A Research Proposal Submitted to the Faculty of Obstetrics and Gynaecology,
National Postgraduate Medical College, in Partial Fulfilment of the
Requirements for the Part II Fellowship Examination of the College.

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CERTIFICATION PAGE

We hereby declare that the contents of this Proposal were conceptualized and developed after a problem identification and discussion with us by the candidate. We supervised the conduct of the study, analysis of the data and write-up of the final report. We are certain that the candidate did the study conscientiously.

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Re: “Vaginal cleansing with antiseptic solution prior caesarean section and effect on preventing post-operative infections: a randomized control trial”.

I am pleased to inform you that a renewal of approval to continue with the above named study is hereby given.

This renewal is for one year and will accordingly lapse on 31st December 2017.

Best Wishes.

Dr. M Iamda
Chairman (UATH HREC)
ABBREVIATIONS

1. CS…………………………………………….…Caesarean section
2. CDC……………………………………………..Center for Disease control and prevention
3. EDD……………………………………………….Expected date of delivery
4. EGA……………………………………………….Estimated gestational age
5. ICD-10…………………………………………..International classification of diseases
6. IV. ........................................................intravenous
7. i.e........................................that is
8. LMP.....................................................last menstrual period
10. PCV.....................................................packed cell volume
11. RCOG................................................Royal college of obstetrics and gynaecology.
12. SCBU................................................Special care baby unit
13. SPP....................................................Species
14. SSI.....................................................Surgical site infections
15. VE....................................................Vaginal examination
16. %.................................................... Percentage
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ABSTRACT

Background

Caesarean delivery is one of the most common surgical procedures performed by Obstetricians. Post-operative infections following Caesarean delivery could cause maternal morbidity and mortality. Despite the widespread use of prophylactic antibiotics, post-operative infectious morbidity still complicates caesarean deliveries.

Objective

To determine if cleansing the vagina with an antiseptic solution before a caesarean delivery decreases the risk of maternal infectious morbidities including endometritis and wound infection.

Materials and methods

This was a randomized control trial of pregnant women who had emergency caesarean section at University of Abuja Teaching Hospital, Gwagwalada. They were recruited by simple random sampling. All consecutive pregnant women at ≥ 28 weeks gestational age with an indication for emergency caesarean section were counselled for the study. The participants, who met the criteria and consented, were allocated to a study group by a non-blinded simple probability technique with allotment concealment. A total of 266 consecutive participants were recruited, each randomly picked a card in an envelope that assigned her to either control or povidone iodine group. There were 133 participants in the control group and another 133 in the povidone iodine group. At recruitment, bio-social data, gestational age, parity and indication for caesarean section were obtained. Vital signs including temperature and pulse rate were noted. After instituting spinal or general anaesthesia and before cleaning the patient, the participants in the povidone iodine group had their vagina cleansed by rotating once up to 360° with a swab on sponge holding forceps soaked with 10% povidone iodine solution. Such intervention was not done in the control group. The urethral catheter was passed after the vaginal cleansing if not passed earlier in the ward. The time interval between vaginal cleansing and skin incision was within 30 minutes. Routine antibiotics in the form of intravenous ceftriaxone 1000mg and metronidazole 500mg was administered immediately after skin incision. Duration of surgery was recorded. Post-
operatively, endometritis, wound infection and povidone side effects were looked for. SPSS version 20 was employed. Categorical data were analysed using Chi-square and Fisher exact test adjusted to odds ratio; mean values were analysed using t-test. The significance of an association was determined at P<0.05 and at 95% confidence interval.

**Result**

A total of 260 participants (131 in the control group and 129 in the povidone iodine group) were eventually analysed as 2 from control group and 4 from povidone iodine group were lost to follow up. Out of 131 participants in the control group 18 (13.7%) had endometritis compared to 4 (3.1%) out of the 129 participants in the povidone iodine group. Risk reduction for endometritis with povidone iodine was 8%; and 9 participants need to be treated to prevent one case of endometritis. Incidence of endometritis was significantly higher among participants with ruptured membranes in the control group 14 (77.8%), OR (CI) = 0.1 (0.01-1.2), p = 0.040. Also endometritis was significantly more among participants with prolonged labour of ≥24hrs duration in the control group 10 (55.6%), OR (CI) = 1.3(0.1-10.9), p = 0.041. Other demographic, obstetrics and surgical factors did not show any significant difference between the two groups. Wound infection was more in the control group (11/131 or 8.4%) than in the povidone iodine group (4/129 or 3.1%). Risk reduction of wound infection after using povidone iodine was 6.2%; and 20 participants need to be treated to prevent one case of wound infection. Wound infection was significant among participants with ruptured membranes in the control group 10 (90.9%); OR(CI)=0.3(0.01-0.7), p=0.033. Other demographic, obstetrics and surgical factors did not show any significant difference between the two groups.

No adverse effect was noticed from the use of povidone iodine.

**Conclusion**

Antiseptic vaginal preparation with 10% povidone iodine solution prior to emergency caesarean section, prevents post-caesarean endometritis and wound infection.

The procedure is safe, cheap, simple and easy to perform.
CHAPTER 1: INTRODUCTION

Caesarean delivery is one of the most common surgical procedures in obstetric practice and its incidence is rising worldwide probably due to fear of litigation and use of electronic fetal monitoring.\(^1\) Two separate studies in Nigeria showed caesarean section rate of 34.5% and 35.5% respectively.\(^2,3\) The caesarean section rate is 21.5% in UK and 29.5% in USA.\(^4,5\) Notwithstanding, it could be complicated with post-operative infections in the form of endometritis. This may spread locally to cause salpingitis, oophoritis, peritonitis and wound infection.\(^6,7\) It may cause bacteraemia which may progress to septicaemia and infect any other distant tissue, organ or system.\(^6,7\) Despite employing aseptic techniques and the widespread use of prophylactic antibiotics, these post-operative infectious morbidities still complicates caesarean deliveries.\(^8\)

Post-caesarean endometritis and its sequelae are often the result of the presence of bacteria in the vagina and cervix that move higher in the genital tract to infect the uterus.\(^9\) These bacteria have been shown to be responsible for failure of antibiotic prophylaxis during caesarean deliveries.\(^3\) Some antibiotics do not consistently eradicate some bacteria (such as *enterococci*) and the vagina has been shown to become colonized with antibiotic-resistant bacteria after preoperative surgical antibiotic prophylaxis.\(^10,11\) Vaginal cleansing solutions such as povidone iodine have very few side effects in general, with low rates of noted allergies or irritation symptoms.\(^8\) Studies comparing povidone iodine with chlorhexidine before uterine surgery showed lower morbidity in the iodine group with improved activity against anaerobic pathogens.\(^12,13\) However, results from other studies have shown otherwise.\(^14,15\) Furthermore, even though chlorhexidine is on WHO list of essential medicines,\(^16\) it did not meet the current European specifications for hand disinfectant as there was no significant difference in efficacy between its 4% solution and soap.\(^17\) Thus, povidone iodine was chosen for this study for its efficacy and safety over other antiseptic agents.\(^16,17\)
Studies on the use of antiseptic vaginal cleansing prior to caesarean section in Nigeria and other African countries are scarce. However, a recent study in Nigeria by Aworinde O et al on skin preparation (not vaginal cleansing) prior to caesarean section has demonstrated a slight reduction of SSI and less side effect in chlorhexidine-alcohol group than povidoniodinegroup.¹⁸ Currently, it is not a standard care to prepare the vagina with an antiseptic solution before caesarean delivery.⁸ By cleansing the vagina of bacteria before a caesarean delivery, there may be less of a bacterial load in the vagina that might cause infectious post morbidity operatively.⁸ In fact, Osborne and Wright demonstrated a decrease of 98% in vaginal flora with pre-operative vaginal cleansing using povidone iodine. Therefore, finding an easy and inexpensive method to reduce this risk could have a major public health impact in both developed and developing countries.⁸ The aim of this study is to assess the effect of vaginal preparation with antiseptic solution (povidone iodine) on prevention of post caesarean section infection.
1.1 Justification for the study

Post-caesarean infectious morbidity and mortality are said to be higher in developing countries including Nigeria.\(^8\) Most of these occur following emergency caesarean section.\(^8\) In a recent nationwide study on 998 maternal deaths and 1451 near-misses in Nigeria, puerperal sepsis is said to account for 14.2\% but with significantly high mortality index of 79.3\%.\(^{19}\) This has revealed that sepsis is better prevented than treated. This study has shown that vaginal cleansing with povidone iodine prior to emergency caesarean section can prevent post-operative endometritis (reducing the rate from 13.7\% in the control group to 3.1\% in the treatment group) and post-operative wound infection (reducing the rate from 8.4\% in the control group to 3.1\% in the treatment group). No side effects or adverse outcome was recorded from the use of povidone iodine.

