Surgical site infections comparing two field versus three field antiseptic skin preparation for abdominal surgery: A multicentre prospective cohort study

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ABSTRACT

Background: Surgical site infection are preventable yet remain a major contributor of hospital acquired infections. The highest incidences of 7.2% are seen in Africa. One cornerstone for prevention is preoperative skin antiseptic application. However, while some jurisdiction use the World Health Organisation recommendation of a single alcohol based solution such as chlorhexidine gluconate-alcohol, public facilities in Zambia still use combination such as aqueous based antiseptics and methylated spirit.

Objectives

To compare the incidence of surgical site infections at among patient undergoing open abdominal surgery after two field aseptic cleaning versus three field aseptic cleaning.

Methods

The two-field method comprising of aqueous chlorhexidine gluconate and methylated spirit will form the first cohort, while the three-field method which includes the two-field plus aqueous povidone iodine will make the second cohort. Either the two-field or three-field antiseptic technique will be applied sequentially. A total of 1,054 patients undergoing elective open abdominal surgery will be selected from various healthcare facilities across seven provinces. Patients will be prospectively followed up for 30 days after surgery using the World Health Organisation surgical site infection checklist. Gene sequencing for surgical site infection cultured isolates will be done. Data will be collected electronically using REDCap for a period of Six months and analysed using SPSS version 29. The Z test for two proportions will be used for hypothesis testing

Keywords: Surgical site infections, incidence, abdominal surgery, antiseptics, Zambia

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INTRODUCTION

Incidence and prevalence of Surgical Site Infections or background

The global incidence of surgical site infections (SSI) has a pooled value of 2.5% and varies across regions with the highest rates seen in Africa (7.2%) and the lowest rates seen in the pacific region (0.6%) (Mengistu et al., 2023). While SSI are preventable, they are a major healthcare problem accounting for a large share of the morbidity and mortality for post operative patients and responsible for millions of nosocomial infections (Raoofi et al., 2023). A surgical site infection is a post operation infection which is attributed to the surgery and must occur within 30 days after surgery (WHO, 2018). Patients with SSI experience higher length of stay, higher readmission rates, increased out of pocket spending, and overall increased healthcare costs (Shambhu et al., 2024).

Morbidity and mortality of SSI

SSI also contribute to a fair share to the mortality of patients with an overall mortality between 1.05% to 7.3% across various jurisdictions (Paladini et al., 2022; Vicentini et al., 2023; Fadeil et al., 2024; Okidi et al., 2024). However, some specific mortality rates due to colonic surgery is 3.35% with a Case Fatality Rate of over 6.6% (Paladini et al., 2022; Vicentini et al., 2023).

Various risk factors associated with mortality include having another surgery within 30 days (14 times risk), urine catheterisation (14 times risk), emergency surgery (8 times risk), valvular replacement (4 times risk), high qSOFA score (3 times risk), and advanced age (1 time risk) (Erdem et al., 2025). In the African setting risk factors included deranged functions such as hypotension preoperatively, postoperative use of vasopressor or assisted ventilation, and abnormal renal function (Okidi et al., 2024).

Effectiveness of antiseptics agents

For preoperative skin preparation, there are several antiseptic solutions used in clinical practice and include Iodine based (Povidone iodine, iodophor), alcohol and chlorhexidine gluconate, olanexidine.

Povidone iodine is a broad spectrum antiseptic active against microorganisms such as viruses, bacteria, fungi, protozoa, does not impede wound healing, is able to penetrate biofilms, and less susceptible to resistance. Chlorhexidine has similar activity to povidone iodine thou considerably less effective against spores and actinobacteria (Bigliardi et al., 2017). Despite these subtle differences, overall numerous authors have shown that chlorhexidine is more overall effectiveness compared to povidone iodine (Peristeri et al., 2023; Deng et al., 2025; Hsieh et al., 2025).

Despite these antiseptic agents being effective against a range of microorganisms, the technique of application of these agents may also affects the effectiveness

Recommendations for skin preparation

World Health Organisation (WHO), the US Centre for Disease Control and Prevention (CDC) and UK National Institute for Health and Care Excellence (NICE) all provide conflicting statements on antiseptic choice for skin preparation and there is lack of consensus on concentration. While WHO and UK NICE propose the use of chlorhexidine in alcohol for preoperative skin preparation, US CDC advocates for any alcohol-based solution (Jalalzadeh et al., 2022).

For surgical site skin preparation, the latest WHO global guidelines for prevention of SSI recommends using chlorhexidine gluconate which is an alcohol based antiseptic agent (WHO, 2018). Despite these recommendations a number of jurisdictions still use CHG and one or more antiseptics to enhance the antimicrobial effectiveness. For instance, Zambia traditionally uses a 3 three field antiseptic technique (CHG, PVI and Methylated spirit) for preoperative skin preparation of composition of 3% to 5% chlorhexidine gluconate (aqueous based) and 10% strength of povidone iodine solution.

Study Justification

SSIs increase hospital stay, morbidity and healthcare costs. While three field antiseptic preparation may offer better microbial reduction than two field, most studies show no significant difference in reducing SSI. In addition, the cost and resource use for three-field are significantly higher. This study's results will guide evidence-based practice and highlight the potential cost-saving benefits hence helping to promote more cost-effective surgical procedures.

