MAGNITUDE AND RISK FACTORS FOR PUERPERAL SEPSIS AT THE PUMWANI MATERNITY HOSPITAL.

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H58/69529/2013

A dissertation submitted as a part of the requirements for the award of a degree in Master of Medicine in Obstetrics and Gynaecology, at the University Of Nairobi.

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DECLARATION:

I hereby declare that this dissertation is my original work and to the best of my knowledge contains no materials previously published or written by another person, nor material which to a substantial extent has been accepted for the award of any other degree or diploma at the University of Nairobi or any other educational institution.

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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Naima Abdallah Shatry MMed. student registration number H58/69529/2013, Department of Obstetrics and Gynecology, College of Health Sciences, University of Nairobi, supervised by Prof. Guyo Jaldesa and Dr. Kizito Lubano. It has not been presented in any other university for award of a degree.

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DEDICATION:

To my dear mother, family and mentors, who went above and beyond.

LIST OF ABBREVIATIONS:

APL- Active phase of labour

CI- Confidence Interval

CS- Caesarian section

FBC- Full blood count

HB- Haemoglobin

HVS- High Vaginal Swab

LAB- Laboratory

LB- Live Birth

MDG- Millennium Development Goals

MMR- Maternal Mortality Ratio

PMH- Pumwani Maternity Hospital

PROM- Premature Rupture of Membranes

SPSS- Statistical Package for the social sciences

UK- United Kingdom

UTI- Urinary tract infections

VE- Vaginal exam

WHO- World Health Organisation

WBC- White Blood Cells

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ABSTRACT:

Background: Puerperal sepsis is the third commeonest cause of maternal mortality in the world. It remains one of the leading preventable causes of maternal mortality, despite advances in modern medicine. Puerperal sepsis is defined as any infection occurring in a woman between the onset of labour or rupture of membranes to 42 days postpartum. Maternal complications as a result of puerperal sepsis include septicaemia, endotoxic shock and peritonitis or abscess formation leading to surgery and compromised future fertility. Given its significant burden in terms of morbidity, mortality and cost implications on the heath budget, studies on hospital specific incidences and patterns are important to help inform policy for its prevention.

Objective: This study was conducted to determine the magnitude of, and factors associated with puerperal sepsis at Pumwani Maternity Hospital, Kenya.

Methodology:

A descriptive cohort of 793 consenting women were followed over two weeks to determine the magnitude of puerperal sepsis among women who delivered at Pumwani Maternity Hospital (PMH) in Nairobi, between March to November 2015. A case cohort was then analysed, in which 69 women who met the predetermined criteria for puerperal sepsis within the two week follow-up period were compared, each, to 3 controls selected for each case from the descriptive cohort

Data was collected using an interviewer administered questionnaire, in which data from patients' records were obtained at baseline and in the two week follow-up period. Socio-demographic, antenatal and intrapartum details were obtained at day one and those in whom infection was suspected were excluded. Data was cleaned, coded, and entered into STATA. The measure of association between the independent and dependent variables was the odds ratio and the corresponding 95% confidence interval. A p-value of <0.05 denoted significant association.

Results: Seven hundred and ninety three postnatal mothers at Pumwani maternity hospital were recruited for the study. At two weeks follow-up, data from 566 of the 793 women was obtained, representing a loss to follow up of 28.6% (227/793). 69 women among the 566 met the criteria for puerperal sepsis. This corresponded to a magnitude of 12.2% at two weeks post partum(95% CI 9.5 – 14.9%). Further analysis of the case cohort was done using 69 cases each with 3 randomly selected controls. Therefore, a total of 276 women formed the analysis in the case cohort. No deaths were reported. Risk factors included labour lasting >24hours, c/section, obstructed labour, and multiple vaginal examinations. No significant association was noted with anaemia, HIV, and other co-morbidities.

Conclusion: The magnitude of puerperal sepsis at two weeks postpartum at Pumwani, was at 12.2%(95% CI 9.5-14.9). Two or more vaginal examinations, prolonged and obstructed labour, and caesarian section were found to be significantly associated with an increased risk. Appropriate measures like proper use of the partograph, should be put to use in order to prevent prolonged and obstructed labour. Reduction in the number of vaginal examinations is recommended. In those with more than 2 vaginal examinations done, universal precautions and antibiotic prophylaxis should be made. Further studies on adherence to guidelines, infection prevention and control may be done.

INTRODUCTION:

Globally, there were an estimated 303 000 maternal deaths in 2015; the sub-Saharan Africa region alone accounted for 66% of global deaths. (1)

Improving maternal Health is one of the eight MDGs adopted by the International Community in 2000. Under MDG 5, countries planned to reduce maternal mortality by 75% between 1990 and 2015. The average annual % change in MMR in sub-Saharan Africa was at 2.4% from 1990-2015; while in Kenya it was at 1.2% hence its classification for MDG as having made no progress in terms of reduction of maternal mortality .(1)

In a systematic analysis by WHO on global maternal deaths, sepsis (excluding abortions), accounted for 10.7% of maternal deaths(2). Women who get peri-partum infections, other than the severe morbidity and mortality, are also at risk for long-term sequelae such as chronic pelvic pain, fallopian tube blockage and secondary infertility.(3) Ante-partum, intra- and post partum infections are also associated with an estimated 1 million newborn deaths each year(3).

LITERATURE REVIEW:

Ignaz Semmelweis is acknowledged as the first to reveal the contagious nature of puerperal fever(4). He was also among those who advocated for simple measures like hand-washing which resulted in reduction in cases of puerperal sepsis(4). In fact, such ideas had been present for at least a century before Semmelweis' work. Moreover, it is known that Alexander Gordon, an obstetrician working in UK, was the first to prove the contagious nature of puerperal sepsis in the late 1700's(4).