Pre-operative vaginal preparation with povidone iodine was cheap, safe and easy to apply in this study as was described in other studies.\(^8\) It could therefore be recommended as a standard procedure in our environment and other low socio-economic countries to reduce economic burden, morbidity and mortality from post-caesarean section infections. Similar studies are scarce in Africa and thus this study may give room for geographical and racial information and comparison. The outcome of this study could also reaffirm outcome of similar studies done elsewhere.
2.0 CHAPTER 2: OBJECTIVES AND HYPOTHESES

2.1 The Aim:

The aim of this study was to determine if preparation of the vagina with an antiseptic solution (povidone iodine) before an emergency caesarean delivery decreases the risk of post-caesarean maternal infectious morbidities.

2.2 The Objectives:

1. To determine if cleansing the vagina with povidone iodine solution before an emergency caesarean delivery decreases the risk of post-caesarean endometritis.

2. To determine if cleansing the vagina with povidone iodine solution prior to emergency caesarean delivery decreases the risk of post-caesarean wound infection.

2.3 The Hypothesis:

2.3.1 Null Hypothesis

Vaginal preparation with antiseptic solution prior to emergency caesarean delivery does not prevent post-caesarean endometritis and wound infection.

2.3.2 Alternate Hypothesis

Antiseptic vaginal preparation with povidone iodine prior to emergency caesarean section does prevent post-caesarean endometritis and wound infection.
3.0 CHAPTER 3: LITERATURE REVIEW

3.1 BACKGROUND

Use of antisepsis for infection prevention has been employed many years ago.\textsuperscript{20} The ancient Egyptians were the first civilization to have trained clinicians to treat physical ailments.\textsuperscript{21} Medical papyri such as the Edwin Smith papyrus and the Ebers papyrus provided detailed information of management of disease, including wound management with the application of various potions and grease to assist healing.\textsuperscript{21,22} Hippocrates, the father of medicine, used vinegar to irrigate open wounds.\textsuperscript{23} Semmelweis, a Hungarian physician, demonstrated a five-fold reduction in puerperal sepsis by hand washing with chlorine solution between performing postmortem examinations and entering the delivery room.\textsuperscript{24} Joseph Lister recognized that antisepsis could prevent infection and in 1867, he placed carbolic acid into open fractures to sterilize the wound and to prevent sepsis.\textsuperscript{24} Several studies have shown povidone iodine to be a safe and effective antiseptic agent\textsuperscript{8,16,17} and this prompted its choice for this study.

Previous studies following vaginal antiseptic cleansing before a caesarean delivery with povidone iodine showed a varied outcome.\textsuperscript{8} A study of 5 randomized control trials showed that vaginal cleansing with povidone iodine prior to caesarean delivery significantly lowered the rates of post-caesarean endometritis overall, from 7.2\% in the control group to 3.6\% in the treatment group.\textsuperscript{8} Subgroup analysis showed more effect among women with ruptured membranes where the rate of endometritis was seen to decrease from 15.4\% in the control group to 1.4\% in the treatment group.\textsuperscript{8} There was no difference increase in infectious morbidity between women in labour versus women not in labour.\textsuperscript{8}

Studies elsewhere showed similar results,\textsuperscript{25,26,27} but no significant difference in the biodata.\textsuperscript{28} Conversely, studies done by Reid et al showed no reduction in infectious morbidity following pre-operative vaginal cleansing with povidone iodine.\textsuperscript{28} Sub group analysis by Reid et al also showed no difference between groups in maternal age, parity, race, education, prior caesarean section, type of anesthesia, labour before current caesarean section, number of vaginal examinations during labour, internal monitoring, prophylactic antibiotic use, gestational age at delivery, or payment status.\textsuperscript{29} None of these studies showed any form of adverse outcomes such as irritation, allergy, fever or wound complications.\textsuperscript{8,26-29} However,
the findings in the 5 randomized control trial has prompted Haas DM et al to recommend preoperative vaginal cleansing with povidone iodine before performing caesarean deliveries, especially in women whose membranes have ruptured. 

3.2 Post-operative infections following caesarean delivery

Post-operative infectious morbidities following caesarean section include wound infection and endometritis. Endometritis is the infection or inflammation of the endometrium. It can be obstetric or non-obstetric and it can be acute or chronic. Obstetric or postpartum endometritis occurs after delivery and it is an outcome of interest in this study. The symptoms can vary and include: fever, abdominal pain, offensive smelling lochia, postpartum haemorrhage, abnormal vaginal discharge, dyspareunia, dysuria and general malaise. Signs of endometritis include pyrexia, tachycardia, supra-pubic tenderness, adnexal tenderness and sometimes generalized abdominal tenderness if peritonitis had set in. Acute endometritis is characterised by the presence of more than five neutrophils in a 400 power field in the endometrial glands while Chronic endometritis is characterised by the presence of more than one plasma cell and lymphocytes in a 120 power field in the endometrial stroma. Usually microbes migrate from the lower genital tract and attack the endometrium. Spread occurs from there to the tubes and ovaries, causing salpingo-oophoritis. It may progress to peritonitis and wound infection.

Wound infection or surgical site infection (SSI) has been defined by centre for disease control to standardize data collection for the National Nosocomial Infections Surveillance (NNIS) program. Surgical site infections (SSIs) are classified and defined as follows:

**Superficial incisional SSI is when Infection involves only the skin and the subcutaneous tissue of incision. Examples include Superficial Wound infection without endometritis following caesarean section, etc.**

**Deep incisional SSI is when Infection involves deep tissues such as fascial and muscle layers; this also includes infection involving both superficial and deep incision sites and organ/space SSI draining through incision. Examples include Infection of the Skin Wound, subcutaneous tissues, uterine incision and endometrium (endometritis) following caesarean section.**
Organ/space SSI is when Infection involves any part of the anatomy in organs and spaces other than the incision, which was opened or manipulated during operation, e.g. Skin wound infection with associated endometritis and abdomino-pelvic peritonitis/abscesses following caesarean section.\textsuperscript{32}

### 3.2.1 Burden of post-operative infections

Postpartum endometritis occurs following 1-3% of births.\textsuperscript{33} It is up to ten times more common after caesarean section.\textsuperscript{34,35} Post-operative wound infections following caesarean section are usually deep incisional primary SSI\textsuperscript{35} and there rate of occurrence varies from 0 to 20.5% in a hospital survey conducted by Moir-Bussy and colleagues.\textsuperscript{36} In Nigeria, studies in Kano, Lagos and Ile Ife reported rates within this range.\textsuperscript{37,38,39} Puerperal sepsis is the most common cause of postnatal morbidity between day two and day ten.\textsuperscript{8} It causes around 10 maternal deaths a year in the UK.\textsuperscript{7} Currently, puerperal sepsis has the highest index rate of maternal mortality in Nigeria.\textsuperscript{20} The true incidence of wound infections is probably under-estimated because some wound infections occur when the patient is discharged and these infections may be treated in the community without hospital notification.\textsuperscript{8}

### 3.2.2 Consequences of Post-operative infections

Post-operative wound infections are associated with enormous consequences.\textsuperscript{21,30} The patient is delayed from discharge, required to do more investigations and receive more antibiotic treatment and probably surgical re-exploration which incurs more economic burden.\textsuperscript{21,30} The patient may not be able to breast feed and take care of her new born.\textsuperscript{21,30} Although, with the use of antibiotics, 90% cases of postpartum endometritis should improve within 48-72 hours, mortality may occur especially in developing countries like Nigeria.\textsuperscript{30} Morbidities include local spread of infection to cause salpingitis, oophoritis, peritonitis, wound infection and pelvic abscess.\textsuperscript{8,21,30} Infection may cause septicaemia and spread to any organ or system and even cause mortality.\textsuperscript{8,21,30} Long term complications include uterine synechiae, pelvic adhesions, tubal factor infertility and chronic pelvic pain.\textsuperscript{8,21,30}

### 3.2.3 Risk factors of post-operative infections

Caesarean section is one of the obstetric risk factors for post partum endometritis and wound infection.\textsuperscript{8,30} According to CDC, caesarean section is said to be a clean wound when performed with intact membranes; clean contaminated wound when there was prior rupture.
of membranes; contaminated wound when there was prior prolonged rupture of membranes; and dirty/infected wound if done in the presence of chorio-amnionitis. Other obstetric causes include, HIV positive women, severe meconium staining of liquor, prolonged labour with multiple vaginal examinations, manual removal of placenta, retained products of conception, mother's age at extremes of reproductive span, low socio-economic status, home delivery in a poor hygiene environment, maternal anaemia, obesity, diabetes mellitus, internal fetal monitoring, bacterial vaginosis and general anaesthesia.\textsuperscript{8,40}

Non-viable tissue or foreign material in a wound, haematoma, dead space and poor skin preparation increases risk of wound infection.\textsuperscript{41,42} Poor operative techniques during caesarean section such as not packing paracolic gutters with abdominal packs in cases associated with chorioamnionitis; lengthy operation (>2 hours) which may occur in repeat caesarean section with severe adhesions; intra-operative contamination due to inadvertent urinary bladder or bowel perforation; and from theatre staff and instruments or inadequate theatre ventilation.\textsuperscript{43,44}