Main Objective

To compare the incidence of surgical site infections among patient undergoing open abdominal surgery after two field aseptic cleaning versus three field aseptic cleaning.

Specific Objectives

- Determine the incidence of surgical site infections among patient undergoing open abdominal surgery after two field aseptic cleaning
- Determine the incidence of surgical site infections among patient undergoing open abdominal surgery after three field aseptic cleaning
- Identify the causative organism for surgical site infections among patient undergoing open abdominal surgery

Hypothesis

Null: There is no difference in the incidence of SSI after open abdominal surgery for two field and three field antiseptic skin preparation

LITERATURE REVIEW

This section explores surgical site infections rates stratified according to different antiseptic options to compare aqueous versus alcohol based, chlorhexidine versus povidone iodine, single antiseptic versus multiple antiseptics and various antiseptic concentrations. The section also identifies risk factors and commonly isolated organisms.

Antiseptics and Common Isolated Organisms

Preoperative skin antisepsis is a cornerstone of SSI prevention. A prospective study by Roth et al. (2020) involving non-emergency patients undergoing cardiac or abdominal surgery assessed the microbial reduction using alcohol-based solutions—either chlorhexidine or povidone iodine. Swabs taken before antisepsis and after each of three applications showed a progressive reduction in Colony Forming Units (CFUs), with the majority of patients having no CFUs after the third application. However, there was no significant difference in microbial reduction between the two-field and three-field techniques, and the study did not examine SSI or its risk factors (Roth et al., 2020).

Alcohol-Based vs Aqueous-Based Skin Preparation

Various authors have evaluated alcohol-based versus aqueous antiseptic solutions in abdominal surgery. The general consensus is that alcohol-based solutions significantly reduce SSI rates and are superior to aqueous-based options (Charles et al., 2017; Peristeri et al., 2023). Charles et al. (2017) compared 0.5% chlorhexidine in 70% alcohol to aqueous chlorhexidine for minor skin excisions. The alcoholic formulation showed slightly better outcomes, with an SSI rate of 6.3% and a relative risk of 0.85. Despite adverse effects like ocular irritation and contact dermatitis, S. aureus, P. aeruginosa and pan-sensitive S. aureus were isolated.

Chlorhexidine Gluconate vs Povidone Iodine

A randomised trial by Luwang et al. (2021) involving 311 women undergoing caesarean sections compared 2% chlorhexidine-alcohol to 10% aqueous povidone iodine. Preoperative skin preparation utilised skin painting starting from the planned surgery site using gentle pressure with outward circular motion to reach the peripherals. A 3 minutes wating period was allowed after the antiseptic was applied. For each patient, a swab before and after antiseptic skin preparation was collected. Though the chlorhexidine-alcohol group had a lower SSI rate (5.4% vs 8.6%), the difference was not statistically significant. Common organisms included gram-negatives like E. coli, A. baumannii, and K. pneumoniae (Luwang et al., 2021).

Whitham et al. (2018), through a systematic review and meta-analysis found chlorhexidine-alcohol significantly reduced SSI risk by 28% (RR 0.72; 95% CI: 0.52–0.98) compared to povidone iodine. However, subgroup analysis revealed no significant difference for deep (RR 0.50) or superficial (RR 0.76) SSIs (Whitham et al., 2018).

Conversely, Hsieh et al. (2025) reported no significant difference in SSI between alcohol-based chlorhexidine and alcohol-based povidone iodine in abdominal surgeries, including subgroups like obstetrics/gynaecology, general surgery and clean-contaminated wounds (Hsieh et al., 2025). Notably, the difference with the Whitham et al. (2018) study stems from the type of povidone iodine used, aqueous versus alcohol-based which suggests that alcohol-based antiseptics, regardless of type, may offer greater protection.

Concentration and Combination of Antiseptics

A review by Yang et al. (2024) evaluated chlorhexidine-alcohol in varying strengths (0.5%–4%) combined with either aqueous or alcohol-based povidone iodine. Chlorhexidine-alcohol of strength 2% to 2.5% was the most effective in reduction of antimicrobial activity and incidence of SSI for both clean and non-clean procedures due to consistent significant lower relative risks across studies (Yang et al., 2024).

Few studies have investigated sequential or combination antiseptics. Ngai et al. (2015) and Davies & Patel (2016) explored the use of sequential povidone iodine and chlorhexidine gluconate and showed enhanced antimicrobial activity though not statistically significant (Ngai et al., 2015; Davies & Patel, 2016). No study has yet examined the use of three sequential antiseptics such as chlorhexidine, povidone iodine, and methylated spirit.

Application Techniques for Antiseptic Agents

The application technique for preoperative skin preparation is equally important for prevention of SSI. However, there is a paucity of data on application techniques for preoperative antisepsis skin preparation hence this implies certain current practice may be traditional practices passed down over the years (Humzah, 2023). The sequence of application and whether to scrub, paint, smear or flood the surgical site with the antiseptic solution; if two or more antiseptics are used, how long to leave each antiseptic before applying the next; waiting period before first incision is made are all important variations to consider. Most trials report that application techniques are comparable and show no difference in rates of surgical site infection reported. Hence the application technique is inconsequential to the development of SSI (Kamel et al., 2012; WHO, 2016).