Definition of puerperal sepsis

There are several definitions to puerperal sepsis(3,5):

1. Infection of the genital tract occurring anytime between the onset of rupture of membranes or labour and 42 days postpartum, in which fever and one or more of the following is present:

i) Pelvic pain

ii) Abnormal vaginal discharge eg. Pus

iii) Abnormal smell/ foul odour of discharge

iv) Uterine subinvolution (<2cm/day over the first 8days)

(Mother-baby package: Implementing Safe Motherhood(WHO)(6)

2. Puerperal sepsis is any bacterial infection of the genital tract which occurs after delivery. It is usually more than 24 hours after delivery before the symptoms and signs appear. (7)
3. A complication of the puerperium with endometritis, fever, peritonitis and septicaemia but excluding obstetric pyaemic and septic embolism, and septicaemia during labour. (ICD-10)

The puerperal sepsis/pyrexia presents commonly with fever and other symptoms like pelvic pain, foul smelling vaginal discharge and sub-involution(5). Puerperal infections is a broader term and includes other causes which are urinary tract infections (UTI), wound infection, mastitis and breast abscess(8).

Multiple types of bacteria may be involved when a woman develops puerperal sepsis(7).

Epidemiology of puerperal sepsis:

Sepsis was the most common cause of maternal mortality in the 19th century, responsible for half of all cases(9). Improvement of socioeconomic circumstances and the initiation of antiseptic techniques, the breakthrough of antibiotics caused a sustained fall in deaths until 1980(9). Since then, in a review of maternal deaths in the UK, it was surprisingly noted that maternal mortality due to sepsis was actually on the rise. Although death as a result of pregnancy-related sepsis is not common in the UK and some other high-income countries, mortality rates due to sepsis have more than doubled over the last two decades in the UK and have also increased in other European countries(10).

Dushyant D et al study reported that puerperal fever and sepsis are highly preventable problems that are among the leading causes of maternal morbidity and mortality not only in the developing countries but also in developed countries as well(11).

In a systematic review, of the top four causes of maternal deaths including haemorrhage and hypertensive disorders, those as a result of sepsis showed the highest inequity between developed and developing countries, with odds ratios of 2.7 in Africa, 1.9 in Asia as compared to developed countries(5). Individual studies in developing countries suggest that the incidence of puerperal sepsis is between 0.1-10% of deliveries(5). Case fatality rates are recorded between 4 and 40% in sub-saharan Africa(12).

15% of maternal mortalities in Western Kenya were accounted for by puerperal sepsis between 2003-2008(13). Most estimates of puerperal sepsis in sub-Saharan Africa are

from retrospective studies of maternal deaths, thus, these show the burden of clinically defined puerperal sepsis as a cause of mortality, rather than the actual incidence of puerperal sepsis(14). There are several studies done in sub-Saharan Africa, some of which were interventional in countries like Malawi, Mozambique and some in South Africa. These provided a prevalence ranging widely from between 1.1 upto 12 %(14). None however, are available in Kenya.

Aetiology of puerperal sepsis:

Infections may either be acquired outside a health facility or may be nosocomial. Some of the most common bacteria are: *streptococci, staphylococci, Escherichia coli (E.coli), clostridium tetani, Clostridium welchii, Chlamydia, and gonococci*(7). Uterine infections usually result from infections ascending from the vagina into the uterine cavity.

Different regions have different bacteriological profiles that change with time. A study done in 1988 by Achola et al showed Neisseria gonorrhoeae or Chlamydia trachomatis, or both, were isolated from the endometrium of five out of 35 women with clinical postpartum endometritis compared with none of a control group of 30 puerperal women without endometritis (p < 0 05) in Nairobi, Kenya(15). Most of the incidence studies also, are limited by the lack of bacteriological data(14).

Risk factors for puerperal sepsis may be divided into several categories(5):

a) Socioeconomic:

- Low status/ education for women
- Delay in seeking care

b)Antenatal:

- Malnutrition
- Anaemia
- Systemic illnesses
- History of prolonged rupture of membranes.
- Chorioamnionitis
- Group B Streptococcal infection
- Bacterial Vaginosis

c) Labour and delivery:

- Poor infection control practices
- Prolonged labour
- Multiple vaginal examinations
- Instrumental deliveries
- Caesarian section
- Lacerations of the genital tract
- Retained products of conception
- Haemorrhage

It is therefore possible, based on the risk factors, to prevent puerperal sepsis both ante-natally and intrapartum(5).

If not dealt with, puerperal sepsis may result in severe complications. These complications include septicaemia, endotoxic shock and peritonitis or abscess formation leading to need for surgery and compromised future fertility(16). There are few studies that identify these in African populations and fewer still are able to quantify the magnitude to which these affect the incidence of puerperal sepsis. A trial in South Africa identified episiotomies, PROM and multiple vaginal examinations to be among some of the risk factors, with other risk factors being similar to those of 'high resource' settings(14). It is important to be aware of the level to which these factors affect puerperal sepsis and their prevalence in the region.

Prevention of puerperal sepsis:

The concept of infection control encompasses a range of technologies, interventions and strategies of varying complexity(5). Infection control measures of interest to puerperal sepsis include: Hand washing, clean equipment and delivery kits, surgical asepsis, and prophylactic antibiotics during caesarian section(5).

The infection control campaign by WHO placed hand hygiene as its first priority, and as an underlying action promoted clean products, practices and equipment(5). In a study done in Tanzania, to determine the effectiveness of an intervention that incorporated education about the use of a clean delivery kit in preventing cord infection and puerperal sepsis, women who used the kit for delivery were 3.2 times less likely to develop puerperal sepsis than women who did not use the kit(17).

This indicates that there are simple measures that can be taken to further reduce the magnitude of puerperal sepsis.