### 3.2.4 Bacteria isolated from post-operative infections (Aetiology)

This is usually a mixed aerobic and anaerobic infection.\textsuperscript{43} The causative organisms include: Gram-positive cocci such as Staphylococcus SPP., Streptococcus SPP. especially Group B streptococcus and more recently Streptococcus pyogenes.\textsuperscript{45} Gram-negative bacteria include Escherichia coli, Klebsiella SPP., Chlamydia trachomatis, Proteus SPP., Enterobacter SPP., Gardnerella vaginalis and Neisseria SPP.\textsuperscript{45} Anaerobes are Bacteroides SPP. Peptostreptococcus SPP. Others include Mycoplasma SPP., Ureaplasma SPP and mycobacterium tuberculosis.\textsuperscript{45}

In endometritis, it is due to ascent of these bacteria from the vagina to the uterus.\textsuperscript{30} SSIIs may arise from endometritis following caesarean section; or from contamination by the patient's own endogenous flora which are present on the skin; or when there is bladder or bowel trauma.\textsuperscript{8,21,30} Inadvertent bowel trauma during caesarean section may contaminate wound with multitude of intrinsic bowel flora, which include gram-negative bacilli such as Escherichia coli and gram-positive microbes, including enterococci and anaerobic organisms.\textsuperscript{45} The microbial concentration highly associated with SSIs is that of bacterial counts higher than 10,000 organisms per gram of tissue.\textsuperscript{44} Some of these bacteria that cause endometritis co-
exist with lactobacilli as normal flora but cause disease when environment becomes favourable.45

3.3 Normal vaginal flora
The vaginal microflora were discovered by the German gynaecologist Albert Döderlein in 1892.45 The primary colonizing bacteria of a healthy individual are of the genus lactobacillus.46 More than 20 vaginal species of Lactobacillus have been detected but about 5 namely, Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus iners, Lactobacillus jensenii and Lactobacillus Vaginalis dominate the vaginal econiche.47,48 These Lactobacilli adhere to vaginal epithelial cells, blocking the adherence of bacterial pathogens. They also produce lactic acid (lowering the PH),49 hydrogen peroxide,47 bacteriocin such as lactocin 160 and crispasin A and bacteriocin-like substances which have been shown to inhibit growth of pathogenic micro-organisms.50,51,52 The displacement of pathogens from vaginal wall and the antimicrobial activity of lactic acid, hydrogen peroxide, bacteriocin and bacteriocin-like substances could eventually prevent post-operative infections.48-54 This could be a determinant factor for the effectiveness of the standard procedure group (no intervention) in preventing post-operative infections in this study.

3.3.1 Effect of pregnancy on vaginal flora
The various species and number of colonies of these protective lactobacilli, seem to vary depending on the physiological status of a woman.53,54 Generally, in pre-menarchial and postmenopausal women, vagina is usually keratinized and devoid of lactobacilli due to low eostrogen and it is rather populated with normal bacterial flora similar to that of the skin.55 In women of reproductive age group, including pregnant state and post-menopausal women on hormonal replacement therapy, the lactobacillus tend to dominate.57 In pregnancy, the diversity of species and number of colonies of lactobacilli is reduced.55-58 A study done by Kjersti Aagaard et al compared vaginal flora of pregnant and non-pregnant women and found that; there was much less diversity in lactobacilli species and fewer colonies in pregnant women.56 Other vagina flora found in pregnant women include staphylococcus aureus, epidermidis and micrococcus; Beta haemolytic streptococci, streptococcus faecalis, and streptococcus pneumonia; these are capable of causing infection when conditions becomes favourable.57,56 Therefore, cleansing the vagina of these bacteria prior to caesarean section could prevent post-partum infections.
3.3.2 Consequences of changes in vaginal flora in pregnancy

The decrease in number and species diversity of lactobacillus in the vagina during pregnancy has been shown to increase the number of bacteria that causes bacterial vaginosis like Bacteroides SPP, Mobiluncus SPP, Mycoplasma hominis and Gardnerella SPP, some of which could ascend after delivery to the endometrium and cause postpartum endometritis.\(^{54-57}\) Supporting this view are studies which showed prevalence of bacterial vaginosis among non-pregnant women to range from 15% to 30%; while that of pregnant women to be 50%.\(^{54-57}\) Other studies among non-pregnant women throughout the menstrual cycle reported a high rate of bacterial vaginosis during the follicular phase of the menstrual cycle and a spontaneous resolution during the luteal phase.\(^{59,60}\) These results suggest that endogenous sex hormones may support and assist in sustaining high levels of Lactobacillus SPP.\(^{57,58}\)

3.3.3 Effect of Antibiotics on vaginal flora

Antibiotic alone, may not be the answer to prevention of post-caesarean infections.\(^{61}\) Just as was seen in other studies using other forms of antibiotics, Studies by Kurowski et al on effect of clarithromycin on vaginal flora showed complete eradication of protective lactobacillus while the number of potentially pathogenic organisms were either doubled (Escherichia coli) or mildly suppressed (Enterococci) while candida species increased from 17% to 33%.\(^{59}\)

Since in pregnancy, there is decrease in number of colonies and various species of Lactobacillus;\(^{54-57}\) and antibiotics are shown not to completely eradicate the pathogenic bacteria in the vagina,\(^{61}\) the use of vaginal antisepsis could play a major role in preventing post-partum infections. Povidone iodine can eradicate 98% of vaginal bacteria\(^ {19}\) therefore preventing post-operative infections. However, the protective Lactobacillus SPP re-colonize and increase to their normal values in the second week of vaginal preparation.\(^{60}\) Therefore, the risk of opportunistic infection is minimal.

3.4 Vaginal Antiseptics

Different types of antiseptics have been tried to cleanse the vagina prior to caesarean section and other uterine surgeries to prevent post-operative infections.\(^{26}\) Commonly used include povidone iodine, chlorhexidine and metronidazole.\(^{26}\) Results of this efficacy over another is conflicting, but their safety have been widely documented.\(^{26}\)
3.4.1 Povidone Iodine versus other vaginal Antiseptics

Studies comparing iodine with chlorhexidine prior to uterine surgery showed lower morbidity in the iodine group with improved activity against anaerobic pathogens,\textsuperscript{12,13} although result of other studies has shown otherwise.\textsuperscript{14,15} A randomized control trial comparing vaginal preparation with povidone iodine, chlorhexidine and isopropyl alcohol solutions showed no statistical difference in preventing post-operative infections.\textsuperscript{61} Intra-vaginal metronidazole has also been tried and found to be effective in preventing infections,\textsuperscript{62} but this seems unnecessary since it can be given parenteral. Furthermore, it only acts against anaerobes and hence the need for another antibiotic or antiseptics for complete antimicrobial action.\textsuperscript{65} This makes it more expensive than povidone iodine. Another study compared povidone iodine, chlorhexidine and octenidine solutions for vaginal preparation prior to genital surgeries.\textsuperscript{65} The outcome showed povidone iodine to be more effective than chlorhexidine and is better if immediate and long period of action is needed.\textsuperscript{63}

Generally, more studies have been done with povidone iodine as vaginal antiseptics probably do its low side effects and acceptability. In U.S.A, povidone iodine is preferred to chlorhexidine as vaginal antiseptics prior to caesarean section and other uterine surgeries and chlorhexidine has not been approved off label as vaginal antiseptics in the same country.\textsuperscript{64} However, 43 hospitals in Sweden preferred and used chlorhexidine to povidone iodine.\textsuperscript{65} Although chlorhexidine is on WHO List of essential medicines\textsuperscript{16} it did not meet the current European specifications for hand disinfectant as there was no significant difference in efficacy between its 4% solution and soap.\textsuperscript{17} Thus povidone iodine has been chosen for this study for its efficacy and safety over other antiseptic agents.\textsuperscript{16,17}

3.4.2 Rational and Scientific bases of Povidone Iodine

Povidone-iodine, is a stable chemical complex of polyvinylpyrrolidone and contains 9.0% to 12.0% iodine.\textsuperscript{17} It is completely soluble in cold and mild-warm water which makes it suitable for vaginal cleansing.\textsuperscript{17} It kills microbes by iodination of lipids and oxidation of cytoplasmic and membrane compounds. Pathogens do not show resistance to this agent and it exhibits a broad range of microbicidal activity against bacteria, fungi, protozoa, and viruses including HIV and Herpes simplex.\textsuperscript{66} It is available within the range of 7.5 to 10.0% concentration.\textsuperscript{67}
The fact that povidone iodine is effective against viruses, bacteria, fungi and trichomoniasis, one could assume that it could reduce post-operative infectious morbidity by inactivating these vaginal pathogens favoring interventional group in this study. However, the antiseptic agent may also destroy non-pathogenic vaginal microflora which protects against infection and therefore, could be an advantage for the standard (control) group over povidone iodine (interventional) group in this study.

