(n=33) and Spinal anaesthesia to 89.5%(n=281). Registrars performed most of the caesarean section deliveries followed by SHOs and lastly by SRMOs Women who developed post-partum haemorrhage were 11.6%(n=36) compared to 4.5%(n=13) in the pre intervention period. Use of antimicrobial soap increased from 46.9%(n=113) to 53.3%(n=126) in the post intervention period. There was no change in use of aqueous betadine as the agent for preoperative skin preparation. A decrease was noted on women who were shaved in the anaesthetic room and on the operating table from 75.3(n=55) to 24.7%(n=18) and 62.2%(n=84) to 37.8%(n=51) respectively. Women who shaved themselves at home increased in the post intervention period from 6.1%(n=18) to 11.5%(n=36). Interrupted skin closure was used on 2.2%(n=7) of the women compared to only 1%(n=3) in the pre intervention period.

Table 0-12: Comparison of Operation characteristics in the Pre-intervention and Post-Intervention Cohorts

Variable	Pre intervention N=290(%)	Post Intervention N=314(%)	p value
Type of operation: Elective Emergency	53(18.3) 237(81.7)	79(25.2) 235(74.8)	0.1
Previous Caesarean section: No Yes	225(77.6) 65(22.4)	207(66) 107(34)	0.001
Type of anaesthetic: Spinal General	259(89.3) 31(10.7)	281(89.5) 33(10.5)	0.9
Duration of operation: *Missing data	50(40,60) 0(0.0)	55(45.65) 3(1.8)	0.001
Surgeon Grade: Consultant Registrar SHO GMO SRMO JRMO	 11(3.8) 103(35.5) 135(46.6) 4(1.4) 29(10) 8(2.8)	 7(2.2) 114(36.3) 94(29.9) 2(0.6) 74(23.6) 23(7.3)	<0.001
Post-partum haemorrhage: No Yes	 277(96.1) 13(4.5)	 274(88.4) 36(11.6)	0.001
Antibiotic prophylaxis given: Yes No Record	 237(81.7) 53(18.2)	 280((89.2) 34(10.8)	0.02
Time antibiotic prophylaxis given Missing data	60(30,115) 120(41.4)	60(40,103) 124(39.5)	0.364
Preoperative skin preparation: Aqueous betadine	 290(100)	 314(100)	-
Surgiscrub: Anti-microbial soap Plain soap	 113(39) 177(61)	 129(41) 185(59)	0.6
Patient was shaved: Operating room Anaesthetic Ward Home	 84(29) 55(19) 133(45.9) 19(6.1)	 51(16.2) 18(5.7) 209(66.6) 36(11.5)	<0.001
Skin closure: Continuous Interrupted	287(99) 3(1)	307(97.8) 7(2.2)	0.25

4.10.2 Pre-Operative Antibiotic Prophylaxis

Women who had record of having received antibiotic prophylaxis were 81.7% (n=237) in the post intervention period compared to 89.2%(n=280) in the pre intervention period. There was a decrease noted on missing data on whether antibiotic prophylaxis was given or not. from 18.2% (n=53) to 10.8% (n=34). Significant amount of data was missing on time antibiotic prophylaxis was given for pre and post intervention periods respectively 41.4%(n=120) and

39.5%(124). The median time pre-operative antibiotic prophylaxis was given was almost similar within both periods 60 minutes (30,115) for pre intervention and 60 minutes (40, 103) for post intervention period. There is not much difference noted in the proportion of women who had record of time antibiotic prophylaxis given in their clinical notes from 58.6% (n=170) compared to 60.5%(n=190) in the pre and post intervention periods respectively. The type of antibiotic prophylaxis given was indicated in all the cases in the pre intervention period but in post intervention period only 1.8% (n=5) did not have type recorded. Ceftriaxone was the preferred type of antibiotic prophylaxis followed by a combination of Chloramphenicol and Benzyl penicillin and Metronidazole and Ceftriaxone.

Table 0-13: The type of antibiotic given in both pre and post intervention periods

Type of Antibiotic	**Pre intervention period n= 237%**	**Post intervention n = 275%**
Ceftriaxone	123(51.9)	141(51.3)
Chloramphenicol & Benzyl penicillin	44(18.6)	109(39.6)
Metronidazole &Ceftriaxone	31(13.1)	20(7.3)
Ampicillin & Chloramphenicol	28(11.8)	1(0.4)
Metronidazole & Chloramphenicol	1(0.4)	0(0)
Ceftriaxone & Chloramphenicol	4(1.7)	1(0.4)
Benzyl penicillin and Metronidazole	0(0)	1(0.4)
Metronidazole	1(0.4)	1(0.4)
Chloramphenicol	2(0.8)	1(0.4)
Benzyl penicillin	3(1.3)	0(0)

There were significant differences in several aspects of peri-operative factors in the period before and after the intervention. These included whether there was a previous Caesarean section, the duration of the operation, the surgeon grade, the occurrence of post-partum haemorrhage and the use of antibiotic prophylaxis. These represent potential confounding factors in this analysis, as discussed below.

4.11 SSI Incidence Rate

Women who were lost to post discharge follow up were 13.1%(n=38) and 7.6%(n=24) in the pre and post intervention periods respectively and were not included in the final analysis as their outcome could not be defined. The chance of developing SSI among women in the post intervention period was 12% compared to those in the pre intervention period which was 29%. The overall SSI incidence rate was 19.9%. The crude Relative Risk was 0.41(CI 0.30-0.60). This suggests that the intervention managed to reduce the risk of developing SSI by 59% among the women in the post intervention period. However, it is important to consider the possibility of confounding by other factors.

4.12 Risk factors for SSI

In the pre intervention period these variables were found to be associated with development of SSI by chi square: duration of labour (0.002), surgical wound class (0.03), type of operation (0.001), surgeon grade (0.04) and where patient was shaved (<0.001). In the post intervention period the variables that were significant were type of operation (0.001), surgical wound class (0.001) and type of skin closure (0.001). Thus, the only variable that was consistently associated with SSI in both periods was the surgical wound class.

To act as a confounder, a variable must be associated with both the exposure (here intervention status – pre or post) and with the outcome of interest (here SSI risk) and not lie on the causal path between these. As the intervention-status itself could not plausibly modify the surgical wound class, it is reasonable to assume that it is not on the causal path.