Problem statement:

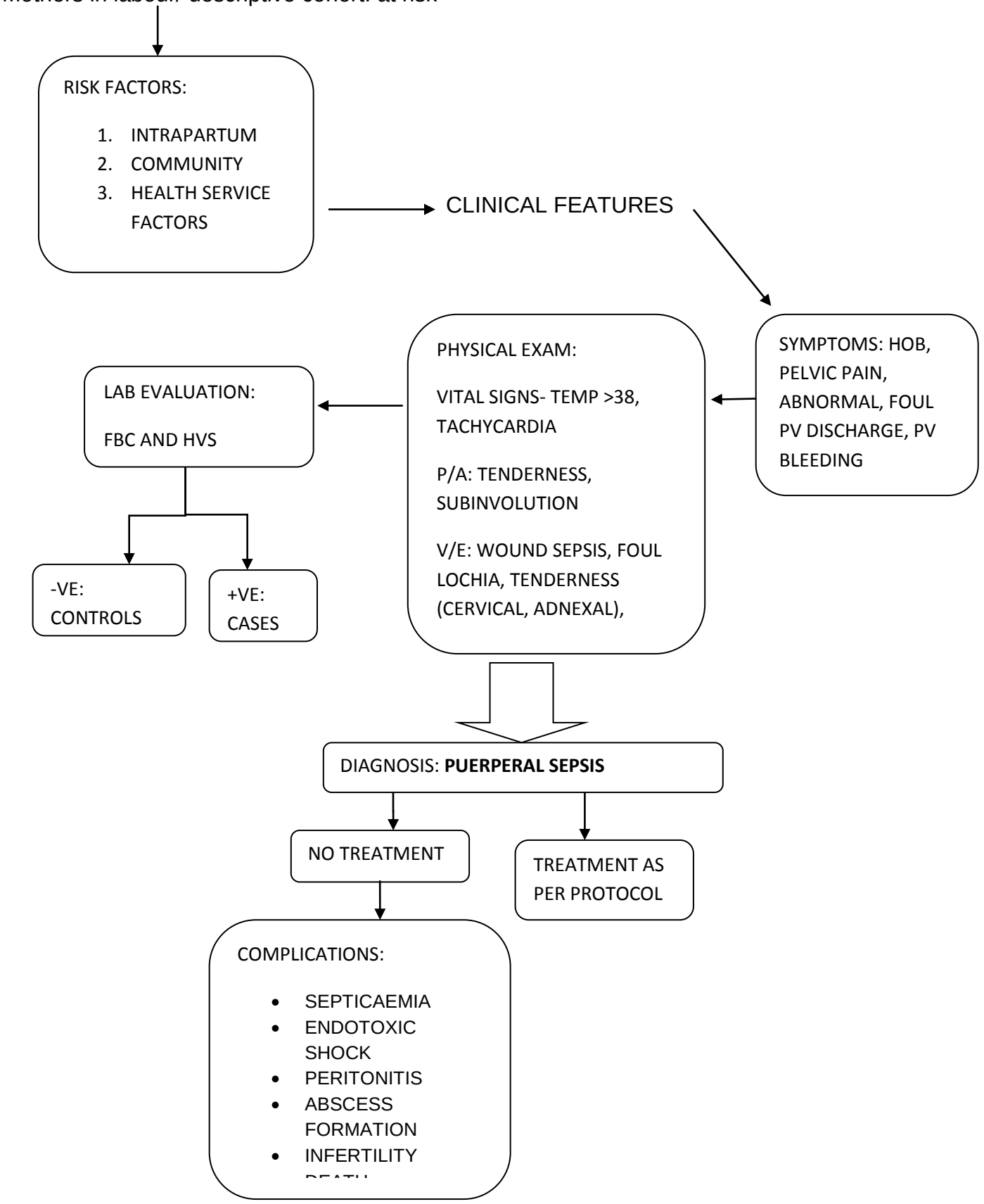
Puerperal sepsis still remains a current problem which goes to indicate that it is a far more complex matter. Puerperal sepsis remains one of the leading causes of maternal mortality, despite advancement in modern medicine.

There are quite a few controversies with regards to puerperal sepsis. Leading amongst them is that comparisons may be difficult due to variations in definitions amongst different studies(9). The clinical presentation of puerperal sepsis is also quite varied. Some may not present with the typical fever, some may not have pelvic pain while others may not present with foul lochia. Also, presentation of most postpartum infections take place after hospital discharge, which in our case, is usually within 24 hours after vaginal birth. Therefore, in the absence of postnatal follow-up, as is often the case in low-income countries, puerperal infections can go unreported(9). Microbiological investigations may be useful to confirm diagnosis but may not always be available especially in low resource settings(5,12). In addition to the difficulties experienced with clinical diagnosis, estimation of incidence has been a problem as proven by a wide range of incidences(0.1-11%) in various countries in Africa and around the world.

According to some studies, most of the puerperal sepsis cases present within the first month of delivery. According to a study done in Brazil, the interval in which the puerperal infection manifested itself in humanized care to normal and caesarean deliveries in all cases was within 30 days after the discharge, more specifically between the fifth and twenty-sixth day after hospital discharge(18). In a study by Yokoe et al,

nearly all postpartum infections manifested after hospital discharge (94%). In addition, most (74%) of these infections acquired after discharge were diagnosed and treated entirely in the outpatient setting without the patients' returning to the hospital where they delivered for examination or treatment, emphasizing the need for surveillance methods that are independent of hospital-based data after discharge from hospital(19).

SCHEMA OF CONCEPTUAL FRAMEWORK: PUERPERAL SEPSIS



CONCEPTUAL FRAMEWORK: NARRATIVE:

Puerperal sepsis is a high risk period occasioned by the procedures and interventions during the peripartum, intrapartum and immediate postpartum phases. Due to effects on the tissue and physiological changes in the placental bed of the uterus. They offer an environment that is conducive for microbes to grow. Interventions conducted during this period, for instance, vaginal examinations may introduce microbes which could result in infection.

Puerperal sepsis is known as the third commonest cause among women of reproductive age. Conceptually, some factors which may predispose to puerperal sepsis occur at community level and facility level which would include interventions by the skilled birth attendants.

Some of the early manifestations of puerperal sepsis may be non-specific like constitutional symptoms including fever, tachycardia. Other symptoms include foul lochia and uterine tenderness.

If untreated, puerperal sepsis may result in septicaemia, shock, infertility and death.

RATIONALE:

Sepsis is the third most common cause of maternal death as a result of childbirth, after haemorrhage and abortion(5), accounting for 11% of global deaths. Maternal mortality in Kenya did not show the decline that was needed in order to have met the target for achieving MDG 5 by 2015. There is therefore a need to reassess and get a closer look at the causes of mortality in Kenya and be able to identify the gap. Puerperal sepsis has been a neglected area as evidenced by the scarcity of data available on the same locally.

In order to be able to intervene in terms of management, one needs to identify the magnitude to which these risk factors contribute to puerperal sepsis. This may be different from resource rich settings. It is also important therefore, to be able to have data on prevalence of the same in the region to be able to determine its relative importance locally.