SSI and Type of Surgery

Surgical approach also influences SSI incidence. Studies by Caroff et al. (2019) and Kulkarni & Arulampalam (2020) show that laparoscopic surgery has a lower SSI rate than open abdominal surgery, largely due to smaller incisions and faster recovery (Caroff et al., 2019; Kulkarni & Arulampalam, 2020). However, for the current study, focus remains on open abdominal surgery, which is associated with higher SSI risk.

Wound Irrigation in Clean-Contaminated Procedures

Traditionally, WHO has recommended irrigating clean-contaminated wounds with aqueous 10% povidone iodine before final skin closure. However recent advances in surgical techniques especially Enhance Recovery After Surgery (ERAS) protocols warrant re-exploration of this guidance (Maemoto et al., 2021). This view was supported by another controlled trial which showed that the incidence incisional SSI where slightly higher at 7.6% for patients who underwent irrigation with aqueous 10% povidone iodine compared to saline before final skin closure for clean contaminated wounds after gastrointestinal surgery (Maemoto et al., 2021).

Risk Factors for Surgical Site Infection

SSI risk varies based on patient and procedural characteristics. Modifiable risk factors are few and include obesity and smoking (Xu et al., 2021; Marzoug et al., 2023; Doan et al., 2025), while non-modifiable ones include male gender, ASA score ≥3, emergency or open surgery, wound classification, diabetes mellitus, inflammatory bowel disease, blood transfusion, stoma formation, and surgery lasting over 3 hours (Xu et al., 2021). Interestingly, Xu et al. found no association between SSI and respiratory comorbidities or neoplasms. Different SSI types also have distinct risk profiles; for instance, stoma placement correlates more with incisional SSIs, while obesity and transfusion are stronger predictors for organ/space infections.

Summary of Findings

Evidence shows alcohol-based antiseptics are superior to aqueous solutions for reducing SSI, with chlorhexidine gluconate outperforming povidone iodine. Some facilities still combine antiseptics, enhancing microbial kill without conclusive superiority. While application techniques show minimal impact on SSI, standardisation remains limited. Risk factors for SSI are often non-modifiable, though efforts to manage modifiable ones are essential. Finally, while most settings use single antiseptic agents, limited data exist on using multiple agents—particularly the combination of aqueous chlorhexidine, povidone iodine, and methylated spirit hence creating a knowledge gap that this study aims to address. Hence the purpose of this study is to compare surgical site infections for patients undergoing open abdominal surgery by comparing two field versus three field aseptic techniques. Two field will comprise of aqueous chlorhexidine and methylated spirit and three field will consist of two field and povidone iodine.

METHODOLOGY

Study Design

A multicentre prospective cohort study will be conducted in the department of surgery in the study sites and will involve two groups. Both groups will include patients undergoing abdominal surgery with the first group using the traditional 3 field aseptic technique and the second group using the two field aseptic technique. The traditional 3 field aseptic technique utilises chlorhexidine, povidone iodine and methylated spirit while the two field for this study will be chlorhexidine and povidone iodine. Individuals exposed to either the two or three field technique will then be followed within 30 days to determine surgical site infections (i.e., the outcome). The post operative followup schedule will be at: 48 hrs, 14 days and 30 days. This study was designed in accordance with the 2018 World Health Organisation (WHO) Global guidelines for the prevention of surgical site infection. This study type was chosen because it is better suited to answer the research question by allowing real-time observation of SSI incidence across diverse hospital settings while minimising recall bias and enhancing generalisability of findings across multiple provinces.

Study sites

A multicentre interprovincial approach will be utilised, healthcare facilities include Roan Antelope General Hospital (RAGH), Ndola Teaching Hospital (NTH) in Copperbelt province, Mansa General Hospital (MGH) in Luapula province, St Francis Mission Hospital (SFMH) in Eastern Province and Solwezi General Hospital in North Western province, Lewanika General Hospital in Western Province, Levy Mwanawasa Teaching Hospital in Lusaka Province and Livingstone General Hospital in Southern Province. These facilities were chosen because they are the largest in their provinces. The estimated bed capacity is 164, 800,404, 386,202, 200, 850 and 350 respectively and obtained from various studies. These hospitals all provide surgical services to their catchment areas.

Target Population

The target population is all individuals undergoing surgery at the study sites while the study population is all patients undergoing elective abdominal surgery at the study sites.

The Intervention

Prerequisites to the intervention include standard operating procedures for infection prevention such as hand washing using soap or alcohol solution, and use of the WHO surgical checklist.

This study will compare the SSI incidence when using two field aseptic technique (aqueous Chlorhexidine and Methylated spirit) versus the traditional three field (aqueous Chlorhexidine, aqueous Povidone iodine and Methylated spirit).

Antiseptic application technique

Sequential application starting with chlorhexidine then povidone iodine and lastly methylated spirit. The traditional scrub technique will be employed.