Surgical wound class was associated with SSI in both periods (pre and post) and it was also shown to change between pre and post interventions periods (i.e. it was associated with time-period), then it was assumed to be potential confounder. Surgical wound was then categorized into two categories “Clean” (= class I + II) and Contaminated/Dirty (=class III +IV) as illustrated in the tables below

Clean + Clean-Contaminated operations

	Before intervention	After intervention
SSI	27	14
No SSI	93	121
Total	120	135

Risk Ratio for Clean = (a/a+c)/ (b/b+d) = 27/120 /14/135 = 0.46 (CI 0.25 – 0.83)

Contaminated Dirty operations

	Before intervention	After intervention
SSI	43	19
No SSI	72	116
Total	115	135

Risk Ratio for Contaminated = (a/a+c)/ (b/b+d) = 43 / 115 /19 / 135 = 0.37 (CI 0.23 – 0.61)

Comparing these risk ratios to the crude risk ratio of 0.41, (0.30-0.60) It can be assumed that wound class is not a confounder because the risk ratio is not substantially changed.

4.13 Qualitative report of facility Assessments Pre and Post- intervention periods

This is a qualitative assessment done in the CSSD and theatres before and after intervention using a structured questionnaire. Although the facility assessments were done once in the pre and post intervention periods and were not related to individual patients the assessments do provide data on quality of Sterile services department and theatre environment. In the context of future studies plans to reduce SSI using this background should be taken into account. The results were summarized in table 4:14 below.

4.13.1 Theatres

a) Before intervention

The theatres were not mechanically ventilated, although Harare Hospital theatres are air conditioned. The air conditioning was not connected to conventional ventilation therefore there were no air changes and no filtration of air. At Parirenyatwa Hospital the mechanical ventilation was not working. There was no record of when the ventilation system was last serviced or when the filters were changed. This may explain why the theatre staff kept their door to the theatres open all the time. Medical devices and other respiratory equipment i.e. ventilator tubing were cleaned and reprocessed in the theatres by soaking in Cidex OPA. The Cidex OPA was changed after two weeks. On average, the number of people in the theatres at any given time was 15, which included staff working in the theatre as well medical students, midwifery students, and student nurses vary on a daily basis. The theatres are adjacent to the labour ward and during weekly ward rounds to the theatres it was observed that doctors could be seen moving in and out of the theatre going to the labour w

b) After Intervention

After training and feedback of pre intervention data all medical devices were sent to be reprocessed in the CSSD. There was no change though in mechanical ventilation as this needed a considerable amount of funding to repair.

4.13.2 CSSD

a) Before intervention

The issue of competence and training is a big challenge to infection control in CSSD. The only person who had some basic CSSD training was the Sister-in Charge of CSSD at Parirenyatwa hospital who got this training during her training for the Operating Theatre Nursing Diploma. This has not been followed up with refresher courses. The operators at both hospitals have been handed down knowledge and skills over the years which is apparently becoming dilute with time. Thus it was noted that the operators needed to be trained so that they are aware and up to date with developments taking place in the field of

decontamination. As it is, they succumb to pressures of producing quantities of packs without paying much attention to quality. It was therefore recommended that everyone working in CSSD should be trained and this training documented. This will ensure that all the documentation needed in CSSD such as SOPs for processing, dealing with recalls, tracking, training and others are put in place. There was no standard operating procedure for cleaning of reusable equipment. Medical devices were soaked in a disinfectant as a method of cleaning. The CSSD staff was overwhelmed with processing a lot of medical devices with minimal attention to quality. Appropriate reprocessing was compromised because there was not enough time for each decontamination process. There is no dedicated staff for cleaning medical devices; it is considered everyone's duty. There was no documentation of whether Bowie Dick Tests or other sterilizer tests (physical tests, leak rate) were being performed. There were no in pack chemical indicators no tracking or traceability mechanism. Packs and gowns were reported to be wet at times when they come out of the sterilizers and when this happens, they sometimes repacked, depending on demand. No formal training was provided only on-the-job training was conducted at induction.

b) After intervention

The CSSD staff received training on proper decontamination of medical devices as well as general IPC Training. Cleaning of medical devices greatly improved after training. Introduction of Bowie Dick tests and all the other tests like physical observations of temperature and pressure, leak rate tests, Bowie Dick test and use of chemical indicators were introduced and documentation started. A standard operating procedure on cleaning of medical devices was developed before the post intervention period. A tracking and recall system was introduced. Improvement was made in labelling of items and a register of all instruments processed in CSSD was kept. Labelling included adding the cycle number and sterilizer number on the sterile packs to facilitate easy tracking of items.

Table 0-14: Summary of facility assessment

Variable	Pre	Comments	Post	Comments
Separation of clean and dirty areas	Yes	CSSD clearly demarcated	Yes	CSSD clearly demarcated
Pre -soaking of instruments	Yes	Instruments being soaked to achieve cleaning and rinsing effect. Instruments soaked in disinfectant before cleaning.	No	No pre-soaking. Standard operating procedure being implemented
Regular maintenance of autoclaves	No	Autoclaves only attended to when broken down	Yes	Process started
Sterilization Number of indicators working	1/5	Only the autoclave tape being used as indication that sterilization has been achieved.	4/5	Visual observations of temperature and pressure, leak rate tests, daily bowie dick tests and use of in pack chemical indicators were introduced and these were being documented
Instruments processed in theatre	Yes	Instruments such as forceps were being soaked in Cidex OPA	No	All instruments were being sent for sterilization
Theatres mechanically ventilated	No	Harare Hospital theatres are air conditioned and not linked to conventional air flow and at Parirenyatwa Hospital the mechanical ventilation system is not working	No	No change in the ventilation systems as this needed financial support
Anesthetic equipment reprocessed in theatre	Yes	Ventilator tubings and oxygen face masks being soaked in Cidex OPA	Yes	Anaesthetic equipment continued to be reprocessed in theatre due to non-availability of a substitute to reprocess e.g. ethylene oxide.
Air changes	None		None	None
Entry into OT	12-15 per case		6 per case	Improved after training and follow ups
General IPC knowledge	Average Pretest 40%		Average Posttest 70%	Great improvement in knowledge after training

CHAPTER 5: Discussion

The SSI incidence rate including post discharge surveillance found in the women recruited in the pre intervention period was 29%. This is higher than the SSI rate of 25% reported in Zimbabwe previously in a study to investigate the infective morbidity in HIV positive and HIV negative women whose babies were delivered by caesarean section (Zvandasara et al 2007).The SSI rate is also lower than previously shown in a study on abdominal surgical site infections who recorded a 38% SSI rate among gynecology patients (Muchiwetu et al, 2013). Perhaps risk factors which had missing data such as weight, when antibiotic prophylaxis was given and duration of rupture of membranes prior to caesarean section may have been associated with SSI. Factors that were not examined in this study that may have been confounders include when woman started ART, CD4 count and number of vaginal examinations.