In the absence of antibiotic treatment or in more severe cases, puerperal sepsis may be complicated by pelvic chronic pain, pelvic inflammatory disease, bilateral tubal occlusion and infertility(20). The most significant long-term complication is infertility resulting from tubal occlusion, estimated to affect some 450,000 women each year globally (20).

Complications of puerperal sepsis like secondary infertility are also a burden in Kenya. According to a systematic analysis done by Mascarenhas, Flaxman and Stevens in 2012, Sub Saharan Africa was among those with leading prevalence for infertility. The

same showed that the overall burden of infertility has remained the same since 1990(21).

Most of the data available on incidence in other sub-Saharan countries are from single-centered studies and can therefore not be used to correctly extrapolate for local use in our country, hence the need for our own local data.

As mentioned, most studies done are retrospective and therefore show the burden rather than actual magnitude for puerperal sepsis.

There is no local data available on the same.

RESEARCH QUESTION:

What is the magnitude of puerperal sepsis, at two weeks post partum, among women delivering at Pumwani maternity hospital (PMH) between March-November 2015?

HYPOTHESIS:

Null: There are no differences among patients with puerperal sepsis and those without.

Alternate: There are differences among patients with puerperal sepsis and those without.

BROAD OBJECTIVES:

To determine the magnitude and risk factors for puerperal sepsis in mothers delivering at PMH.

SPECIFIC OBJECTIVES:

A) To determine the socio-demographic characteristics of mothers presenting with puerperal sepsis and those without.

B) To determine the magnitude of puerperal sepsis at PMH.

C) To determine risk factors associated with puerperal sepsis at PMH.

METHODOLOGY:

This study was conducted at Pumwani Maternity Hospital between March and November of 2015. Mothers were recruited after admission, at delivery, or within 24hours of delivery; and were followed up for a two week period. They were evaluated for puerperal sepsis as defined by clinical criteria as follows: 2 or more of:

Pelvic pain, fever (38 degrees C and above), uterine sub involution, abnormal PV discharge/ Foul smelling lochia, episiotomy/ perineal tear infection, caesarian section wound infection.

Those found to meet the clinical criteria had a full blood count and a high vaginal swab done. Data was collected in the form of questionnaires at different points including: Labour ward, post natal wards and post natal clinic.

Study design:

The study design was that of a case cohort study.

A case cohort study is a variation of a case-control study in which only a subset of controls from the cohort are compared to the incident cases. In this case, of the 793 women, 69 were considered cases, and each of the 69 cases was matched with 3 controls within the same cohort.

Study setting:

Pumwani Maternity Hospital (PMH), Nairobi Kenya.

PMH is a referral Maternity Hospital located east of the Nairobi City. It is an obstetric and referral Hospital for delivery of expectant mothers in Nairobi and adjoining regions.

With daily normal deliveries more than 50-100 with more than 10-15 caesarian sections a day. It is equivalent to a provincial hospital.

Uncomplicated deliveries at PMH are managed routinely without any use of antibiotics. However, those who undergo episiotomies or perineal tears are given antibiotics post delivery.

Study population:

All mothers admitted at Pumwani Maternity Hospital within 0- 24hours of delivery.

INCLUSION & EXCLUSION CRITERIA:

Inclusion:

Mothers in labour above 28 weeks gestation

Mothers within 24 hours post delivery.

Willing to give consent.

Exclusion:

Those diagnosed clinically with chorioamnionitis (presenting with symptoms and signs).

Sample size calculation:

Sample size is calculated using the formula(22):

$$n = (\frac{r+1}{r}) \frac{(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Sample size assumptions:

n = Sample size in the case group

r=**ratio** of controls to cases

Z_{β} Represents the **desired power** (typically .84 for 80% power).

$Z_{\alpha/2}$ Represents the desired **level of statistical significance** (typically 1.96)

p_1 = percentage of women with puerperal sepsis (cases) with risk factor (estimated conservatively at 50%)

p_2 = percentage of women without puerperal sepsis (controls) with risk factor

$p_1 - p_2$ is the **effect Size** (the difference in proportions set at 20%)

$\bar{p}$ is the average of p1 and p2 used to estimate the overall variability associated with risk factor

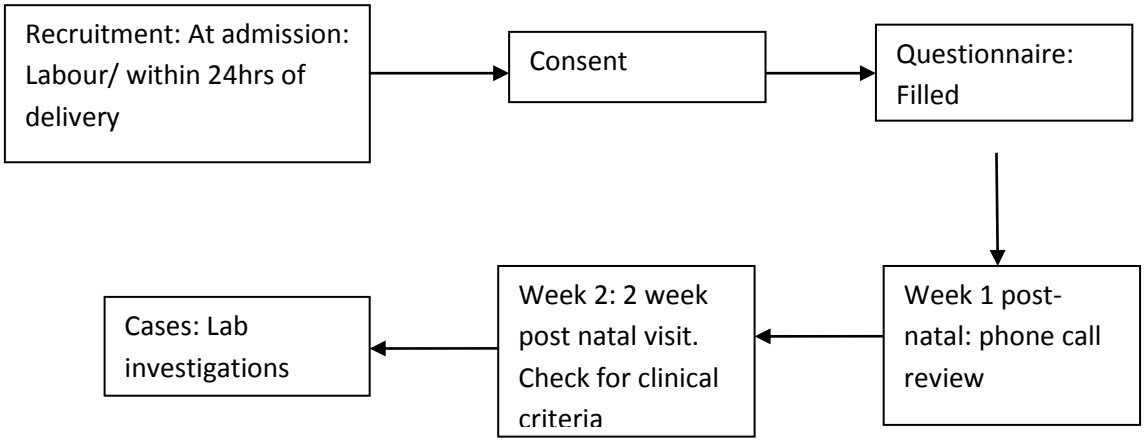
$n = (\frac{3+1}{3}) \frac{(0.4)(1-0.4)(0.84+1.96)^2}{(0.5-0.3)^2}$ = 65 cases and 3n=195 controls

Case-cohort analysis:

Further analysis for the risk factors of puerperal sepsis was conducted using a case cohort design with the outcome being cases diagnosed with puerperal sepsis at 2 weeks (n = 69). For each case, 3 controls were selected at random from among the postnatal mothers who did not have puerperal sepsis giving a total of 207 controls (unmatched) for the case cohort. The findings of the analysis are presented in the results section.