Composition and types of antiseptics

For this study only aqueous based chlorhexidine or aqueous based povidone iodine will be used. Concentrations between 2% to 5% chlorhexidine gluconate are commercially available and 10% povidone iodine will be used. Methylated spirit consists of methanol and ethanol. For intraoperative wound irrigation, only 10% povidone iodine will be employed. Alcohol based preoperative antiseptic solutions for skin preparation such as Chlorhexidine-alcohol or povidone iodine in alcohol are not commercially available in Zambia and will not be used for this study (ZAMRA, 2025).

Intraoperative irrigation

All patients in the study to undergo intraoperative irrigation with 10% povidone iodine prior to final skin closure as per WHO recommendation. However, case by case use of abdominal lavage using povidone iodine or normal saline as determined by the operating surgeon will not be considered in this study.

Outcome

Primary outcome: Proportion of Surgical site infection (%) and this will be calculated as number of patients having SSI divided by the total number of patients undergoing elective abdominal surgery

Sample size

The required sample size to compare SSI incidence between the two antiseptic techniques is 1054 patients. The sample size was calculated using the Epitools calculator (https://epitools.ausvet.com.au/twoproportions) for comparing two independent proportions after applying the Fleiss method for continuity correction. The parameters used were 80% power, α = 0.05, equal group sizes and assuming 10% vs 5% proportions for two field versus three field techniques. The assumed SSI rates are compared with the African region rates of 7.2% (Mengistu et al., 2023). An initial 948 was calculated, however, to account for a 10% potential data loss or non-response especially when patients are followed over time to mimic real life clinical scenarios, the sample was increased to 1,054 participants. This sample size was proportionally distributed across the five referral hospitals based on their bed capacity as follows.

Institution	Beds	% of total beds (1956)	Allocated sample (of 960)
Ndola Teaching Hospital (NTH)	800	22.6%	238
Mansa General Hospital (MGH)	404	11.4%	120

St Francis Mission Hospital (SFMH)	386	10.9%	115
Solwezi General Hospital (SGH)	202	5.7%	60
Lewanika General Hospital	200	5.6%	60
Levy Mwanawasa Teaching Hospital	850	24.0%	253
Livingstone General Hospital	350	9.9%	104
Roan Antelope General Hospital (RAGH)	350	9.9%	104
TOTAL	3542	100.0%	1054

Data collection, each study site will continue until the calculated minimum sample size is achieved as this will ensure adequate statistical power to detect differences in the incidence of surgical site infections between the two exposure groups. However, to enhance the precision of the estimates and maximise the robustness of study findings, where feasible participant enrolment will be sustained throughout the planned 12-month period, even if the minimum sample size is reached earlier. This approach aligns with good epidemiological practice, enabling more comprehensive data capture while maintaining the original study design and ethical commitments.

Inclusion and Exclusion criteria

All patients > 18 years undergoing elective abdominal surgery will be eligible for inclusion. Those undergoing emergency abdominal surgery, patients undergoing surgery for orthopaedics, obstetrics, or urology, patients with surgical site infections from surgery not done at the study site, individuals < 18 years, pregnancy will be excluded

Data collection tool

The WHO "surgical site infection surveillance post operative data collection form" will be utilised. This is a validated tool which contains patient demographics, follow up schedule, types of surgical site infections such as superficial, deep or organ and other surgical complications. Laboratory information is also included in form of organisms identified and sensitivity pattern. Additional information will be obtained from the patient file to include ASA score, smoking status, surgical history, type and duration of surgery, and comorbidities. Permission to use the data collection tool will be obtained from WHO. All data will be exported from the online data collection servers.

Data collection process

Data collection will be conducted from 1st January 2026 to 30th June 2026. Each healthcare facility will have a focal point person (the surgeon) for the study and will lead the research activities in their hospital. For each healthcare facility, eligible individuals scheduled for elective surgery will be approached and the purpose of the study explained, thereafter written consent will be obtained. A designated room such as any office for the surgery department in the study sites will be utilised to ensure privacy and confidentiality. The detailed history and physical examination for each participant will be collected prior to the scheduled operation

and will include information relevant to fill in the **online** data collection tool via Research Electronic Data Capture (REDCap). At each study site, if the first patient is arbitrarily assigned to the two-field group, the next is assigned to the three-field group then alternating thereafter until the desired sample size is reached. For each patient who has undergone abdominal surgery, the standard post operative principles of wound cleaning once a day and wound dressing will be followed. The clinical features of SSI include unwell patient, fever > 38°c, red or warm skin, localised wound breakdown or wound swelling, pain beyond normal for operation, drainage of fluid from wound such as pus, serous or bloody (WHO, 2018). Whilst admitted, all patients will be reviewed every morning by medical officers during ward rounds and SSI is diagnosed when a patient has or complains of any one of the clinical feature listed above within 30 days of an operation. The clinical features for the diagnosis of SSI will be confirmed by an independent physician to reduce bias. Confirmation will be done via laboratory after a pus swab using microscopy culture and sensitivity test. Pus swabs will be collected by any senior surgery department staff and will be also be oriented before the start of the study. The details will then be entered in the data collection tool.

All abdominal surgery patients will be kept in the hospital for a minimum of two days before discharge to allow for the first follow up review and data collection. For patients who are discharged, further data will be collected during the followup period at 14 days and 30 days. However, for deep surgical site infection and organ specific, followup may be extended to 90 days with followup at 60 days and 90 days. For patients who may not be able to make it for their scheduled review, they will be contacted and interviewed via telephone to assess for the clinical features of SSI. Patients with positive features will be requested to come to the hospital for further investigations. Each data collection sheet will be cross-checked and electronically signed by the attending surgeon.