The SSI rate reported in this study is higher than previously reported in a Tanzanian district hospital where the SSI rate following cesarean section and hysterectomy was 24% and 36%, respectively (Fehr et al., 2006). Similar studies in Tanzania and Kenya have reported lower rates of SSI incidences than found in this study(Aiken et al., 2013),(Mpongoro et al., 2014). It is important to note that comparison of SSI rates is restricted by the variety of SSI definitions and the different surveillance approaches used in these studies. Variations in study design and methods used to identify SSIs affect comparison of SSI rates. Using standardized definitions implies the availability of microbiology data which in this study was limited. The SSI incidence following caesarean section has been noted to vary generally depending on the intensity of surveillance, criteria used to define SSI, postoperative hospital stays, antibiotic prophylaxis, the prevalence of risk factors for SSI in the patient group being audited, and whether the survey contains post discharge data (Mitt et al., 2005).

Interventions made in terms of the surveillance itself, training in IPC, implementation of standard operating procedure when cleaning of instruments and introduction of post-operative wound management fact sheet for the patient reduced the SSI rate and proved to have a positive influence on extrinsic risk factors. The post intervention SSI rate is still higher than previously reported in other studies in Africa, 9.3% and 9.1% Nigeria, 11.4% in Ethiopia and 7.8% in Kenya (Jido et al, 2012),(Amenu et al., 2011),(Koigi-Kamau et al., 2005). The difference between the pre intervention and post intervention period SSI rate clearly shows that surveillance and the interventions significantly lowered the SSI rate. This is supported by previous studies which concluded that surveillance of SSI with feedback to clinicians is critical to reducing SSI incidence (Evaldson et al 1992),(Haley et al 1985).

Follow-up of women through telephone contact identified 89.8% of SSIs that would not have been identified using inpatient surveillance. Inpatient surveillance alone would only have identified only 10.1% of the SSIs. Use of telephone calls for purposes of SSI detection has been reported in two recent studies in Kenya, one clinical trial used this approach Nthumba et al 2010 and another study examined the reliability of phone calls in comparison to outpatient clinical review (Aiken et al 2013). The rate of surgical site infections reported in this study may still be an underestimate since some women were lost to post discharge follow-up. Post discharge surveillance data is important if it is to be used for feedback to improve performance. Since the length of postoperative hospitalization continues to decrease, studies have demonstrated that many SSIs may not be detected for several weeks after discharge (Sands et al., 1996)(Sands K et al., 1996),(Reimer et al., 1987),(Weigelt et al., 1992). Literature has shown that over 50% of surgical site infections following caesarean section manifest post discharge. Although post discharge surveillance is imperfect it has been highlighted to provide better alternative to clinical based diagnosis(Aiken et al., 2013) .

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In both pre-intervention and post-intervention groups several of the risk factors investigated which were found to have no association with development of SSI include; age, whether the patient was referred, gestational age at delivery, diabetes mellitus, length of operation, history of previous caesarean section, type of anaesthesia used, timing of antibiotic prophylaxis and type of surgical hand scrub. However, this was a relatively small study that may not have been adequately powered to detect all of these effects. Furthermore, the study relied on data collection from notes, so any information that was missing or inaccurately recorded would also have reduced the ability of the study to detect true associations.

All the women noted to be HIV positive in our study were on ART. Women tested for HIV and found to be positive during ANC visits were put on ART on the Option B+ program. On the Option B+ program HIV positive pregnant mothers tested during ANC visits are given Tenolam E despite their CD4cell count. Counselling is done and on delivery baby is given Nevirapine for 6 weeks. The baby is then tested at six weeks and if found to be HIV positive, put on Cotrimoxazole. Bivariate analysis showed no significant association between being HIV positive and on ART with developing SSI.This lack of association between HIV and SSI was also demonstrated in two other studies in South Africa and Zambia. In a prospective study done in South Africa HIV infection did not influence the outcome of general surgical admissions and neither did CD4 count influence in-hospital outcomes in their cohort of patients (Cacala et al, 2006). Also in Zambia, HIV infection did not influence the outcome of general surgery and trauma patients (Kalima et al 1988) .Being HIV positive was shown to be associated with a higher morbidity than in HIV-negative women undergoing caesarean section, with a higher rate of the need for blood transfusion, a higher incidence of post-operative fever and wound infection, even with the use of peri-operative antibiotics (Zvandasara et al 2007). In another study done in South Africa to establish the prevalence of postoperative wound infection in major gynaecological surgery, HIV infection and SSI development were shown to be statistically significant In Tanzania HIV seropositive surgical patients were associated with a higher hospital mortality than seronegative patients (Jjuuko

et al , 2002) (Mkony et al , 2003). HIV positivity alone as a predictor of surgical outcome has not been extensively studied in regions of high prevalence.

It is difficult to deduce that the variables which had no association with development of SSIs in this study are unimportant, as there were small number of cases to demonstrate any statistical significance. Further studies with extended duration should be conducted to examine their association with development of SSIs. No association was found between being hypertensive and developing an SSI. In other studies hypertensive disorder of pregnancy was a predictor of SSI when analyzed by both Univariate and multivariate analysis (Cardoso Del Monte et al, 2010),(Schneid-Kofman et al, 2005) This link could be explained by the chronic alteration of peripheral blood supply due to the increased vascular resistance.

Several studies have reported an increased SSI rate in patients operated under general anesthesia as compared to patients operated under regional anaesthesia (Johnson et al., 2006 Hager et al 2004).In our study only 64 cases were operated under general anaesthesia compared to 540 under spinal anaesthesia. In such low numbers, it was difficult to establish a significant association.

The majority of SSIs found in this study in both periods were superficial infections accounting for 73.2%, followed by deep incisional infections (26.8%). Superficial infections are less serious and were managed on an outpatient basis by repeated dressings and broad spectrum oral antibiotics. However deep incisional infections led to prolonged hospitalization and some required readmission and the wounds were laid open and repeated dressings along with broad spectrum antibiotics intravenously were administered. Although most of these SSIs were noted to be superficial, this represents a significant burden to the underfunded health system, given the high number of women undergoing this type of surgery. Other studies have also demonstrated that the majority of SSIs after caesarean

section are superficial as noted in a study to determine rates and risk factors for obstetric cases 67% were superficial SSI followed by deep SSI 21.6% and organ /space 11.4%.(Amenu et al., 2011)

In the pre intervention period surgeon grade was s noted to be a significant factor. An increased risk of SSI was noted between the senior surgeon (consultant and registrar) versus junior surgeon (SHO, GMO, SRMO, JRMO) with a two times the risk in those who had caesarean section deliveries done by the Junior surgeon in a multivariate analysis. This could be assumed that the fact that majority of junior surgeons had less experience in performing caesarean sections procedures. In the post intervention period no association could be determined using bivariate analysis between surgeon grade and developing SSI. It is possible, or even likely, that the surveillance had an influence on the outcome of SSI as these doctors were aware of the results of the pre intervention data.