PROCEDURES:

Recruitment:



Patients were recruited as they came in for delivery. All mothers who came in labour above 28 weeks were eligible. Informed consent was sought and obtained. The symptoms and danger signs of infection to look out for were explained to the women. If these were to occur they were advised to report back to the study site immediately. These mothers were followed up via phone and were seen at two weeks to assess for the symptoms, for a physical examination and collection of specimen for lab analysis.

DEFINITIONS OF CASES AND CONTROLS:

A case: a woman who had come in for delivery and had presented with two or more of the following, post partum:

Pelvic pain, fever (38 and above), uterine sub involution, abnormal PV discharge/ Foul smelling lochia, episiotomy/ perineal tear infection, caesarian section wound infection.

A control: a woman who had come in for delivery and had one/no symptoms.

Site preparation:

Research assistants were used and educated on study. Staff were educated and informed regarding the study and its requirements. Stations were based in labour ward, post natal wards, and post natal clinics.

Specimen collection:

This was done at the time of examination. Blood samples were taken for full blood counts including differentials and a High vaginal swab for microscopy, culture and sensitivity during speculum exam.

Upon insertion of the speculum using sterile techniques, the swab was inserted carefully without contamination, into the vagina to swab the posterior fornix.

The swab was then recapped and correct labeling was confirmed.

Processing:

Samples were checked for correct labeling and requisition, stored and immediately transferred to the lab for analysis.

VARIABLES:

The variables for this study were as shown in the table below. They included independent variables like: premature rupture of membranes, presence of anaemia and number of vaginal examinations. These had their own indicators as stated.

Dependent variable: the presence of puerperal sepsis; whose indicator included the stated clinical criteria like pelvic pain, and foul lochia.

TABLE INDICATING VARIABLES:

VARIABLE	INDICATOR	MEASUREMENT	DATA SOURCE	DATA INSTRUMENT
INDEPENDENT				
a) Premature Rupture of membranes	Drainage of Liquor	Presence or absence of liquor	Patient examination	Speculum exam
b) Anaemia	Haemoglobin levels	Grams/deciliter	Patients blood sample	FBC results
c) Number of Vaginal examinations		Count number of VEs	Patients / partograph	Questionnaire
d) Mode of delivery		Caesarian/ SVD/ Assisted vaginal	Patient/ patient records	Questionnaire

DEPENDENT a) Presence of puerperal sepsis	Pelvic pain Foul lochia Fever Tachycardia	 Temperature in degrees Pulse rate	Patient	Questionnaire Questionnaire, Thermometer
a) Presence of Puerperal sepsis	Elevated WBC count Cultures	Cells/ul Positive/Negative		Questionnairre, Lab result-FBC Questionnaire, Lab result-HVS

DATA COLLECTION AND ANALYSIS:

Data collection and storage: Data was collected by use of questionnaires (appendix 1), clinical examination and by lab investigations. Consent was sought, as per the consent form (appendix 2). The information was stored safely and patients' confidentiality was observed.

Each questionnaire was reviewed by the principal investigator for completeness. Data was cleaned coded and entered and analysed using STATA. Categorical factors e.g. marital status, education level and employment status were summarized using univariate frequency distribution tables showing frequencies and percentage of participants in each category. Bivariate analysis was then conducted using chi

square test to identify risk factors showing association with puerperal sepsis. Odds ratios (OR) and their 95% confidence intervals (CIs) were calculated, while p≤0.05 was considered statistically significant.

STUDY LIMITATIONS AND STRENGTHS

Loss to follow up (2 weeks) at 2 weeks was at 28%, resulting in a lack of generalisability. However follow up by phone was used to maintain contact and encourage revisits at 2 weeks.

The study was a single site and therefore the results may not be a representation of the whole country.

The possibility of misdiagnosis at week one, since this was over a phone-call. However, these were followed up by a visit(clinical exam) at second week visit.

STRENGTHS: The study followed up patients for 2 weeks after discharge from hospital, which enabled the study to capture a majority of the cases.

The study was based in the largest maternity centre in east and central Africa therefore recommendations from this study will impact greatly on other facilities.

ETHICAL CONSIDERATIONS:

Ethical approval was obtained from the KNH and PMH research and ethics committee.

Patients' data was anonymous, and patient information was treated with confidentiality. Data was collected, safely stored and only accessible to the principal investigator.