In each study site, the attending surgeon and three surgery department ward nurses will be oriented on the online data collection tool. The attending surgeon will however be required to confirm SSI to minimise interrater variability in each study site.

Laboratory analysis

All samples collected from the various study sites will be sent to an (ISO 15189:2022) accredited lab at National Health Research and Training Institute (NHRTI) in Ndola. As per Standard Operating Procedure (SOP's), the dacron swab samples will be ferried via specific transport medium using a triple-packaging system, and maintaining a cold chain to ensure sample integrity and safety. At the lab, samples will be subjected to microscopy culture and sensitivity. Furthermore, all cultured SSI will be subjected to gene sequencing.

Data analysis

Data will be analysed using SPSS version 29. The dependent variable will be proportion of surgical site infection coded a percentage, while predictor variables will include demographics (patients age, sex, residence), clinical details (ASA score, smoking status, type and duration of

surgery, comorbidities such as hypertension, cardiac disease, diabetes, functional status, immunocompromising illnesses, surgical history, hospital stay duration, type of wound), followup date, organism identified and sensitivity results.

The incidence of SSI during the data collection period will be calculated as follows:

$$\text{SSI Incidence} = \frac{\text{Number of new SSI after elective abdominal surgery}}{\text{Total number of elective abdominal surgery}} \times 100$$

Descriptive statistics will be presented using proportions, mean and standard deviation. Inferential statistics will be done using Z test for two proportions (if normally distributed) or Mann Whitney u test (if not normally distributed) which will test the hypothesis that ‘there is no difference in the proportion of SSI when comparing two field versus three field antiseptic technique’. Binary logistic regression analysis using the standard ‘enter’ method will be employed to assess for risk factors for SSI in both groups. For all analysis, a two tailed p value of 0.05 will be used for statistical significance. Subgroup analysis will be done by operation type, comorbidity status, and institutions to assess whether the effect of antiseptic technique on SSI incidence varies across strata. Within each subgroup, the proportion of SSI will be compared between the two techniques using the Z-test for two proportions. Interaction terms will be assessed using logistic regression

Ethics

Ethical approval was obtained from the National Health Research and Training Institute in Ndola (NHRTREC/217/10/25). Gate keeper permission will be obtained from the various Provincial Health Offices and healthcare facilities. The National Health Research Authority will also be informed as guided by the laws of the land. Confidentiality and privacy will be maintained as all records will be store in a password protected computer with restricted access to only the research team. All ethical principles for the study will be guided via the Declaration of Helsinki.

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APPENDIX

APPENDIX 1 – DATA COLLECTION SHEET

1 DEMOGRAPHICS **ID……………**

Age (years): ……………………………………

Gender: ☐Male ☐Female

Residence (District only): ……………………………………………

Marital status: ☐Married ☐Unmarried

Referral: ☐Yes ☐No If yes facility name: ………………………………

2 CLINICAL DETAILS

Social History

Smoking (since January 2024): ☐Yes ☐No

Alcohol (since January 2024): ☐Yes No

Comorbidities

Haemoglobin (g/dl): …………………

HIV: ☐Yes ☐No

Diabetes Melitus: ☐Yes ☐No

Hypertension: ☐Yes ☐No

Other, specify ……………………………………………………………………………

Surgical History

Any previous (abdominal) surgery: ☐Yes ☐No

If yes, specify type ………………………………………………………………………

3 SURGERY DETAILS

Pre-Operative antibiotic: ☐Yes ☐No Shaving within 24 hours: ☐Yes ☐No

Bathing within 24 hours: ☐Yes ☐No

ASA classification: ☐I ☐II ☐III ☐IV ☐V ☐VI

Type of wound: ☐Clean ☐Clean contaminated ☐Contaminated ☐Dirty

Functional status (ECOG status): ☐0 ☐1 ☐2 ☐3 ☐4 ☐5

Drainage: ☐Yes ☐No

Name of Operation: ……………………………………………………………………………………………………

Indication for Operation: ………………………………………………………………………………………………

Date of Operation: ………………………………………………………………………………………………………

Done by: ☐JRMO ☐SRMO ☐Registrar ☐Consultant surgeon

Chlorhexidine strength %______ Povidone iodine strength %______

4 FOLLOWUP PERIOD (If yes to any SSI fill in section 6 below)

Follow-up period	Surgical site infection		Follow-up method	
48 hours	☐Yes	☐No	☐Physical	
14 Days	☐Yes	☐No	☐Physical	☐via telephone
30 Days	☐Yes	☐No	☐Physical	☐via telephone
Other (60 days):	☐Yes	☐No	☐Physical	☐via telephone
Other (90 days):	☐Yes	☐No	☐Physical	☐via telephone

5 SURGICAL SITE INFECTION DETAILS (To be filled in if patient has a surgical site infection)

Surgical site infection screening questions

unwell patient   Fever > 38°c   Red or warm skin   Localised wound breakdown
Wound swelling   Pain beyond normal for operation   Drainage of fluid from wound
such as pus, serous or bloody

Patient re-admitted for Surgical Site Infection? ☐ Yes ☐ No (note reason) ....