The duration of surgery in this study was not significantly associated with the risk of SSI. Different studies have used different standards of how long a C-section should last with some studies using one hour as the 75th percentile. In this study we used the 60 minutes as the T percentile. The NNIS cut off for caesarean sections according to NNIS is 57 minutes(Edwards, et al 2008).

In both the pre and post intervention period wound class was noted to be a significant factor. Women who presented with purulent amniotic fluid (Class IV) had a 3 times the risk and a 4 times risk in the pre and post intervention periods respectively of developing an SSI. The results in this study showed that the surgical wound classification was an important risk factor in predisposing women to SSIs. Normally in pregnancy the cervical mucus plug, foetal membranes and amniotic fluid all serve as barriers to infection when foetal membranes rupture, this protective effect is gradually lost with time. Bacteria will then cross the cervical

canal into the amniotic cavity leading to chorioamnionitis. Other studies have shown that wound classification remains a cornerstone of SSI risk stratification (Ezechi OC et al., 2009)(Taye M, 2005). Women with pre rupture of membranes should be closely monitored for development of infections.

There was no statistically significant difference in SSI rates from use of plain soap or antimicrobial soap as surgical hand scrub. This has been illustrated in a study done in Kenya to compare the efficacy of plain soap and water with an alcohol-based hand rub for surgical hand preparation and prevention of surgical-site infection (SSI) in a Kenyan rural hospital. So significant association could be established (Nthumba et al 2010).

Several studies on the method of skin closure following caesarean section have focused on post-operative pain and cosmetic appearance rather than risk of SSI. Of the ten women in both periods who had interrupted sutures, 4.6% (n=5) out of the 108 SSIs developed SSI. The present study identified a higher risk of SSI associated with closure using interrupted sutures rather than continuous subcuticular sutures in the post intervention period even though the numbers were very few. The method of skin closure depends on personal choice, with different surgeons preferring one technique over another. Surgical skill and patient-related characteristics also influence the suitability and effectiveness of a skin closure material, with subsequent impact upon the risk of infection.

As shown in the results section the time pre-operative antibiotic prophylaxis was given was not documented in most cases. The choice of antibiotic administered was based on availability and choice of the surgeon. The local guidelines on antibiotic prophylaxis recommend the use of Ceftriaxone 1g intravenously 10-15 minutes before incision (The 7th essential medicines list for Zimbabwe). All the 604 women recruited in the study received antibiotics post operatively for five days as this is the current practice at the hospital. This may explain why women in this study developed more minor post-operative complications

and less severe infective morbidity. Prophylactic antibiotics have been shown to reduce the rate of SSIs after surgical procedures and are progressively being used as performance indicators. (Fry 2008) Locally there is no data available on antimicrobial resistance therefore susceptibility patterns are unknown. Common causative organisms that have been identified with post- Lower segment caesarean section (LSCS)SSI include Gram-negative bacteria, anaerobes, and *Staphylococcus aureus*(Cunningham and Van Dorsten 2002). Other causative bacteria include *Streptococcus spp,* Gram negative species such *Escherichia coli, Klebsiella* spp *and Pseudomonas* spp (Mangram et al., 1999).The omission or untimely use of single dose of perioperative antimicrobial prophylaxis was shown to be associated with increased incidence and severity of postoperative SSIs(Taye 2005).

All the women who had caesarean section were shaved or shaved themselves prior to caesarean section. In this study women who shaved themselves had seven times the odds of developing an SSI than women shaved just prior to caesarean section. Shaving with a razor may result in minor cuts and abrasions and may increase risk of developing an infection by producing microscopic infected lacerations by the time of operation. Several consensus panels strongly recommend the avoidance of preoperative shaving unless absolutely necessary. If hair removal is absolutely necessary, use of clippers or depilatory creams is preferred(Alexander et al., 1983),(Tanner et al, 2011). The benefit of the use of depilatory creams was demonstrated in 1973 by Cruise and Foord.(Cruse and Foord 1980). They found an infection rate of 2.3% in patients who were shaved but only 1.7% in patients who were not shaved but had their hair clipped, whilst in those patients who were neither shaved nor clipped the infection rate was 0.9%. It is a practice at the two hospitals where this study was conducted that the patient should be shaved preoperatively in the belief that removal of the hair reduces the incidence of wound infection. A change in local guidelines is needed for the practice to be fully implemented. No studies have been conducted in low resource settings to prove that shaving predisposes women to SSIs. More research on this

matter is important in order to provide clinicians with evidence based information from African settings

Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.(Mangram et al., 1999) The importance of routinely monitoring the quality of sterilization was highlighted and implemented after the intervention phase. Increased awareness on this risk factor, together with strict implementation of standard operating procedures in decontaminating surgical instruments should be done in order to minimize and prevent the development SSIs after caesarean section. A study in done in Tanzania to assess risk factors for SSI found that pathogens may have been introduced by contaminated instruments into deeper layers during surgical intervention. Holes in overused and improperly reprocessed surgical drapes were assumed to have increased the risk of intraoperative contamination (Fehr et al., 2006). In this study we found that appropriate reprocessing was jeopardized because there was not enough time for each cleaning step as there was pressure to produce a lot of sterile packs to meet the clinical demand with little consideration for quality and a big compromise on infection control.

5.1 Recommendations for further study

Future studies should investigate association between decontamination of surgical instruments and development of SSI. There are challenges in low income countries in terms of reprocessing surgical instruments. It is further recommended that a standard tool be devised for low income countries to enable inter country comparison of SSI rates. Further studies should look at implementing the SSI bundle in low resource settings to provide evidence based data to influence change in behavior. There is need for an intensive health worker and patient education strategy aimed at reducing inappropriate hair removal.