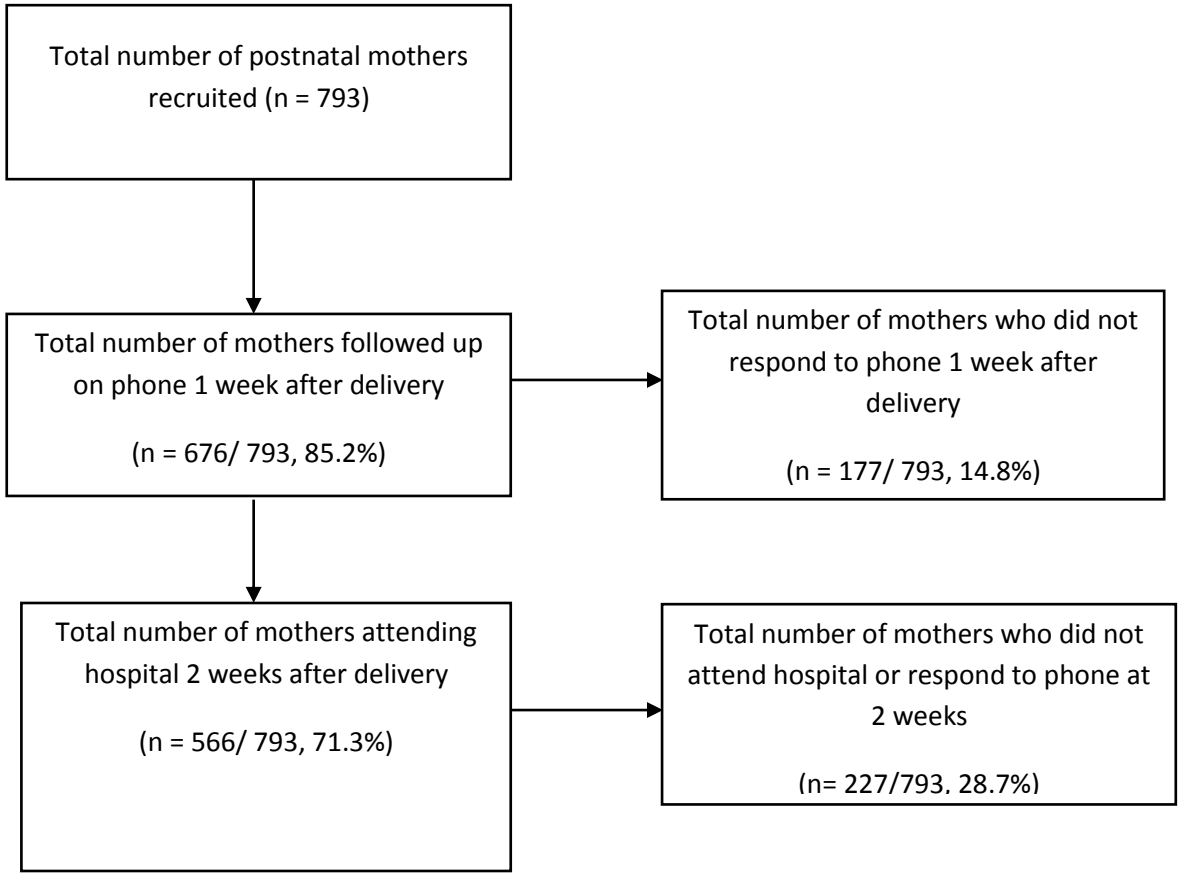
Informed consent was sought and obtained without inducement or coercion.

Patients who opted not to participate still received standard of care. No additional risks were anticipated from the procedures done.

Those that were found to be cases were treated as per the exiting protocols.

RESULTS:

FIGURE 1: PARTICIPANT FLOW FROM RECRUITMENT TO WEEK TWO FOLLOW UP AFTER DELIVERY AT PUMWANI MATERNITY HOSPITAL:



A total of 793 postnatal mothers at Pumwani maternity hospital were recruited in the study.

Out of the 793 mothers recruited immediately after delivery, 177 (14.8%) mothers did not respond to phone calls made 1 week after delivery.

At week 2 follow up 566 (71.3%) of the 793 women responded and 227 (28.6%) mothers did not attend hospital and could not be traced on phone.

FIGURE 2: **MAGNITUDE OF PUERPERAL SEPSIS IN WOMEN DELIVERING AT PMH AT WEEK 1 AND WEEK 2:**

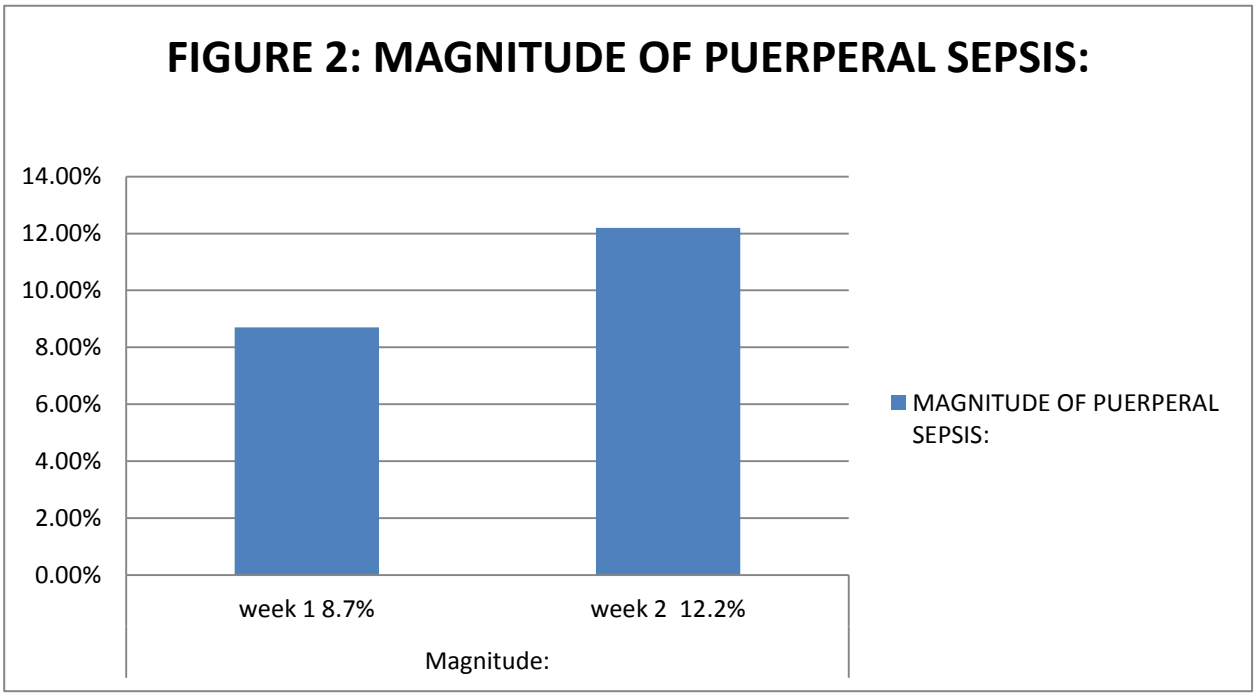


Figure 2 presents the magnitude of puerperal sepsis in mothers delivering at PMH at two time points in the post delivery period (1 week and 2 weeks), after excluding the loss to follow up. Out of the 676 patients contacted by phone a week after delivery 59 patients met the criteria for diagnosis of puerperal sepsis based on reported clinical signs and this corresponded to a magnitude of 8.7%, for sepsis. Based on reassessment of 566 mothers, it was established that a total of 69 mothers met the criteria for puerperal sepsis diagnosis based on reported symptoms and clinical examination; corresponding to a magnitude of 12.2%, for puerperal sepsis.