Date of re-admission for Surgical Site Infection: ...../...../......... Discharge date: ...../...../.........

☐ **Superficial SSI** (skin/subcutaneous) e.g. cellulitis	☐ **Deep SSI** (fascia/muscle) e.g. deep abscess	☐ **Organ/space SSI**** Deeper than fascia/muscle e.g. endometritis (organ), peritonitis (space)
☐ Purulent drainage (pus) from superficial incision **OR** ☐ Organism identified (if culture done)* **OR** ☐ Superficial incision deliberately re-opened **AND** ☐ Infection symptoms[1] **OR** ☐ Surgeon/attending physician diagnosis	☐ Purulent drainage (pus) from deep incision **OR** ☐ Deep incision dehiscence or deliberately opened by surgeon **AND** ☐ Organism identified (if culture done)* **AND** ☐ Infection symptoms[1] **OR** ☐ Deep infection/abscess found on imaging/examination	☐ Purulent drainage (pus) from sterile organ or space (from an inserted drain) **OR** ☐ Organ or space infection/abscess found on imaging/examination **OR** ☐ Organism identified from fluid/tissue from organ/ space*

Other surgical complications

☐ Non-infectious **local** wound complications including bleeding and abnormal skin reactions

☐ Patient death: Date ...../...../......... Cause of death (as far as known) ....

Microbiology culture results*	**Specimen taken** Date...../...../.......... type.............	**Organism(s) identifed**	**Antibiotic resistance/sensitivities**

*Note: most surgical wounds that have broken down rapidly become colonized with bacteria. Bacterial growth from a wound is only significant when a sample to identify organisms by microbiological culture is collected aseptically under sterile conditions with symptoms of infection also present.

**List of specific organ/space infection sites

Code	Site	Code	Site
BONE	Osteomyelitis	MED	Mediastinitis
BRST	Breast abscess or mastitis	MEN	Meningitis or venticulitis
CARD	Myocarditis or pericarditis	ORAL	Oral cavity (mouth, tongue, or gums)
DISC	Disc space	OREP	Other infections of the male or female reproductive tract
EAR	Ear, mastoid	PJI	Periprosthetic joint infection
EMET	Endometritis	SA	Spinal abscess without menigitis
ENDO	Endocarditis	SINU	Sinusitis
GIT	Gastrointestinal tract	UR	Upper respiratory tract
IAB	Intraabdominal, not specified	USI	Urinary System infection
IC	Intracranial, brain abscess or dura	VASC	Arterial or venous infection
JNT	Joint or Bursa	VCUF	Vaginal cuff
LUNG	Other infections of the lower respiratory tract		

To understand specific criteria for defining these infections please refer to CDC/NHSN Surveillance Definitions for Specific Types of Infections https://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf

APPENDIX 2 – INFORMATION SHEET

Research title: Surgical site infections comparing two field versus three field antiseptic skin preparation for abdominal surgery: A multicentre prospective cohort study

Study locations: Roan Antelope General Hospital, Ndola Teaching Hospital, Mansa General Hospital, St Francis Mission Hospital, Solwezi General Hospital, Lewanika General Hospital, Livingstone General Hospital and Levy Mwanawasa Teaching Hospital.

Principal Investigator:	Research Coordinator:	Study Site coordinator:
Dr Maka Silungwe	Dr Imukusi Mutanekelwa	……………………………………….…
Organisation: Roan Antelope General Hospital	**Organisation:** Roan Antelope General Hospital	………………………………………
P O Box 90297	P O Box 90297	**Organisation:**
Luanshya	Luanshya	……………………………………….
Zambia	Zambia	……………………………………….
+260975511290	+260977855076	…………………………………………
makasilungwe@yahoo.com	Kusi789@gmail.com	……………………………………….
		…………………………………………
		…………………………………………

RAGH Surgery Team: Dr Jeremiah Chilunjika, Dr Elizabeth K. Ngulube, Dr Naomi Mweemba, Dr Simon Mugwagwa

PART I: Information Sheet

Introduction

*I am Dr Maka Silungwe, a consultant surgeon working at Roan Antelope General Hospital with our team in more than six other sites (*Roan Antelope General Hospital, Ndola Teaching Hospital, Mansa General Hospital, St Francis Mission Hospital, Solwezi General Hospital, Lewanika General Hospital, Livingstone General Hospital and Levy Mwanawasa Teaching Hospital*). Each of these sites has a study coordinator who will be handling the research affairs. We are doing a research on surgical site infections which is very common in our country Zambia. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.*

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

Surgical site infection occur within 30 days after an operation, they are quite common with 7 out of 100 people having developing surgical site infections in Zambia and they have serious consequences when they occur. One way to prevent surgical site infections is through preoperative skin preparation using antiseptics. While the World Health Organisation promotes the use of one antiseptic solution for skin preparation, as a country we still use three antiseptic solutions despite constraints in resources in always ensuring all three are available.

The reason we are doing this research is to find out if using two antiseptics for skin preparation is the same as using three antiseptics.