5.2 Limitations of this study

In this study, there are various limitations that may pose a challenge to the generalizability of the results to other smaller hospitals in Zimbabwe. The study was done at the two central hospitals which are also referral hospitals and women cared for at the two central hospitals might have presented with more complicated pregnancies and therefore at higher risk for SSI. Microbiology laboratories are functional at both hospitals but we could not collect any information on wound swabs as the wound swab collectors were out of stock during the study period. There was poor documentation of patients' records. The missing data on some of the variables in this study such as weight, duration of operation and on the time antibiotic prophylaxis may have influenced the association between these variables and development of SSI.

Conclusion

The risk of developing SSI after caesarean section is multi-factorial and was found to be influenced by the following factors in this study: emergency surgery, surgical wound class, shaving and interrupted skin suturing which were found to be statistically significant. This study demonstrated that surveillance and training is an important activity in the reduction of SSIs. Although resources are limited with a surveillance system and good IPC practices SSIs can be greatly reduced.

Surveillance that includes follow up is vital as most cases were detected in the post discharge period. Surveillance of SSIs is feasible even in resource settings provided there are adequate dedicated human and financial resources. Since no an association could be found with most of the risk factors previously studied, emphasis should be towards investigating surgery associated infections rather than SSIs. In particular, a clear understanding of how to diagnose an SSI is crucial to accurate data collection. While outcomes are more challenging to identify in resource limited countries, a simple data collection tool can be developed and used on a wide scale across these countries to provide accurate SSI data and comparison of risk factors. The surveillance relied greatly on post-discharge surveillance to capture the majority of infections. This increased the complexity of the surveillance carried out and is an area that requires additional research. We had patients who reported to clinics and were given antibiotics but not meeting criteria for a surgical site infection. This study showed that post discharge surveillance is feasible and is important in determining the true burden of SSIs. The detection of SSIs using clinical parameters is feasible in most resource limited settings.

Appendices

Appendix 1 Surgical Site Infection Data Collection Tool

Surgical Site Infection Data Collection Tool	
1	Patient's ID(unique number) Age: Weight :…….kg Height…….cm
	Hospital: Ward Consultant
	Date of admission: Patient's contact number Is patient referred from another facility : ☐ Yes ☐ No
2	Underlying conditions: ☐Diabetes Mellitus: Yes/No ☐Hypertension: Yes/No ☐Cardiac Failure: Yes/ No ☐HIV status: Positive /Negative ☐ Other…… If HIV positive is patient on ART ☐ Yes ☐ No Is patient on anti TB treatment ☐ Yes ☐ No
3	Gestation Period ☐ <37weeks ☐ 37-40 weeks☐ > 40weeks
4	Time patient was in labour ☐ No Labour ☐ less than 24 hours ☐ More than 24 hours ☐No record
	Length of time membranes ruptured prior to caesarean section: ☐ No rupture ☐ less than 2hours ☐ More than 2 hours ☐Purulent amniotic fluid ☐ No record
5	Date of Operation: Time operation performed: Duration of operation: Start time: End time Type of operation: ☐ Elective ☐ Emergency History of previous caesarean section ☐ Yes ☐ No Type of anaesthetic: ☐ General ☐Regional ■Spinal ■Epidural State whether operation performed by: ☐Consultant ☐ Registrar ☐ SHO ☐ GMO ☐SRMO ☐ JRMO
6	Antibiotic prophylaxis given : ☐ Yes ☐ No If Yes state type and dose of antibiotic given…… Time prophylactic antibiotic given prior to cutting ☐ Exact time……. If exact time not available tick appropriate box ☐ > 15 min ☐ 15 min-30mins☐ 30 mins -45mins ☐ 45 mins -60mins ☐ < 1 hour
7	State solution used for surgeon's hand preparation ☐Plain soap and water ☐Antimicrobial soap and water ☐Other specify…… Antiseptic used for peri operative skin preparation ☐Aqueous betadine ☐2%Chlohexidine/Alcohol ☐Other……
8	Was patient shaved? ☐ Yes ☐ No If yes, state where? ☐ Ward ☐ Anaesthetic room ☐ On the operating table ☐ Home

9	Surgical wound classification for caesarean section Please tick one: ☐ Class I Clean ► Caesarean Section, elective, no pre-rupture of membranes or trial of labour ☐ Class II Clean Contaminated ►Caesarean Section, emergency involving pre-rupture of membranes less than 2hours and / or trial of labour ☐ Class III contaminated ► Rupture of membranes more than 24hours ☐Class IV Dirty ►Purulent amniotic fluid
10	Skin closure: ☐Interrupted sutures ☐Continuous
11	Post-partum haemorrhage ☐ Yes ☐ No

12	**Post op findings**	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**
	Temperature						
	Pulse						
	Day sutures removed						
13	**Antibiotic and dose given**	**Day 0**	**Day 1**	**Day 2**	**Day3**	**Day 4**	**Day5**

14. State presence of any of the following infection symptoms during inpatient stay:

Purulent drainage from the incision ☐Yes ☐ No

Wound dehiscence ☐ Yes ☐ No

Presence of at least one of the following signs or symptoms of infection

☐ pain or tenderness at operation site ☐ fever (>38°C)

☐ localised swelling ☐redness ☐ heat of skin

15. Date of onset of symptoms: ……

Date patient discharged……

Results of wound swab: Organisms isolated: ……

Antibiotic Susceptibility: Sensitive to: ……

Resistant to: ……

16. Post Discharge Surveillance

Review Week 1 Post Discharge Day 4-10	**Review Week 2 Post Discharge Day 11-17**
Is patient experiencing any of the following infection symptoms: Pain/tenderness at operation site: ☐Yes ☐ No Purulent discharge at wound site	Is patient experiencing any of the following infection symptoms: Pain or tenderness at operation site ☐Yes ☐No Purulent discharge at wound site

☐Yes ☐ No Wound dehiscence ☐ Yes ☐ No Localised swelling ☐ Yes ☐ No Redness ☐ Yes ☐ No Heat of skin ☐ Yes ☐ No Date of onset of symptoms…… Outcome ……	☐Yes ☐ No Wound dehiscence ☐ Yes ☐ No Localised swelling ☐ Yes ☐ No Redness ☐ Yes ☐ No Heat of skin ☐Yes ☐ No Date of onset of symptoms…… Outcome ……
Review Week 3 Post Discharge Day 18-24 Is patient experiencing any of the following infection symptoms: Pain/tenderness at operation site: ☐Yes ☐ No Purulent discharge at wound site ☐Yes ☐ No Wound dehiscence ☐ Yes ☐ No Localised swelling ☐ Yes ☐ No Redness ☐ Yes ☐ No Heat of skin ☐ Yes ☐ No Date of onset of symptoms…… Outcome ……	**Review Week 4 Post Discharge Day 25-30** Is patient experiencing any of the following infection symptoms: Pain or tenderness at operation site ☐Yes ☐No Purulent discharge at wound site ☐Yes ☐ No Wound dehiscence ☐ Yes ☐ No Localised swelling ☐ Yes ☐ No Redness ☐ Yes ☐ No Heat of skin ☐ Yes ☐ No Date of onset of symptoms…… Outcome ……
17. SSI detected: ☐Yes ☐ No If Yes state when SSI was detected: ☐ During admission ☐Post discharge Date SSI detected : ……Type of SSI: ☐ Deep ☐Superficial	

Comments

……

……

……

Form completed by ---------- Signature---------- Date……..