TABLE 1: ASSOCIATION BETWEEN SOCIO-DEMOGRAPHIC CHARACTERISTICS AND PUERPERAL SEPSIS AMONG THE STUDY PARTICIPANTS AT PMH:

	Puerperal sepsis		**OR (95% CI)**	**p-value**
	YES (n = 69)	**NO** (n = 207)		
Maternal age				
<20 years	7(10.1)	14(6.8)		
20-24 years	32(46.4)	87(42.0)	0.74(0.27-1.99)	0.545
25-29 years	16(23.2)	64(30.9)	0.50(0.17-1.44)	0.2
30-34 years	10(14.5)	30(14.5)	0.67(0.21-2.12)	0.492
35 years and above	4(5.8)	12(5.8)	0.67(0.16-2.84)	0.584
Marital status				
Single	12(17.4)	27(13.0)		
Married	55(79.7)	178(86.0)	0.70(0.33-1.46)	0.338
Divorced	2(2.9)	2(1.0)	2.25(0.28-17.91)	0.444
Education				
None	2(2.9)	2(1.0)		
Primary	28(40.6)	78(37.7)	0.36(0.05-2.67)	0.317
Secondary	29(42.0)	100(48.3)	0.29(0.04-2.15)	0.226
Tertiary	10(14.5)	27(13.0)	0.37(0.05-2.99)	0.352
Occupation				
Housewife	31(44.9)	100(48.3)		
Business or farming	20(29.0)	49(23.7)	1.32(0.68-2.54)	0.412
Formal employment	3(4.3)	16(7.7)	0.60(0.17-2.21)	0.447
Informal employment	15(21.7)	42(20.3)	1.15(0.56-2.35)	0.698

In Table 1, the largest categories in the mothers who were recruited in both groups were in the 20-24 yr old age group (puerperal sepsis group: 46.4%, without sepsis: 42.6%), married (with sepsis: 79.7%, without sepsis: 86.0%), having attained secondary level education (with sepsis: 42%, without: 48.3%), with the highest number in terms of occupation being housewives (with sepsis: 44.9%, without: 48.3%).

There was no association between the socio-demographic characteristics and odds of puerperal sepsis.

TABLE 2: ANTE NATAL FACTORS ASSOCIATED WITH PUERPERAL SEPSIS IN WOMEN DELIVERING AT PMH:

Risk factor	Puerperal sepsis		OR(95% CI)	p-value
	YES (n = 69)	NO (n = 207)		
Hemoglobin				
5.1-8 g/dl	1(1.4)	3(1.4)	1.00	
8.1-10 g/dl	6(8.7)	10(4.8)	1.80(0.15-21.48)	0.642
>10g/dl	62(89.0)	194(93.7)	0.95(0.10-9.33)	0.967
HIV test				
Reactive	3(4.3)	12(5.8)	0.74(0.2-2.7)	0.647
Non-reactive	66(95.7)	195(94.2)		
Foul smelling discharge 2 weeks prior to delivery				
Yes	23(33.3)	28(13.5)	3.20(1.69-6.1)	<0.001
No	46(66.7)	179(86.5)		
BMI				
<18	3(4.3)	17(8.2)		
18-24.9	35(50.7)	113(54.6)	1.76(0.49-6.34)	0.391
25-30	24(34.8)	61(29.5)	2.23(0.60-8.31)	0.232
>30	7(10.1)	16(7.7)	2.48(0.54-11.28)	0.24
Parity				
Primigravid	35(50.7)	81(39.1)		
Multigravid	31(44.9)	120(58.0)	0.60(0.34-1.05)	0.072
Grand multigravidity	3(4.3)	6(2.9)	1.16(0.27-4.89)	0.843

As shown in table 2, a majority of those who had puerperal sepsis had a BMI of 18-24.9 (35/69, 50.7%), and a haemoglobin level of >10g/dl (62/69, 89%). Of the 69 patients who developed puerperal sepsis, 66 were HIV negative (95.7%). History of foul smelling vaginal discharge two weeks prior to delivery was associated with increased risk of puerperal sepsis (OR 3.20, 95% CI: 1.69-6.1; p-val <0.001).

TABLE 3: INTRAPARTUM FACTORS ASSOCIATED WITH PUERPERAL SEPSIS IN WOMEN DELIVERING AT PMH:

	PUERPERAL SEPSIS			
Duration of Active Phase of Labour	**YES (n = 69)**	**NO (n = 207)**	**OR (95% CI)**	**P-VALUE**
<12 hrs	49(71.0)	177(85.5)		
12-24 hrs	9(13.0)	19(9.2)	1.71(0.73-4.02)	0.218
>24 hrs	11(15.9)	10(4.8)	3.97(1.59-9.90)	0.003
Duration/ time since drainage				
<12 hrs	30(43.5)	124(59.9)		
12-24 hrs	7(10.1)	12(5.8)	2.41(0.87-6.65)	0.089
>24 hrs	3(4.3)	5(2.4)	2.48(0.56-10.96)	0.231
Number of V/ Es				
<2	9(13.0)	56(27.1)		
2 to 4	49(71.0)	133(64.3)	2.29(1.05-4.98)	0.036
5 and above	11(15.9)	18(8.7)	3.80(1.36-10.64)	0.011
Tear				
Yes	19(27.5)	62(30.0)	0.89(0.48-1.63)	0.703
No	50(72.5)	145(70.0)		

Table 3 shows that intra-partum factors that were significantly associated with increased risk of puerperal sepsis were >24hours in active phase of labour (OR 3.97, 95% CI: 1.6-9.9, p val; 0.003), 2 or more vaginal examinations (p val < 0.05).