### 3.4.3 Safety of Povidone Iodine

Povidone iodine is safe to humans. The sensitization rate to the product is only 0.7%. However, povidone iodine is contraindicated in patients with hyperthyroidism and other diseases of the thyroid. It is also contraindicated after treatment with radioiodine and in patients with dermatitis herpetiformis (Duhring's disease).

### 3.4.4 Conclusion

There are conflicting reports on the outcomes of povidone iodine for vaginal cleansing prior to caesarean section. The outcome of this research will add to the body of knowledge and serve as a guide between the results. There is paucity of similar studies in Africa, thus this study may give room for geographical and racial information and comparison. This study aims to reduce bias by recruiting only patients with indications for emergency caesarean section unlike most previous studies that included both emergency and elective caesarean section. The prospective design of the study may address the weakness of the meta-analysis of retrospective studies. Details of exclusion criteria that may affect the study such as chorioamnionitis were not documented in some studies. Routine pre-operative prophylactic antibiotic in our facility was ceftriaxone and metronidazole which was the standard recommended by CDC41 but was varied in other studies.
4.0 CHAPTER 4: MATERIALS AND METHODS

4.1 Study location
This study was done at the Department of Obstetrics and Gynaecology of the University of Abuja Teaching Hospital, Gwagwalada, Abuja. This was a 350-bed tertiary health facility. It served as a referral centre for the Federal Capital Territory and the neighbouring states such as Nassarawa, Niger, Kaduna, and Kogi. Gwagwalada is located between longitude 7.092 and latitude 8.941 in the federal capital territory. It has an area of 1069.589 km$^2$ and currently has an estimated population of about 1 million, though the official figure in 2006 census was 158,618.\(^\text{69}\)

4.2 Study design
This was a randomized controlled trial on the effects of antiseptic vaginal preparation with povidone iodine prior to caesarean section on post-operative infections.

4.3 Study Population
The sample population included pregnant women who have indications for emergency caesarean section within the period of study.

4.4 Inclusion Criteria
- All pregnant women with gestational age of 28 weeks and above.
- Pregnant women with indication for emergency caesarean section.
- Patient must give informed consent.

4.5 Exclusion Criteria
- Pregnant women who do not give consent.
- Pregnant women with gestational age less than 28 weeks.
- Those with allergy to povidone iodine or on treatment with radio-iodine.
- Pregnant women with thyroid disorders and dermatitis herpetiformis.
- Those with immunosuppression e.g. diabetes mellitus, anaemia, HIV infection.
- Those with pre-existing infections e.g. chorioamnionitis.
- Those who present with ruptured uterus.
- Those with Antepartum haemorrhage (Abruptio placenta and placenta praevia).
- Fetal distress requiring immediate delivery.
- Those presenting with cord prolapse.
- Face presentation with ruptured membranes so as to avoid contact to fetal eyes.
- Those with febrile illness like malaria.

4.6 Study Period
The study duration was seven months from 09/01/2017 to 09/08/2017. The study was commenced after obtaining the written permission from the College and ethical clearance from the Hospital's scientific and research committee.

4.7 Sampling technique
This was by Simple random sampling. All consecutive pregnant women who had emergency caesarean section and met the inclusion criteria were recruited for the study.

4.8 Randomization technique
This was by non-blinded simple randomization. Each consecutive participant that met the criteria for the study picked a card at random from an envelope that contains 266 shuffled deck cards. Half of the cards with even numbers P002, P004...P266 belonged to the povidone iodine group while the remaining half of the cards with odd numbers C001, C003...C265 are for the control group. These were mixed such that each number in the envelope had the same probability to be picked every time. Each participant was allocated to the group based on what she picked.

4.9 Sample size determination
This was determined based on similar studies done in Hyderabad, Pakistan a developing country like Nigeria, which showed 1% and 7% occurrence of infectious morbidity in the intervention and control groups respectively. The sample size was calculated using the formulae:
\[ n = \frac{1}{1-f} \times \left[ \frac{2x(z\alpha + z\beta)^2 \times px(1-p)}{(p_0 - p_1)^2} \right] \]

Where:

\( n \) = minimum sample size.

Using the study in Pakistan as reference, 7% of control group had infectious morbidity and 93% in the same group did not have infectious morbidity. Therefore:

\( P_0 = 93\% = 0.930 \), which is the proportion of the participants in the control group expected not to have infectious morbidity.

Also, from the same study in Pakistan, 1% of intervention group had infectious morbidity and 99% in the same group did not have infectious morbidity. Therefore:

\( P_1 = 99\% = 0.990 \), which is the proportion of the participants in the intervention group expected not to have infectious morbidity.

\( \alpha \) = probability of making type I error

\( \beta \) = probability of making type II error

\( Z_\alpha \) = level of significance of type I error probability; determined from a statistical table based on the value of the level of significance.

For this study, \( \alpha \) is set at 0.05. Therefore \( Z_\alpha = 1.96 \) for two tailed tests (standard normal variate)

\( Z_\beta \) = type II error probability determined from a statistical table based on the acceptable power of 80% (0.8). Therefore \( Z_\beta = 0.84 \).

\( F \) = is the attrition rate. It was the proportion of study participants who were expected to leave the study due to withdrawal, lost to follow up or any other reason. For this study \( f = 10\% = 0.1 \).

\[ P = \frac{p_0 + p_1}{2} \text{ i.e } \frac{0.930 + 0.990}{2} = 0.960 \]
Inserting the required information into the formula gives

\[ n = \frac{1}{1-0.1} x \left[ \frac{2x(1.96+0.84)^2 \times 0.960 \times x(1-0.960)}{(0.930-0.990)^2} \right] \]

\[ = \frac{1}{0.9} x \left[ \frac{2x(2.8) \times 2 \times 0.960 \times 0.04}{(-0.060)^2} \right] \]

\[ = 1.11 x \left[ \frac{11.2 \times 0.960 \times 0.04}{(-0.060)^2} \right] \]

\[ = 1.11 \times \left[ \frac{0.430}{0.0036} \right] \]

\[ n = 132.6 \]

The calculated sample size was 132.6 which was rounded up to 133 per one arm of the study. Total population for the study was 133+133=266.

4.10 Per protocol analysis

I expected to drop or to have lost 10% subjects from the study and these will not be analysed. For this reason, 10% attrition rate (f) has been added to the sample size of each arm.

4.11 Limitations

- Multiple observer error. Two research assistants (senior registrar and registrar) from each of the four teams of the department including myself, were involved in randomising participants, collecting data and monitor patients for outcome of interest. For this reason, proper education of colleagues and personal supervision was done to reduce this limitation.

- Limited literature review for comparison from Nigeria and other parts of Africa.
4.12 Subjects and Methods

Awareness of this study was created among the hospital staff at the antenatal clinic, obstetric emergency suit, labour ward, maternity ward, anaesthesia department and the theatre. All consecutive pregnant women at ≥ 28 weeks gestational age with an indication for emergency caesarean section who met the criteria were counselled on the objectives of the study. Consent form was administered after the prospective participant fully understood the concept of the research.

Consecutive pregnant women that met the criteria were recruited for the study. Each participant was allocated to a group by a non-blinded simple randomization with allotment concealment. There were shuffled deck cards numbered 1 to 266 in an envelope. The even numbers represented povidone iodine group and were labelled P002, P004, P006...P266 while the odd numbers represented the control group and were labelled C001, C003, C005...C265. Each number had the equal chance of been picked at any time. Every eligible participant picked a card at random from the envelope and the number on the card allocated her to either the povidone iodine group or the control group. Each participant was thereafter given an enrolment code to ensure confidentiality. Demographic factors such as age, parity, booking status, gestational age, ethnicity and occupation of each participant were recorded. The indication for caesarean section, duration of labour, integrity of membranes and number of vaginal examinations were noted. Other clinical and obstetric histories of each participant were obtained. Vital signs including temperature and pulse rate were also noted.

Two residents, one senior registrar and one registrar from each of the four teams of the O&G department (total of 8 residents, myself the researcher included), were involved in the randomization of the participants. Vaginal cleansing was done after instituting spinal or general anaesthesia and before cleaning the patient. The urethral catheter was passed after the vaginal cleansing if not passed earlier in the ward. The time interval between vaginal cleansing and skin incision was within 30 minutes. The vagina was cleansed by rotating once up to 360° with a swab on sponge holding forceps soaked with 10% povidone iodine solution in the intervention group but no such procedure in the control group. The 10% povidone iodine solution was purchased and provided by me (the researcher).
Routine antiseptic cleaning and draping of patients and other antiseptic technique were maintained by the surgeon, surgeon assistant and peri-operative nurse. As a routine, each patient was administered intravenous ceftriaxone 1000mg and intravenous metronidazole 500mg immediately after skin incision.