Appendix 2 Facility Assessment Tool

Name of facility:…….

Operating Theatres designated for caesarean section

Total number of staff working in theatre

RGN……. Nurse Aides…… General Hands…… Others ……

	Operating Theatres	Yes	No
1	Average number of caesarean sections performed monthly		
2	How many people on average are there in the operating theatres at any given time		
3	How many Operating Theatres are there?		
4	Is there a dedicated theatre for caesarean section?		
5	Is the scrub area located close to the changing rooms?		
6	Does the scrub area have elbow operated taps?		
7	Is the theatre mechanically ventilated?		
8	If yes state type of ventilation: i)Mechanical ii)Natural iii)Air conditioning		
9	Record number of air changes per hour		
10	How often is the theatre ventilation tested? Please state		
11	Is this documented?		
12	Are any anaesthetic or clinical equipment reprocessed in the OT?		
13	If yes how are they reprocessed? State		
14	Is there an adequate supply of protective clothing?		
15	Do you sometimes receive wet packs from CSSD?		

16	Are instruments soaked in the OT before being transported to CSSD?		
17	Are any surgical instruments processed in the theatres		
18	Is there a dedicated working area for reprocessing these instruments		
19	Is there a dedicated area for storing sterile packs stored in the theatre		
	CSSD		
1	Average number of packers on duty at any given time		
2	Number of packers dedicated for cleaning dirty instruments		
3	Is the CSSD located within the theatre department?		
4	Is there controlled mechanical ventilation in all CSSD areas?		
5	Is there clear separation of clean and dirty areas and traffic patterns adhered to and enforced?		
6	How are the surgical instruments cleaned? i)Manual ii)Mechanical		
7	Is there pre-soaking of instruments before cleaning?		
8	Are instruments cleaned in the theatre and processed there?		
9	Are they any instruments that are processed in the theatres without sending them down to CSSD?		
10	If yes state method of reprocessing i)Disinfection ii)Sterilization		
11	State type of disinfectant available in the theatres: i) Sodium Hypochlorite ii) Cidex OPA iii) Other……		
12	State number of autoclaves in the operating room theatres or CSSD		

13	Are sterilizer physical parameters are reviewed after each run and a record kept?		
14	Is there regular maintenance of these autoclaves? If so state date autoclave last serviced and next service date:		
15	Are Leak rate tests, air detector function test, air detector performance tests are done weekly?		
17	Are chemical indicators placed in each pack?		
18	Is a Bowie Dick test performed daily and documented?		
19	How are sterile instruments transported to the operating theatres?		

Appendix 3 Informed Consent

RESEARCH TITLE:

Surveillance of Surgical Site Infection (SSI) following Caesarian Section at Two Central Hospitals in Harare, Zimbabwe

NAME OF RESEARCHER: Anna Maruta

CONTACT PHONE NUMBER: 0772 893 959

PROJECT DESCRIPTION:

I am an MSc IPC student with Stellenbosch University. I am conducting a study on surgical site infections among women undergoing caesarian section at Parirenyatwa and Harare Hospitals in Zimbabwe. The purpose of this study is to identify risk factors that predispose women to developing surgical site infections post caesarean section.

YOUR RIGHTS

Before you decide whether or not to volunteer for this study you must understand the purpose of this study, how it may help you, the risks to you and what is expected of you. This process is called informed consent.

PURPOSE OF RESEARCH STUDY

Occasionally women who have a Caesarean section develop a surgical site infection any time from two to three days up to two to three weeks after surgery. In order to prevent or minimize the occurrence of these surgical site infections we would like to collect information from you and your medical notes including your HIV status. All information collected will be treated as confidential and protected. Your identity will remain anonymous. We will give you a number which is not linked to any of your records and all your records will be kept under lock and key

PROCEDURES INVOLVED IN THIS STUDY.

Information about you which includes your age, medication you are taking, your HIV status will be gathered from your medical records. If you consent to this study you will be required to provide your contact telephone number or that of your next of kin so that we check on you for any signs and symptoms of infection. After discharge from hospital you will be contacted on several days up to 30 days' post operation. You are also advised to contact this number

0775 217 996 if you develop any signs and symptoms of infection which include gaping wound purulent discharge from incision site, pain, localized swelling, fever redness or heat. You will be required to visit your nearest doctor or clinic if you experience any of these symptoms. The information gathered will lead to the development of a guide that will be implemented at the institutions to address/mitigate the risk factors for SSIs in women undergoing C-section. Your participation in this study is voluntary.

POTENTIAL BENEFITS

The benefit of participating in this study is in the event that you develop an SSI it will be identified and treated early. However, women who will undergo C-sections in future will benefit more from the study results, through the implementation of a guide that will reduce their chance of developing an SSI after a C-section.

STUDY WITHDRAWAL

You may choose to enter the study and should you feel you want to withdraw from the study at any time you are free to do so. Furthermore, if you decide not to participate, it will not affect the health care you are currently receiving.

CONFIDENTIALITY OF RECORDS

Information about you will be completely confidential and the records of the study will be kept private. Access to the records will be limited to the data collectors who are also the sisters in charge of your ward. The results of the study however will be made public through publication and presentation so that they can be of use to others.

PROBLEMS/QUESTIONS

You may ask any questions about this research or consent now. If you have any question in future, please ask

AUTHORIZATION

I have read this informed consent about the study or it was read to me. I understand there are no risks or financial benefits to me for participating in this study. I am making a voluntary decision to participate in the study and understand that I have the choice to opt out of the study at any time without losing my rights to medical care. I will keep a copy of the signed consent form.

Client Signature Date

Client Name (Printed)

Researcher Signature Date

Researcher Name (Printed

Shona Consent Form

Gwaro Retenderano Rine Ruzivo Rwakakwana Nekuita Chibvumirarano

MUSORO WEONGORORO

Ongororo yezvikonzero zvinoita kuti maronda abatire hutachiona shure kwekunge madzimai avhiiwa senzira yekuvabatsira kuzvara pazvipatara zveParirenyatwa neHarare muZimbabwe.