Type of Research Intervention

This research will involve some participants using two antiseptics versus three antiseptics before any non-emergency abdominal surgery as well as four follow-up visits at our hospital

Participant selection

We are inviting all adults scheduled for elective abdominal surgery in the research for surgical site infections comparing the use of two antiseptics versus three antiseptics.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for post-operative patients, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Information on the Antiseptics

The three antiseptics currently used in Zambia include chlorhexidine gluconate, 10% povidone iodine and methylated spirit. The World Health Organisation recommends using only chlorhexidine gluconate as it also contains alcohol which is the active ingredient in methylated spirit. In addition, research shows that chlorhexidine and povidone iodine are comparable in their antiseptic activity. Before abdominal surgery some participants in this research will be cleaned with two antiseptic (chlorhexidine gluconate and methylated spirit) and others with three antiseptics.

Duration

The research takes place over one (1) year from January 2026 to December 2026. Data will be collected from January to June 2026. During that time, it will be necessary for you to come to the hospital for your routine postoperative doctors review. We would like to meet with you for your routine postoperative doctors review for three times after you are discharged.
In total, you will be asked to come 3 times to the hospital in 1 month at 1 week, 2 weeks and lastly at 1 month. At the end of 1 month, the your participation in this research will be finished.

Risks

By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that you may develop a surgical site infection during the research. If however that happens, you will be administered antibiotics guided by drug and sensitivity results to treat you and any supportive medications to make you comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with more information.

Benefits
There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements
You will not be given any other money or gifts to take part in this research.

Confidentiality
With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the research team.

Sharing the Results
The knowledge that we get from doing this research will be shared with you through your hospital before it is made widely available to the public. Afterwards, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this hospital in any way. You will still have all the benefits that you would otherwise have at this hospital. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this hospital will not be affected in any way.

Alternatives to Participating
If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital. People who are undergoing abdominal surgeries are given

Who to Contact
If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Dr Imukusi Mutanekelwa, Roan Antelope General Hospital, +260977855076, kusi789@gmail.com or Dr Maka Silungwe, Roan Antelope General Hospital +260975511290, makasilungwe@yahoo.com

APPENDIX 3 – CERTIFICATE OF CONSENT

PART II: Certificate of Consent
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant___________________
Phone number of Participant________________
Signature of Participant ____________________
Date _____________________________
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness______________________ ***AND*** ***Thumb print of participant***
Signature of witness _______________________
Date __________________________
Day/month/year

Phone number of Participant________________

APPENDIX 4 – BUDGET

Research Activity	#	Monthly rate	12 Months Total
Personnel			
-	-	-	-
Lab consumables & tests			
Culture & sensitivity per sample	*160*	*2000/ sample*	*320,000*
Dacron swab sticks	*160*	*30/ sample*	*4,800*
Field work & travel		***Sub Total***	***110,000***
2 per site in 6 months (10 visits x 2 days = 20 days)	*10 sites*	*-*	*50,000*
Fuel per PI visit	*20 trips*	*3,000 per trip*	*60,000*
Data & Equipment		***Sub Total***	***85,000***
Laptops (x5)	*10*	*5,000 each*	*50,000*
Software (SPSS)	*1*	*-*	*15,000*
Printing & stationary			*20,000*
Training & Meetings		***Sub Total***	***65,000***
Initial site training			*25,000*
Quarterly data review	*4*	*10,000*	*40,000*
Admin & Overheads		***Sub Total***	***113,775***
Ethical clearance	*1*	*3,500*	*3,500*
Communications & internet	*12*	*2000*	*24,000*
Conference attendance	*1*	*30,000*	*30,000*
Contingency (5%)			*56,275*
TOTAL			***698,575***

APPENDIX 5 – GANNT CHART

Research Activity (2025 - 2026)	***MONTH (starting from July 2025 to November 2026)***																
	J	***A***	***S***	***O***	***N***	***D***	***J***	***F***	***M***	***A***	***M***	***J***	***J***	***A***	***S***	***O***	***N***
Finalise study protocol																	
Apply for ethical approval																	
Apply for NHRA approval																	
Apply for provincial permission																	
Apply for facility permission																	
Identify site coordinator																	
Orientation of research staff & tools																	
Finalise preparations																	
Data Collection begins & continues																	
Biweekly meeting for first six weeks then monthly afterwards																	
Monthly review online meeting																	
Preliminary data analysis																	
Data collection ends																	
Data cleaning and analysis																	
Results section																	
Discussion & conclusion																	
Review, comments and correction of final manuscript by all authors																	
Correction of manuscript																	
Submission of manuscript for publication																	
Conference presentation																	

APPENDIX 6 – REQUEST FOR ETHICAL APPROVAL

Ethic Review Committee
Ndola Teaching Hospital
Private Bag 1
Ndola

Roan Antelope General Hospital
P O Box 90297
Luanshya
Zambia

15 August 2025

Dear sir/madam

REQUEST FOR ETHICAL APPROVAL FOR MULTICENTRE COHORT STUDY

Refer to the above captioned subject. The principal investigator is Dr Maka Silungwe, +260975511290, makasilungwe@yahoo.com and the research coordinator is Dr Imukusi Mutanekelwa, +260977855076, kusi789@gmail.com both based at Roan Antelope General Hospital. *The details of the research are as follows;*