Post-operatively, each patient was given prophylactic antibiotics and also monitored by myself or research assistant for possible development of outcome of interest as endometritis and wound infection. All patients that developed infectious morbidity, were evaluated further to isolate offending organisms and antibiotic sensitivity.

4.12.1 Primary outcomes

Postpartum endometritis: For the purpose of this study was recognized as a clinical diagnosis with the features of fever (≥38°C) for ≥24 hours occurring after first post-operative day, uterine tenderness or purulent lochia requiring antibiotic therapy. 8,58

4.12.2 Secondary outcome

(i) Post-operative wound infection: For the purpose of this study was recognized as a clinical diagnosis due to presence of erythema, tenderness, purulent drainage from the incision site, with or without fever, requiring antibiotic therapy. 8,21,30

(ii) Side effects of vaginal preparation (allergy, irritation) was also looked for as secondary outcome. As the solution was applied gently and not absorbed, there were no adverse fetal/neonatal effects. 8

4.12.3 Differential diagnosis

Postpartum endometritis and wound infection were mostly noticed within 5th to 7th days post-operatively in this study. Other causes of post-operative fever were excluded by history taking, clinical examination and sometimes investigations. Those excluded were pneumonia, aspiration pneumonitis, urinary tract infection, blood transfusion and drug reactions, pulmonary embolism and deep vein thrombosis, infections due to intravenous lines and malaria. 73

4.12.4 Follow up
All participants were monitored in the postnatal ward for possible development of outcome of interest. They were discharged when stable 5 to 7 days post-operatively except those that develop complications that necessitate extension of admission. They were followed up to two weeks post-partum. The participants phone numbers was collected and were contacted by the researcher in case of any outcome of interest. However, 6 participants were lost to follow-up, 2 from control group and 4 from intervention group. They could not return for post-natal clinic and effort was made to call their phone numbers but these were unavailable in the network.

4.12.5 Data analysis

The services of Statistical Packages for Social Sciences (SPSS), version 20 was employed. The effect of the intervention was determined by comparing the standard (control) group to the povidone iodine (intervention) group using variables of outcome. Categorical values were analysed using Chi-square and were adjusted to odds ratio while numerical values were analysed using Fisher exact test. T-test was employed to compare the mean values of the variables. A $P$-value $<0.05$ at 95% confidence interval was considered as statistically significant.

4.13 Ethical considerations

Each client’s anonymity was maintained. Clients were only identified by a code of numbers. No client was denied any form of services upon refusal of consent and non was promised facilitation of services to coerce them into giving consent. Ethical approval was sought from the University of Abuja Teaching Hospital Ethical Committee.

FLOWCHART

There were 266 consecutive pregnant women randomised. They had indication for emergency caesarean section and also met the study criteria; each of them picked a shuffled deck card at random and this allocated them to either control group or intervention group (There were 133 cards for each group).
133 women were randomized in the control group; n=133

133 women were randomised in the povidone iodine group; n=133

131 women in the control group were followed up post-partum for outcome of interest; 2 were lost to follow up. n =131

129 women in the povidone iodine group were followed up post-partum for outcome of interest; 4 were lost to follow up.

Chi-square was used to analyse the variables of outcome of interest at \( P < 0.05 \) and 95% confidence interval

Chi-square was used to analyse the variables of outcome of interest at \( P < 0.05 \) and 95% confidence interval

RESULTS

Table 1
As illustrated in the Flow chart and on Table 1, 266 women were recruited but 260 were analysed; 131 (50.4%) in control group and 129 (49.6%) in the study group. Six of them (2.3%) were lost to follow-up and were not analysed. These were 2/133 women in the control group and 4/129 women in the povidone iodine group.

There were 22/260 (8.4%) with post caesarean endometritis and 15/260 (5.7%) participants with wound infection. Thus, there were 37 (14.1%) total cases of infectious morbidities, 29 (11.1%) from the control group and 8 (3.0%) from the study group. The infectious morbidities were more among the control group (6.9% versus 1.5%, and 4.2% versus 1.5%) respectively.

Each infectious morbidity (endometritis or wound infection) was recognized separately. Note that 4 (1.5%) women had both endometritis and wound infection; 3 (1.1%) from the control group and 1 (0.4%) from the povidone iodine group. This makes total individual who develop infectious morbidity to be 33 (12.7%) out of 260 participants.

No participants complained of any side effect or adverse reaction from the use of povidone iodine.

### Frequency distribution of 260 participants analysed

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>CONTROL 131(50.4%)</th>
<th>POVIDONE IODINE 129(49.6%)</th>
<th>TOTAL 260(100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometritis</td>
<td>18(6.9%)</td>
<td>4(1.5%)</td>
<td>22(8.4%)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>11(4.2%)</td>
<td>4(1.5%)</td>
<td>15(5.7%)</td>
</tr>
<tr>
<td>Total infectious morbidities</td>
<td>29(11.1%)</td>
<td>8(3.0%)</td>
<td>37(14.1%)</td>
</tr>
<tr>
<td>Side effects/adverse reactions</td>
<td>0(0.0%)</td>
<td>0(0.0%)</td>
<td>0(0.0%)</td>
</tr>
<tr>
<td>Had no infectious morbidity</td>
<td>105(40.4%)</td>
<td>122(46.9%)</td>
<td>227(87.3%)</td>
</tr>
</tbody>
</table>
### Table 2

**Demographic characteristics of study participants at inclusion by randomisation group**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control (n=131)</th>
<th>Intervention (n=129)</th>
<th>Chi-square</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age in years</td>
<td>28.5±4.8</td>
<td>29.1±4.7</td>
<td>1.0(-1.8 – 0.5)</td>
<td>0.310*</td>
</tr>
<tr>
<td>18-23</td>
<td>17(13.0)</td>
<td>14(10.9)</td>
<td>0.3</td>
<td>0.597</td>
</tr>
<tr>
<td>Age</td>
<td>Control Group</td>
<td>Intervention Group</td>
<td>p-value</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>--------------------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>24-29</td>
<td>63(48.1)</td>
<td>43(33.3)</td>
<td>5.9</td>
<td>0.015</td>
</tr>
<tr>
<td>30-35</td>
<td>44(33.6)</td>
<td>63(48.8)</td>
<td>6.2</td>
<td>0.012</td>
</tr>
<tr>
<td>&gt;35</td>
<td>7(5.3)</td>
<td>9(7.0)</td>
<td>0.3</td>
<td>0.584</td>
</tr>
</tbody>
</table>

### Education

<table>
<thead>
<tr>
<th>Level</th>
<th>Control Group</th>
<th>Intervention Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4(3.1)</td>
<td>4(3.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Primary</td>
<td>15(11.5)</td>
<td>14(10.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>Secondary</td>
<td>34(26.0)</td>
<td>34(26.4)</td>
<td>0.01</td>
</tr>
<tr>
<td>Tertiary</td>
<td>78(59.5)</td>
<td>77(59.7)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

### Ethnicity

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Control Group</th>
<th>Intervention Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Igbo</td>
<td>37(28.2)</td>
<td>33(25.6)</td>
<td>0.2</td>
</tr>
<tr>
<td>Hausa</td>
<td>11(8.4)</td>
<td>15(11.6)</td>
<td>0.8</td>
</tr>
<tr>
<td>Yoruba</td>
<td>24(18.3)</td>
<td>22(17.1)</td>
<td>0.07</td>
</tr>
<tr>
<td>Others</td>
<td>59(45.0)</td>
<td>59(45.7)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

### Occupations

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Control Group</th>
<th>Intervention Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professionals</td>
<td>47(35.9)</td>
<td>44(34.1)</td>
<td>0.1</td>
</tr>
<tr>
<td>Technicians</td>
<td>9(6.9)</td>
<td>7(5.4)</td>
<td>0.2</td>
</tr>
<tr>
<td>and associate professionals</td>
<td>17(13.0)</td>
<td>18(14.0)</td>
<td>0.1</td>
</tr>
<tr>
<td>Clerical support workers</td>
<td>28(21.4)</td>
<td>25(19.4)</td>
<td>0.2</td>
</tr>
<tr>
<td>Craft and related trades workers</td>
<td>2(1.2)</td>
<td>1(0.8)</td>
<td>0.3</td>
</tr>
<tr>
<td>Skilled agricultural, forestry and fishery workers</td>
<td>12(9.2)</td>
<td>17(13.2)</td>
<td>1.1</td>
</tr>
<tr>
<td>Elementary occupations</td>
<td>16(12.2)</td>
<td>17(13.2)</td>
<td>0.1</td>
</tr>
</tbody>
</table>

*t-test statistic

¶ Fisher’s exact test

Table 2 showed analysis of group participants at recruitment using Chi-square at 95% confidence interval (CI).

The mean age of the participants in the control group analysed using t-test was 28.5±4.8 and in the povidone iodine group was 29.1±4.7.
women at the age range of 24-29 years in the control group and povidone iodine groups were 63(48.1%) vs 43(33.3%) and this was significantly high (95% CI=5.9; p=0.015). The age group of 30-35 years with values of 44(33.6%) control group and 63(48.8%) povidone iodine group, was also statistically significant (95% CI=6.2; p=0.012).