ZITA REMUONGORORI: Anna Maruta
NHAMBA DZENHARE: 0772 893 959

TSANANGUDZO PAMUSORO PEONGORORO:

Ndiri kuita dzidzo yeMSc yakanangana nezvekudzivirirwa kwekubatira hutachiwana muzvipatara neUniversity yeStellenbosch. Sechikamu chekudzidza uku ndirikuongorora maronda amadzimai vanenge vavhiiwa vachibatsirwa kubara vana pazvipatara zveParirenyatwa neHarare.

KODZERO YENYU

Musati mabvuma kupinda muongororo munofanira kunzwisisa chinangwa uye zvinobatsira ongororo iyi, njodzi yamusangana nayonezvinotarisirwa kwaqmuri. Aya ndiwo matanho ari mugwaro rino ekuti muve neruzivo nenzwisiso yekubvuma kana kuramba.

CHINANGWA CHEONGORORO

Chinangwa cheongororo iyi ndechekutsvakiridza zvikonzero zvinoita kuti maronda aya abatire utachiwana. Madzimai anenge abatsirwa pakuzvara mwana nenzira yokuvhiiwa vanowanzoonekwa vachiita hutachiwana pamaronda iwayo mushure memazuva maviri kana matatu kusvika kumasvondo maviri kana matatu mushure mekuvhiiwa uku. Kuti tikwanise kuita hurongwa hwekudzivirira kubatira kwehutachiwana pamaronda aya tinokumbira kuti mutibvumidzewo kukubvunzai mibvunzo uye kutarisa zvakanyorwa muma kadhi enyu ekurapwa.

ZVICHAITWA MUONGORORO IYI

Zvinoda kuzivikanwa pamusoro penyu zvinosanganisira makore enyu ekuberekwa, huremu nekureba kwenyu, mishonga yamuri kunwa uye kuti mune utachiwana hweHIV here kana

kwete. Ndichazvitora mumagwaro enyu ehutano.. Kana mabvuma kupinda muongororo iyi munotatrisirwa kutipa nhamba dzenyu dzenhare kana dzehama yenyu yepadyo kuiitira kuti tigopota tichinzwa kuti ronda renyu riri kupora zvakanaka here kana kuratidza kunge ringava riine hutachiwana. Kubva zuva ramunenge mavhiiwa mucharamba muchitevererwa kwemazuva makumi matatu. Muno kurudzirwa kufona panhamba dzinoti 0775217996 kana muchinge maona zvinoratidza kuti ronda renyu rabatira utachiwana zvakaita sekubuda hurwa nepamusono, marwadzo, kuzvimba, kusvibirira nekupisa paronda. Kana zvadaro munokurudzirwa kuenda kwachiremba nekukasika. Zvichabuda muongororo iyi zvichagadziriswa gwaro richashandiswa muzvipatara kudzivirira kubatira hutachiona kwamaronda amadzimai kana vavhiiwa mukuvabaatsira kuzvara. Hamusi kumanikidzwa kupinda muoongororo iyi.

ZVAMUNOGONA KUWANA MUONGORORO IYI

Kupinda kwenyu muchirongwa ichi kuita kuti kunge muchinge maita hutachiona paronda renyu zvikurumidze kuonekwa nekubatsirwa. Avo vachazovhiiwa mushure mekunge ongororo ino yapera ndivo vachanya kubatsirwa negwaro richabuda rokutora matanho okudzivirira kubatira hutachiwana pamaronda avo.

SARUDZO YEKUBUDA MUONGORORO IYI

Munobvumidzwa kubuda muchirongwa ichi chero nguva pamunenge manzwa kuti hamuchadi kuenderera mberi. Zvakare kana musingade kupinda muchirongwa ichi hazvikanganise marapirwo amunofanira kuitwa muchipatara.

KUCHENGETEDZWA KWEMAGWARO EHUTANO

Zvese zvinowanika patsvakiridzo iyi pamusoro penyu hazvisi kuzoshambadzirwa uye zvichanyatsochengetedzwa. Zita renyu harishandiswe asi munopiwa nhamba isina chokuita nemakadhi enyu emuchipatara Zvose zvinechekuita nemi hazvishambadzirwe uye zvichagara zvakachengetedzwa. Vanhu vanecheuita nezve ongororo iye ndivo chete vanokwanisa kuona zvinechekuita neronda renyu vanova ndivo vanamukoti vagara vachikurapai. Humbowo hwese huchabuda muongororo iyi zvichanyorwa bepa nekushambadzwa pagungano rekuonesana nezveutano kuitira kuti vamwe vagodzidzawo.

MIBVUNZO

Munogona kubvunza mubvunzo maererano neongororo iyi kana kuti chbvumirano ichi iyezvino kana imwe nguva.

CHIBVUMIRANO

Ndaverenga/Ndaverengerwa gwaro rino. Ndanzwisisa kuti hapana chandinowana kana kurasikirwa nacho kanaa ndapinda muongororo iyi. Ndiri kuita sarudzo yokupinda muchirongwa ichi pasina kumanikidzwa uye ndichinziva kuti ndinogona kubuda kana ndisisade kuenderera mberi nayo. Ndichasarawo nerimwe regwaro rino rine runyoro rwangu.