Research title: Surgical site infections comparing two field versus three field antiseptic skin preparation for abdominal surgery: A multicentre prospective cohort study

Objectives:

- Determine the incidence of surgical site infections among patient undergoing abdominal surgery after two field aseptic cleaning
- Determine the incidence of surgical site infections among patient undergoing abdominal surgery after three field aseptic cleaning
- Identify the causative organism for surgical site infections among patient undergoing abdominal surgery
- Make recommendation to minimise surgical site infections

Study locations: Roan Antelope General Hospital, Ndola Teaching Hospital, Mansa General Hospital, St Francis Mission Hospital, Solwezi General Hospital, Lewanika General Hospital, Livingstone General Hospital and Levy Mwanawasa Teaching Hospital

I hereby request for ethical approval, find attached the study protocol to guide your decision.

Yours sincerely,

Dr Maka Silungwe
+260975511290,
makasilungwe@yahoo.com

APPENDIX 7 – PROVINCIAL HEALTH OFFICE GATEKEEPER PERMISSION

The Provincial Health Director
…………………………………….. Provincial Health Office
P O Box …………………………..
……………………………………..

Roan Antelope General Hospital
P O Box 90297
Luanshya
Zambia

27th October 2025

Dear sir/madam

REF: PERMISSION TO CARRY OUT A MULTICENTRE COHORT STUDY IN THE PROVINCE

Refer to the above captioned subject. The principal investigator is Dr Maka Silungwe, +260975511290, makasilungwe@yahoo.com and the research coordinator is Dr Imukusi Mutanekelwa, +260977855076, kusi789@gmail.com both based at Roan Antelope General Hospital. *The details of the research are as follows;*

Research title: Surgical site infections comparing two field versus three field antiseptic skin preparation for abdominal surgery: A multicentre prospective cohort study

Objectives:

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- Identify the causative organism for surgical site infections among patient undergoing abdominal surgery
- Make recommendation to minimise surgical site infections

Study locations: Roan Antelope General Hospital, Ndola Teaching Hospital, Mansa General Hospital, St Francis Mission Hospital, Solwezi General Hospital, Lewanika General Hospital, Livingstone General Hospital and Levy Mwanawasa Teaching Hospital

I hereby request for permission to carry out the study in the province, find attached the study protocol to guide your decision.

Yours sincerely,

Dr Maka Silungwe
+260975511290,
makasilungwe@yahoo.com

APPENDIX 8 – FACILITY GATEKEEPEER PERMISSION

The Medical superintendent
…………………………………………………………………. Hospital
P O Box …………………………..
………………………………………..

Roan Antelope General Hospital
P O Box 90297
Luanshya
Zambia

27th October 2025

Dear sir/madam

REF: PERMISSION TO CARRY OUT A MULTICENTRE COHORT STUDY AT THE FACILITY

Refer to the above captioned subject. The principal investigator is Dr Maka Silungwe, +260975511290, makasilungwe@yahoo.com and the research coordinator is Dr Imukusi Mutanekelwa, +260977855076, kusi789@gmail.com both based at Roan Antelope General Hospital. *The details of the research are as follows;*

Research title: Surgical site infections comparing two field versus three field antiseptic skin preparation for abdominal surgery: A multicentre prospective cohort study

Objectives:

- Determine the incidence of surgical site infections among patient undergoing abdominal surgery after two field aseptic cleaning
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- Identify the causative organism for surgical site infections among patient undergoing abdominal surgery
- Make recommendation to minimise surgical site infections

Study locations: Roan Antelope General Hospital, Ndola Teaching Hospital, Mansa General Hospital, St Francis Mission Hospital, Solwezi General Hospital, Lewanika General Hospital, Livingstone General Hospital and Levy Mwanawasa Teaching Hospital.

I hereby request for permission to carry out the study in the facility, find attached the study protocol to guide your decision. Take note that authorship will be given to the various Medical Superintendents.

Yours sincerely,

Dr Maka Silungwe
+260975511290,

makasilungwe@yahoo.com

APPENDIX 9 – NHRA: REQUESST FOR AUTHORITY TO CONDUCT STUDY

National Health Research Authority
P O Box 30075
Lusaka
Zambia

Roan Antelope General Hospital
P O Box 90297
Luanshya

27th October 2025

Dear sir/madam

REF: REQUEST FOR AUTHORITY TO CONDUCT RESEARCH

Refer to the above captioned subject. The principal investigator is Dr Maka Silungwe, +260975511290, makasilungwe@yahoo.com and the research coordinator is Dr Imukusi Mutanekelwa, +260977855076, kusi789@gmail.com both based at Roan Antelope General Hospital. *The details of the research are as follows;*

Research title: Surgical site infections comparing two field versus three field antiseptic skin preparation for abdominal surgery: A multicentre prospective cohort study

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Study locations: Roan Antelope General Hospital, Ndola Teaching Hospital, Mansa General Hospital, St Francis Mission Hospital, Solwezi General Hospital, Lewanika General Hospital, Livingstone General Hospital and Levy Mwanawasa Teaching Hospital

I hereby request for permission to carry out the study, find attached the study protocol to guide your decision.

Yours sincerely,

Dr Maka Silungwe
+260975511290,

makasilungwe@yahoo.com