There was no statistically significant difference in the educational levels, ethnic groups and occupations of the participants. However, in terms of education tertiary level was highest, 78(59.5%) in the control group and 77(59.7%) in the povidone iodine group. The value decreases with level of education with illiteracy been the least.

Table 3:
Obstetrics and surgical characteristics of study participants at inclusion by randomisation group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control</th>
<th>Intervention</th>
<th>Chi-square</th>
<th>OR(CI)</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boking status</td>
<td>n=131</td>
<td>n=129</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Booked</td>
<td>70(53.4)</td>
<td>72(55.8)</td>
<td>0.1</td>
<td>0.9(0.6-1.5)</td>
<td>0.700</td>
</tr>
<tr>
<td>Unbooked</td>
<td>61(46.6)</td>
<td>57(44.2)</td>
<td>0.1</td>
<td>0.9(0.6-1.5)</td>
<td>0.700</td>
</tr>
</tbody>
</table>
### Parity

<table>
<thead>
<tr>
<th>Para</th>
<th>Count</th>
<th>Percentage</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Para 0</td>
<td>40(30.5)</td>
<td>30(23.3)</td>
<td>1.8</td>
<td>1.5</td>
<td>0.8-2.5</td>
</tr>
<tr>
<td>Para 1</td>
<td>31(23.7)</td>
<td>31(24.0)</td>
<td>0.01</td>
<td>0.9</td>
<td>0.6-1.7</td>
</tr>
<tr>
<td>Para 2</td>
<td>32(24.4)</td>
<td>28(21.7)</td>
<td>0.3</td>
<td>1.2</td>
<td>0.7-2.1</td>
</tr>
<tr>
<td>Para 3</td>
<td>11(8.4)</td>
<td>23(17.8)</td>
<td>5.1</td>
<td>0.4</td>
<td>0.2-0.9</td>
</tr>
<tr>
<td>Para 4</td>
<td>14(10.7)</td>
<td>8(6.2)</td>
<td>1.7</td>
<td>1.8</td>
<td>0.7-4.5</td>
</tr>
<tr>
<td>Para ≥5</td>
<td>3(2.3)</td>
<td>9(7.0)</td>
<td>3.2</td>
<td>0.3</td>
<td>0.1-1.2</td>
</tr>
</tbody>
</table>

### Gestational age

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Count</th>
<th>Percentage</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 to &lt; 37 weeks</td>
<td>63(48.1)</td>
<td>65(50.4)</td>
<td>0.1</td>
<td>0.9</td>
<td>0.6-1.5</td>
</tr>
<tr>
<td>37 to &lt; 42 weeks</td>
<td>56(42.7)</td>
<td>56(43.4)</td>
<td>0.01</td>
<td>0.9</td>
<td>0.6-1.6</td>
</tr>
<tr>
<td>≥ 42 weeks</td>
<td>12(9.2)</td>
<td>8(6.2)</td>
<td>0.8</td>
<td>1.5</td>
<td>0.6-3.9</td>
</tr>
</tbody>
</table>

### Duration of CS

<table>
<thead>
<tr>
<th>Duration</th>
<th>Count</th>
<th>Percentage</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of CS ≤ 2 hrs</td>
<td>127(96.9)</td>
<td>129(100.0)</td>
<td>4.0</td>
<td>0.1</td>
<td>0.0-0.1</td>
</tr>
<tr>
<td>Duration of CS &gt; 2 hrs</td>
<td>4(3.1)</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Membranes

<table>
<thead>
<tr>
<th>Membrane Status</th>
<th>Count</th>
<th>Percentage</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS with Intact membranes</td>
<td>86(65.6)</td>
<td>90(69.8)</td>
<td>0.5</td>
<td>0.8</td>
<td>0.5-1.4</td>
</tr>
<tr>
<td>CS with Ruptured membranes</td>
<td>45(34.4)</td>
<td>39(30.2)</td>
<td>0.5</td>
<td>0.8</td>
<td>0.5-1.4</td>
</tr>
</tbody>
</table>

### No. of VE

<table>
<thead>
<tr>
<th>No. of VE</th>
<th>Count</th>
<th>Percentage</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS with no prior VE.</td>
<td>11(8.4)</td>
<td>3(2.3)</td>
<td>4.7</td>
<td>3.9</td>
<td>1.0-14.1</td>
</tr>
<tr>
<td>CS after 1 to 3 VE.</td>
<td>57(43.5)</td>
<td>67(51.9)</td>
<td>1.9</td>
<td>0.7</td>
<td>0.4-1.2</td>
</tr>
<tr>
<td>CS after ≥ 4 VE.</td>
<td>63(48.1)</td>
<td>59(45.7)</td>
<td>0.1</td>
<td>1.1</td>
<td>0.7-1.8</td>
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</table>

### Duration of labour

<table>
<thead>
<tr>
<th>Duration</th>
<th>Count</th>
<th>Percentage</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
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<tr>
<td>&lt;6 hrs</td>
<td>39(29.8)</td>
<td>38(29.5)</td>
<td>0.003</td>
<td>1.0</td>
<td>0.6-1.7</td>
</tr>
<tr>
<td>6–&lt;12 hrs</td>
<td>31(23.7)</td>
<td>41(31.8)</td>
<td>2.1</td>
<td>0.7</td>
<td>0.4-1.2</td>
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<tr>
<td>12–&lt;18 hrs</td>
<td>26(19.8)</td>
<td>18(14.0)</td>
<td>1.6</td>
<td>1.5</td>
<td>0.8-2.9</td>
</tr>
<tr>
<td>18–&lt;24 hrs</td>
<td>17(13.0)</td>
<td>15(11.6)</td>
<td>0.1</td>
<td>1.1</td>
<td>0.5-2.4</td>
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<tr>
<td>≥24 hrs</td>
<td>18(13.7)</td>
<td>17(13.2)</td>
<td>0.03</td>
<td>1.1</td>
<td>0.5-2.1</td>
</tr>
</tbody>
</table>

¶ Fisher’s exact test

The results as shown in Table 3 did not show any variable that showed any statistically significant difference especially in the booking status (p=0.700) and membranes integrity (p=0.478) with uniform p values. Others are gestational age with lowest p value (p=0.371 attributed to ≥ 42 weeks pregnancy); caesarean section with lowest p value (p=0.174 attributed to 1 to 3 VE); duration of labour with the lowest p value (p=0.144 attributed to 6 – <12 hrs).
For parity analysis, the para 0 women were highest, 40(30.5%) in the control group and 30(23.3%) in the povidone iodine group. The value decreases with parity with Para ≥5 been the least ie. 3(2.3%) in the control group and 9(7.0%) in the povidone iodine group.

The duration of caesarean section did not show any significant difference (p=0.122). However, participants with ≤2hrs duration of CS were far more with 127(96.9%) in the control group and 129(100.0%) in the povidone iodine group compared to 4(3.1%) in the control group and nil in the povidone iodine group.

<table>
<thead>
<tr>
<th>Table 4. Demographic characteristics of participants who developed endometritis</th>
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</thead>
<tbody>
<tr>
<td>Characteristics</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Mean age in years</td>
</tr>
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<td>18-23</td>
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</table>
Table 4 showed demographic characteristics of participants who developed endometritis. Out of 131 participants analysed in the control group 18 (13.7%) had endometritis and out of 129 participants analysed in the povidone iodine group 4 (3.1%) developed endometritis. The variables associated were analysed using chi-square at 95% confidence interval adjusted to odds ratio.
The participants mean age, age range, educational level, ethnic groups and occupations did not show any significant difference in the development of endometritis between control and povidone iodine groups.

The mean age was 27.9±3.9 in the control group and 24.3±5.8 in the povidone iodine group. In terms of educational level, endometritis was recorded among those who had primary, secondary (p=0.905) and tertiary education (p=0.746) but none among the illiterates. In terms of occupation, the professionals (control=9(50.0%), povidone iodine=3(75.0%) p=0.594, and the crafts and related trades workers (control=2(11.1%), povidone iodine=1(25.0%), p= 0.470) had participants in both groups who developed endometritis. Other occupations were only in the control group.

Table 5
Obstetrics and surgical characteristics of participants who developed endometritis

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control n= 18</th>
<th>Intervention n= 4</th>
<th>Chi-square</th>
<th>OR(CI)</th>
<th>p-values</th>
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<td>Boking status</td>
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</table>
Table 5 showed obstetrics and surgical characteristics of participants who developed endometritis. The booking status, parity, gestational age, duration of caesarean section and number of vaginal examinations did not show any significant difference in developing endometritis between the control and povidine iodine groups.
However, in terms of integrity of membranes, those with ruptured membranes prior to caesarean section in the control group were 14(77.8%) and was significantly higher than those with intact membranes in the control group, ruptured and intact membranes in the povidone iodine group, with values 1(25.0), 1(25.0), 3(75.0) respectively; OR(CI)= 0.1(0.01-1.2), p=0.040. The duration of labour prior to caesarean section of ≥24 hrs was 10(55.6%) in the control group and 2(50.0%) in the povidone iodine group OR(CI)= 1.3(0.1-10.9), p=0.041. This has shown significant difference in developing endometritis between the two groups.