_____

Runyoro rwenyu Zuva

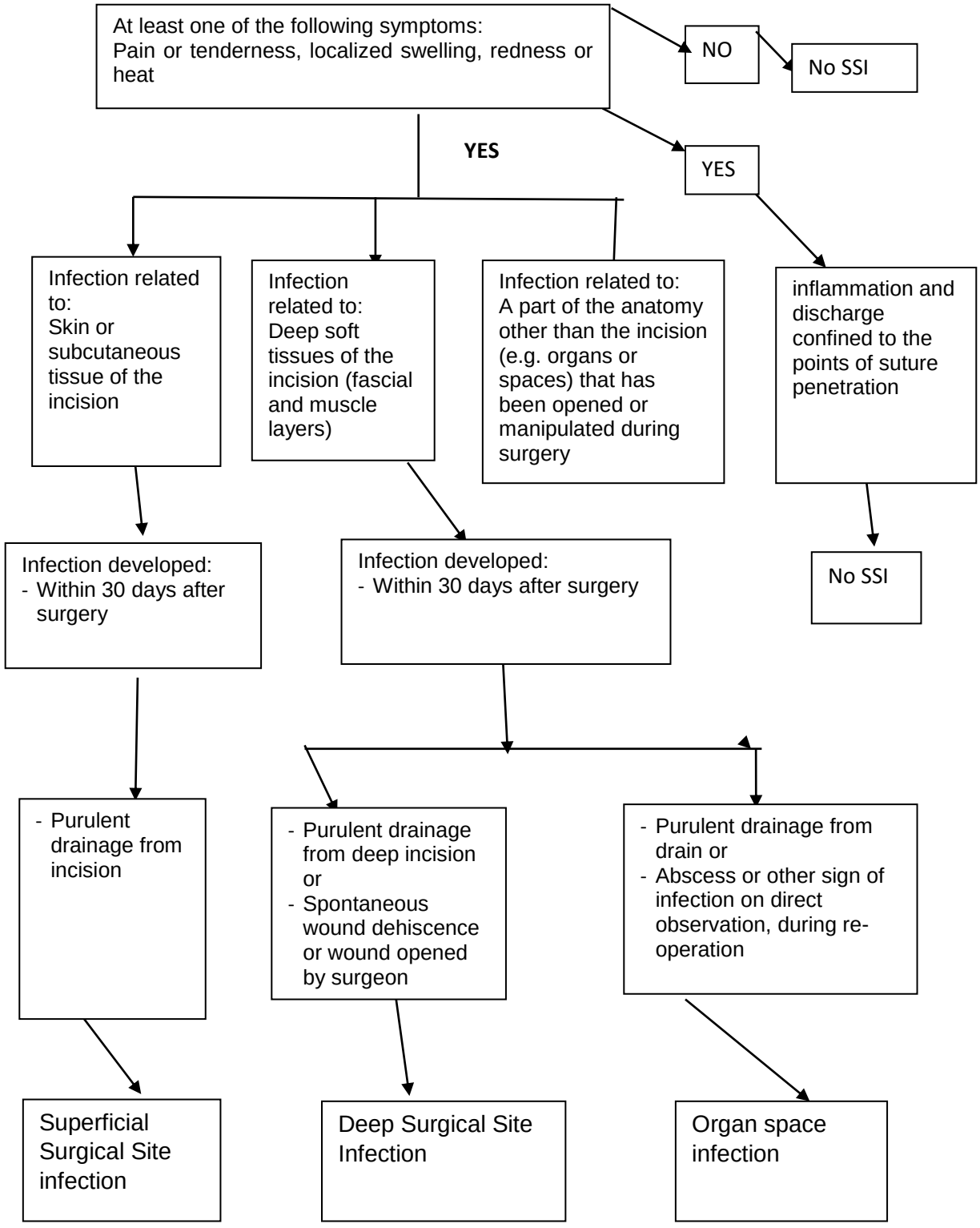
_____

Zita rwenyu

_____

Runyoro rwemuongorori Zuva

Appendix 4: Decision Tree for Assigning the Diagnosis of a Surgical Site Infection



Appendix 5 Topics Taught

1. Basic Microbiology
2. Standard Precautions
3. Transmission Based Precautions
4. Disinfection and Sterilization
5. Surveillance of Healthcare Associated infections: Methods and definitions, Bundles for the Prevention of HAIs.
6. Risk Prone Procedures
7. Appropriate use of PPE

Appendix 6 Standard Operating Procedure

Title	-	Manual Cleaning
Date of preparation	-	30 June 2014
Review date	-	30 June 2015
Area of application	-	Decontamination area
Staff involved	-	Those working in decontamination area.

PURPOSE - To ensure that instruments are properly cleaned.

Related Documents

- Standard precautions
- CSSD procedure manual
- Infection Prevention and Control Manual

EQUIPMENT

Instruments and trays
Cidezyme
Nylon Brushes
Dedicated Sinks
Instruments and trays
Sponges

Heavy duty gloves
Masks, Visors or goggles
Plastic Aprons

PROCEDURE: -

- Put on protective clothing i.e. heavy duty gloves (to protect from contamination and reduce risk of cuts and pricks from sharp items), heavy duty aprons, goggles or face mask with visor
- Fill the sink with appropriate amount of detergent and water Dilute Cidezyme 40ml to 5litres of water or 8ml to 1litre.
- Dismantle or open instruments. Special attention must be paid to the joints of any jointed instrument and meticulous attention paid to the tips or crevices.
- Clean instruments with a clean soft brush or soft cloth/sponge
- Fully immerse the instrument in the solution and keep under water during cleaning process to prevent aerosol formation
- Brush, wipe, irrigate the item to clean
- Drain excess detergent prior to rinsing in a second sink with clean water
- Examine instrument to make sure all parts are clean and intact. Identify any missing screws and broken parts

- Some instruments may require irrigating with a jet gun
- Ensure all the soil or chemical is removed prior to or during cleaning
- Change water when visibly soiled or contaminated
- Dry instruments
- Use fresh water and detergent for each batch of instruments.

N.B if water is visibly stained during the rinsing stage the cleaning stage should be repeated

OUTCOME

Ensure that instruments and trays are cleaned and made safe for handling and prepared for sterilization.

Appendix 7 Patient information

Please note the following when you go home:

- A certain amount of pain is to be expected because the skin and underlying tissues have been cut and manipulated, but sudden increase in pain or throbbing pain could indicate infection. It should be possible to control anticipated levels of pain with a simple analgesic such as Paracetamol.
- You are also advised to contact this number 0775 217 996 if you develop any signs and symptoms of infection which include gaping wound, purulent discharge from incision site, pain, localized swelling, redness, heat of fever. You can also visit your nearest doctor or clinic if you experience any of these symptoms.
- If you are discharged while still taking antibiotics, please make sure you finish the course even if you feel well.
- Dressing materials should be stored in a secure, dry place and hands should be washed before and after dressing changes. Dressings can be wrapped and disposed of with normal household waste
- It is better to avoid bathing until the incision appears healed.
- The site should be dried carefully after showering or bathing.

Wound Care

- Before you care for your wound please wash your hands thoroughly with soap and water and dry thoroughly with a towel.
- Make 3 cotton wool balls.
- With the first cotton wool ball pour betadine on it and clean the top part of your wound once.
- With the next cotton wool ball clean the middle part of your wound.
- The last cotton wool ball cleans the lower part of your wound.
- Discard the cotton wool balls in paper packet and dispose in the household waste.
- Wash your hands.
- Keep your wound dry at all times.
- Avoid wearing tight clothing until your wound is healed.

NB: Do not lift anything heavy things (no more than a full kettle of water) for at least six weeks after surgery.

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