Further more risk of developing endometritis in the povidone iodine group was 4/129=0.03 and in the control group was 18/131=0.14. Relative risk of developing endometritis in the povidone iodine group was lesser than that in the control group ie = 0.03/0.14=0.21 (<1). Relative risk reduction of developing endometritis in povidone iodine group is 1-0.21=0.79 (8% compared to control). Absolute risk reduction in developing endometritis in the povidone iodine group was 0.14-0.03=0.11. Thus number needed to treat (application of povidone iodine) to prevent one case of endometritis was 1/0.11=9. This means for every population treated, 11% will be prevented from having endometritis.

Table 6.

| Demographic characteristics of participants who developed wound infection |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Characteristics                                 | Control n=11    | Intervention n= 4 | Chi-square      | p-values        |
|                                                 |                 |                 |                 |                 |

30
Table 6 showed demographic characteristics of participants who developed wound infection. Out of 131 participants in the control group, 11(8.4%) had endometritis and out of 129 participants in the povidone iodine group 4(3.1%) developed wound infection.

The mean age, age range, educational level, ethnicity and occupations of the participants did not show any significant difference in developing wound infection between the two
groups. However, the mean age in years of those who developed wound infection was 27.9±5.0 in the control group and 27.3±5.3 in the povidone iodine group.

Table 7. Obstetrics and surgical characteristics of participants who developed wound infection

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control n=11</th>
<th>Intervention n= 4</th>
<th>Chi-square</th>
<th>OR(CI)</th>
<th>p-values</th>
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<tr>
<td>Booking status</td>
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<tr>
<td>Booked</td>
<td>5(45.5)</td>
<td>3(75.0)</td>
<td>1.0</td>
<td>0.3(0.02-3.6)</td>
<td>0.310¶</td>
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</table>
Table 7 showed obstetrics and surgical characteristics of participants who developed wound infection. The booking status, parity, gestational age, duration of caesarean section, duration of labour and number of vaginal examinations did not show any significant difference in developing wound infection between the control and povidone iodine groups.
In terms of integrity of membranes, those with ruptured membranes prior to caesarean section in the control group were 10(90.9%) and was significantly higher than those with intact membranes in the control group, ruptured and intact membranes in the povidone iodine group, with values 1(9.1%), 3(75.0) 1(25.0), respectively; OR(CI)= 0.3(0.01-0.7), p=0.033.

Risk of developing wound infection in the povidone iodine group was 4/129=0.03; and in the control group was 11/131=0.08. Relative risk of developing wound infection in the povidone iodine group was lesser than that in the control group ie. 0.03/0.08=0.38 (<1). Relative risk reduction of developing wound infection in povidone iodine group was 1-0.38=0.62(6.2%). Absolute risk reduction in developing wound infection in the povidone iodine group was 0.08-0.03=0.05. Number needed to treat (application of povidone iodine) to prevent one case of wound infection was 1/0.05= 20. Which means for every population treated, 5% will be prevented from having wound infection.

5.1 DISCUSSION
This study was a randomized control trial of pregnant women of various socio-economic background and ethnicity who had emergency caesarean section at university of Abuja teaching hospital, Gwagwalada, Nigeria. These women were recruited at the time they were notified of the indication for the emergency caesarean section and were randomly assigned
to any of the two groups, control versus intervention group (povidone iodine group) as was done elsewhere. Those in the povidone iodine group had their vagina cleansed with 10% povidone iodine while those in the control group had no such procedure as was done in similar studies. Routine prophylactic antibiotics as prescribed by CDC (iv. ceftriaxzone 1000mg and iv metronidazole 500mg), routine cleaning and draping as well as post-operative antibiotics were giving as was done by Memon SL et al in Hyderabad, Pakistan studies.

At booking, out of the 260 women recruited 131(50.4%) were in the control group while 129(49.6%) were in the povidone iodine group which showed approximately equal representation for each group as was seeing in other studies. The mean age of the participants analysed using t-test in the control group was 28.5±4.8 years and in the povidone iodine group was 29.1±4.7 years; this was similar to the mean age of 27.1±4.6 in the control group and 27.2 ±5.0 in the treatment group of similar studies done in Pakistan. Women at the age range of 24-29 years and 30-35years were significantly high (95% CI=5.9; p=0.015) vs (95% CI=6.2; p=0.012) respectively. This was similar to demographic features on women who had caesarean section in kanoby Jido TA et al which showed higher rate of 17% of pregnant women within the age range of 25-29 years, followed by 7% in those of 30-35years range. This is probably because Abuja is an urban environment with people of civil service oriented jobs whose earlier pursuance of education tends to delay their reproductive carrier (marriage and pregnancy).

Educational level of the women did not show any statistical significance association between the control or povidone group. However, those with tertiary level of education were more with 78(59.5%) participants in the control group and 77(59.7%) participants in the povidone iodine group. The number of participants decreases with decrease in educational level and illiteracy was lowest 4(3.1%) for each of the two groups. This may be due to the fact that, Abuja city, being the federal capital of Nigeria is mostly populated by civil servants and educated people who are looking for greener pastures. The lower value of illiterates and higher value of literates in urban regions was similar to report from an unrelated study done in Ghana.
Nigeria is a multi-ethnicity region and none of the tribes was significantly higher than the other between the control or povidone iodine groups. However, other (mixed minority) tribes were more 59(45.0%) in control group and 59(45.7%) in the povidone iodine group. This may be because of the federal character nature of the federal government in terms of employment. This study did not show any statistical significance relating to women’s job. However, majority were professionals 47(35.9%) in the control group and 44(34.1%) in the povidone iodine group. The least were skilled agricultural, forestry and fishery workers 2(1.2%) vs 1(0.8%). This might be due to the civil service nature of most jobs in Abuja.

The booking status did not show any statistical difference between the control and povidone iodine groups (p=0.700). This was similar to report by Jido et al. But we have more booked women. This was probably because most women were literate and therefore, more informed. For parity, the para 0 women were more in the control group 40(30.5%) while para 1 were more in the povidone iodine group 31(24.0%) but none was significantly higher (p=0.186) vs (p=0.945). This is slightly lower than report by Memon et al where by the mean parity of participants in a similar studies were 2.51±2.27 in the control group and 2.40±2.25 in the povidone iodine group. The higher number of low parity might be because most women in the urban area like Abuja, start their reproductive carrier late due to pursuance of education up to tertiary level (which was recorded to be highest in this study) and also due to increased awareness of contraception and family planning among the educated individuals.

The gestational age did not show any statistical significant (p=0.371), however, those at 28 to < 37weeks gestational age were more, 63(48.1%) in the control group and 65(50.4%) in the povidone iodine group. This was similar to studies by Memon et al where by the mean gestational age was 36.86±2.46 in the control group and 36.65±2.05 in the treatment group. The post-term participants at recruitments were very few with 12 (9.2%) in the control group and 8 (6.2%) in the povidone iodine group (p=0.371). This was similar to most studies, due to probably routine elective induction of labour to prevent post-term pregnancy and its complications. Other obstetrics and surgical factors such as number of vaginal examinations (p=0.051), duration of labour prior to caesarean section (p=0.144), membrane integrity (p=0.478) and duration of caesarean section (p=0.122) did not show any significant association at recruitment.
Endometritis was the primary outcome in this study. Out of 131 participants in the control group, 18 (13.7%) had endometritis while out of 129 in the povidone iodine group, 4 (3.1%) developed endometritis. The rate of post-caesarean section endometritis in the control group (13.7%) was similar to the rate of puerperal sepsis recorded in a recent nationwide study on maternal deaths and near-misses in Nigeria (14.2%).20 It is also within the range of post-operative wound infections following caesarean section (0 to 20.5%) reported in a hospital survey conducted by Moir-Bussy and colleagues.37 However, the 3.1% rate of endometritis in the povidone iodine group showed significant advantage over the 13.7% rate in the control group. Similar beneficial outcome (7.2% vs 3.6%) was recorded in the analysis of five randomized control trials by Haas DM et al and (7% vs 1%) by Memon et al as well as other studies.8,26,27,28

The analysis of demographic factors did not show any significant difference in developing endometritis between the control and povidone iodine groups. These were maternal age (p=0.210), educational level (p=0.746), ethnicity (p=0.135) and occupation (p=0.470) of the participants (lowest p values). The result was similar to the outcome of studies by Reid et al which showed no difference in developing endometritis between groups in maternal age, parity, race, education, prior caesarean section, type of anesthesia, labour before current caesarean section, number of vaginal examinations during labour, internal monitoring, prophylactic antibiotic use, gestational age at delivery, or payment status.29 Other studies showed similar results.8,26,27,28

Obstetric factors like ruptured membranes prior to caesarean section with no treatment 14(77.8%); 0.1(0.01-1.2), p=0.040 appears to cause significant endometritis than those in the povidone iodine group. This is similar to report by Haas DM et al where by women with ruptured membranes prior to caesarean section had significant decrease in endometritis from 15.4% in the control group to 1.4% in the treatment group.8 This may be due to inhibition of growth and ascent of bacteria from the vagina in to the endometrial cavity by the effect of povidone iodine. Duration of labour of ≥24hrs in the control group was significantly high in causing endometritis 10(55.6), 1.3(0.1-10.9); p=0.040. Similar result was reported by Memon SL et al.28 However, this variable was not mentioned in most studies probably because similar studies were done in more developed countries where most labours and deliveries are supervised and not allowed to prolong.8
Women who present with prolonged labour are usually associated with other compounding factors such as unbooking status, low socio-economic status, malnutrition, anaemia, prolonged rupture of membranes and dehydration. These factors might have independently increased the risk of endometritis among them. Other obstetrics and surgical factors in this study such as booking status (p=0.269), parity (p=0.696), gestational age (p=0.601), number of vaginal examinations (p=0.386) and duration of caesarean section (p=0.380) did not show any significant difference in developing endometritis as was reported by Haas DM et al in 5 randomized control trials and other studies. Adverse reaction to povidone iodine was not recorded as was shown in other studies. This study reaffirms its safety.

Wound infection was the secondary outcome in this study. Out of 131 participants in the control group, 11 (8.4%) had wound infection while out of 129 in the povidone iodine group, 4 (3.1%) developed wound infection. The rate of wound infection in the control group (8.4%) was within the range of post-operative wound infections following caesarean section (0 to 20.5%) reported in a hospital survey conducted by Moir-Bussy and colleagues. In Nigeria, studies in Kano and Lagos reported rates within this range. Apart of ruptured membranes, other demographic, obstetric and surgical factors did not show any significant difference in development of wound infection between the control and povidone iodine groups. These were maternal age (p=560), educational level (p=0.154), ethnicity (p=0.476) and occupation (p=0.930) of the participants. Others include booking status (p=0.310), parity (p=0.876), gestational age (p=0.282), number of vaginal examinations (p=0.770), duration of labour (p=0.476) and duration of caesarean section (p=0.533). Similar outcome was reported elsewhere. However, ruptured membranes with no treatment (in control group) prior to caesarean section was significantly associated with wound infection than in other subgroups 10 (90.9%); OR(0.3;Cl=0.01-0.7), p=0.033. Similar observation has been reported in other studies. Overall, there was significant reduction in the rate of endometritis and wound infection in the treatment group than in the control group in this study as was reported by other studies. Risk of developing endometritis in the povidone iodine group was 3.1% and in the control group was 13.7%. Relative risk reduction of developing endometritis in povidone iodine group was 8%; and the number needed to treat (application of povidone iodine) to prevent one case
of endometritis was 9. Which means for every population treated, 11% will be prevented from having endometritis. Conversely, rate of developing wound infection in the povidone iodine group was 3.1% as against 8.4% in the control group with relative risk reduction of developing wound infection from 6.2% to 3.8%. Twenty persons needed to be treated in order to prevent one case of wound infection. These outcomes are significant and very important in our environment and other under developed countries with higher rate of post-caesarean section endometritis and wound infection. Coupled with the fact that puerperal sepsis is one of the common cause of maternal mortality in our environment (14.2%) with a high mortality index (79.3%) as was recorded in a nationwide study in Nigeria on maternal mortality and near misses by Oladapo OT et al.²⁰

In addition, those who survive this infection may develop morbidities like local spread of infection to cause salpingitis, oophoritis, peritonitis, wound infection, pelvic abscess, septicaemia and spread to any organ or system.⁸,²¹,³⁰ This results to delay from discharge, required to do more investigations and receive more antibiotic treatment, surgical re-exploration, inability to breast feed and take care of her new born and increase in economic burden.²¹,³⁰ Long term complications that may occur include uterine synechiae, pelvic adhesions, tubal factor infertility and chronic pelvic pain.⁸,²¹,³⁰

This study has shown that, all of these complications can be reduced from the rate of 13.7% (endometritis in the control group) to 3.1% (povidone iodine group) by one simple, safe and inexpensive procedure, notably, cleansing the vagina with 10% povidone iodine prior to emergency caesarean section. This is important in our low socio-economic environment with poorly equipped hospitals, fewer skilled workers, poverty and ignorance among the populace.

5.2. Conclusion
Cleansing the vagina with povidone iodine prior to emergency caesarean section tended to reduce occurrence of endometritis in women who presented with ruptured membranes and prolonged labour (≥24hrs).

The procedure also reduced the occurrence of wound infection in women who presented with ruptured membranes.
None of the participants complained of any side effects or adverse reactions from the use of povidone iodine.

Because this study has shown that, antiseptic vaginal preparation with povidone iodine prior to emergency caesarean section does prevent post-caesarean endometritis and wound infection; null hypothesis has been rejected.

5.3. Recommendation

Vagina should be cleansed with 10% povidone iodine prior to emergency caesarean sections to prevent post-operative endometritis and wound infection especially among women who presented with ruptured membranes and prolonged labour.

References


34. Smaill FM, Gyte GM; Antibiotic prophylaxis versus no prophylaxis for preventing infection after Cochrane Database Syst Rev. 2010; (1):CD007482.


Appendices

INFORMED CONSENT FORM

My name is Dr. Ketare Nathaniel. I am a senior registrar in the department of Obstetrics and Gynaecology in University of Abuja Teaching Hospital. I am conducting a research on antiseptic vaginal preparation using povidone iodine prior to caesarean section and its effect in preventing pelvic and wound infections. Its side effects such as local irritation are usually mild and very rare but I should be informed, if it occurs. I would appreciate your participation in this study. The research is designed to benefit the society by gaining new knowledge.

You will be required to answer some questions which might pertain to your health and personal life. However I shall contact you at delivery to inquire your experience during the period of delivery and 2 weeks thereafter.
Participation in this survey is voluntary and you can choose not to answer any individual question or all of the questions. However, I hope that you will participate in this survey since your views are very important. By signing this form it is taken that you have full understanding of the research and have given your informed consent for participation in the research.

Thank you very much for agreeing to participate in this survey. Whatever information you provide will be kept strictly confidential.

Signature of interviewer ___________________________ Date ____________

Signature of participant ___________________________ Date ____________

Hospital Number…………………………….

Study identification Code ....................... 

Patient phone number..............................

PROFORMA

Vaginal preparation with antiseptic solution (povidone iodine) before caesarean section and effect on preventing post-operative infections at University of Abuja Teaching Hospital, Abuja, Nigeria.

Enrolment code  ----------------------

Bio data
1. Age in years   [ ]18-23   [ ]24-29[ ]30-35[ ]>35
2. Ethnic group: 1=Ibo   2=Hausa    3=Yoruba   4=others (specify)--------
3. Religion: 1=Islam    2=Christianity    3=Traditional 4=others (specify).--------
4. Educational level: 1= None  2=Primary      3= Secondary   4=Tertiary
5. Occupation: 1 = Housewife  2 = Civil servant  3 = Student  4 = Farmer  5 = Others (specify) -------
7. Husband’s occupation: 1 = Civil servant  2 = Student  3 = Farmer  4 = Trader  5 = Others (specify) -------

**Baseline assessment:**
Booking status: Booked [ ], Unbooked [ ]

**Gravidity/Parity** .............................................
LMP [ ]
EGA [ ]
EDD [ ]

Previous relevant pregnancy outcome....................................

**Baseline examination**
Temperature .................°C
Pulse rate ..................beats/min

**Baseline investigations**
PCV .................%
Blood group ..................
Cross matching of blood ..............................................
Genotype ..............................................
Urinalysis ..........................

**Pre-delivery condition**

[ ] emergency CS
patient in labour  Yes=[ ]  No=[ ]
membranes intact  Yes=[ ]  No=[ ]
Number of VEs  Nil=[ ]  1-3=[ ]  ≥4=[ ]

Duration of labour in hours  <6[ ]  6 to<12[ ]  12 to<18[ ]
  18 to<24[ ]  ≥24[ ]

**Intra-operative conditions**
Estimated blood loss  <1litre[ ] >1litre[ ]
Duration of surgery  <2hours[ ]>2hours[ ]

**Puerperal events**
Mother and baby will be followed up for 2 weeks and the following conditions will be noted.

**Maternal**
Endometritis.......................... 
Wound infection.......................... 
Vaginal irritation/allergy..................

**Infant events**
Admission into SCBU/Indication..................
Any side effect..........................

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**ACTIVITY PLAN (Gant’s Chart)**

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