TABLE 4: DELIVERY FACTORS ASSOCIATED WITH PUERPERAL SEPSIS AT PMH:

	PUERPERAL SEPSIS			
	YES	NO	OR (95% CI)	P-VALUE
Mode of delivery				
Vaginal	39(56.5)	156(75.4)		
Breech	2(2.9)	2(1.0)	4.00(0.55-29.30)	0.172
Caesarean section	28(40.6)	48(23.2)	2.33(1.30-4.18)	0.004
Placenta delivery				
Retained	0(0.0)	2(1.3)	-	0.470
Not retained	41(100.0)	157(98.7)		

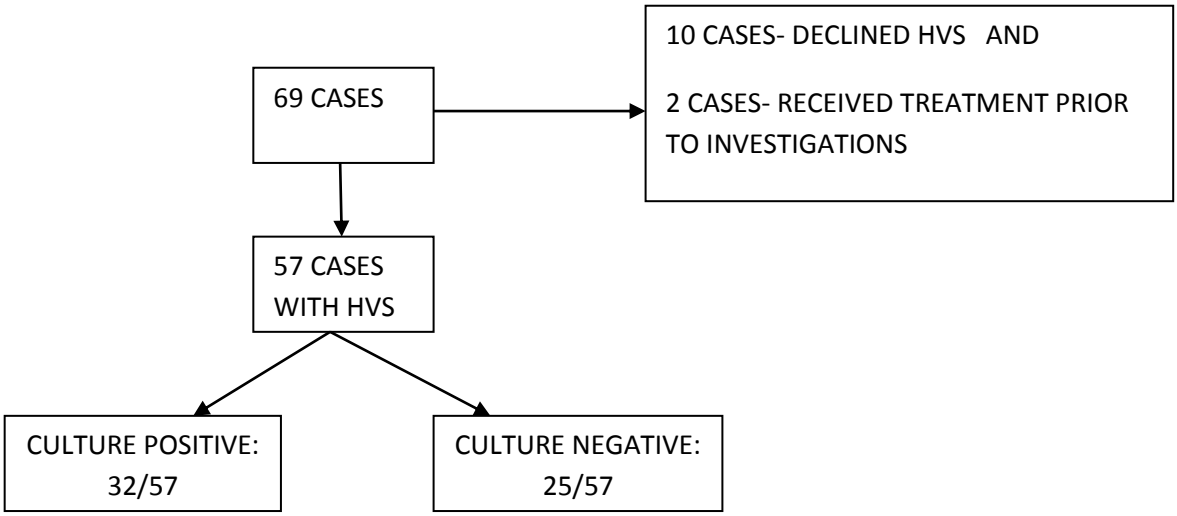
In table 4, 39 women that developed puerperal sepsis had had a vaginal delivery while 28 had undergone a caesarian section. Caesarian section delivery was associated with increased odds of 2.3(95%CI 1.30-4.18; p val <0.05).

TABLE 5: ASSOCIATION BETWEEN POST PARTUM HAEMORRHAGE, DIAGNOSIS AND RISK OF PUERPERAL SEPSIS AT PMH:

RISK FACTOR	PUERPERAL SEPSIS			
Post partum haemorrhage	**YES (N=69)**	**NO (n=207)**	**OR 95% CI**	**P-VALUE**
Yes	2(2.9)	10(4.8)	1.00	
No	67(95.7)	197(95.1)	1.66(0.35-7.76)	0.521
Definitive diagnosis(post delivery)				
Normal labour	49(71.0)	176(85.0)	1.00	
Delayed 2nd stage	1(1.4)	3(1.4)	1.19(0.12-11.69)	0.884
Ante partum haemorrhage	2(2.9)	3(1.4)	1.00	
Obstructed labor	7(10.1)	5(2.4)	4.98(1.51-16.48)	0.009
Non-reassuring fetal status	10(14.5)	20(9.7)	1.78(0.77-4.08)	0.174

Table 5 shows that those that had undergone a c-section based on the diagnosis of obstructed labour were the ones found to have significant risk (OR 4.98, CI: 1.51-16.48; p val-0.009).

FIGURE 3: LAB INVESTIGATION: FLOW OF CULTURE RESULTS:



Of the 69 cases, twelve patients did not have a high vaginal swab as shown in figure 3. Of the remaining 57, those that were culture positive were 32, forming 56% of the group.

TABLE 6: **CULTURE RESULTS OF PATIENTS FOUND TO BE CULTURE POSITIVE.**

Organism	**No.**
S. aureus	9
E.coli	10
S. faecalis	2
S. agalactiae	2
Klebsiella	3
T.vaginalis	2
candida	4
TOTAL	32/57

The lab investigations that were done revealed that 95% of those that presented with clinical features of puerperal sepsis, had a normal haemoglobin and white blood cell count. However, 56% of these were culture positive on high vaginal swab. A majority of the organisms found were S. aureus and E.coli.

DISCUSSION:

This study found the magnitude of puerperal sepsis was found to be 12.2%. This is above the incidence studies done in developing countries in Africa according to a review by J. Hussein, Walker that ranged at 0.1-10%(5).

A study done here in Nairobi in 1987 by Plummer et al, the prevalence of puerperal sepsis was much higher at 20.3%(15). However, they were targeting *N. gonorrhoea* and *C.trachomatis*. This decrease could be explained by the fact that they were taking endometrial biopsies explaining the higher detection rate. Also, our study was looking at symptoms which might not manifest as early.

In a much larger study done across 6 countries in West Africa by Prual et al, 2000, incidence of puerperal sepsis was found to be at 1.4%, much lower than in our study(23). However, they included only those with severe septic features. He also attributed the low level of infections by the wide use of antibiotics by the population and health care staff. Furthermore, he listed improvement in geographical accessibility to health facilities and improvement in hygienic practices.

In a study in the USA by Yokoe, 2001, the rate of puerperal infection was at 2.5% in vaginal deliveries and c-sections at 5.3%.In another prospective hospital based study in the UK, incidence was found to be at 0.03%.

The differences in incidences and the wide range amongst all these studies may becaused by the lack of a clear cut standard definition of puerperal sepsis as evidenced by the different selection criteria used in different studies.

The larger difference in our study compared to those in developed countries would include the advancement in their infrastructure, greater availability of health care services and hence reduction in delay to seeking care which is one of the major social factors affecting puerperal sepsis.

A majority of those with puerperal sepsis turned out to be in the 20-24 year age group, however neither age nor any other of the socio-demographic factors were found to be significant.

Risk factors identified included: obstructed labour(OR: 5), multiple vaginal examinations and prolonged labour >24hours (OR: 3.95), history of foul vaginal discharge within 2 weeks to delivery (OR:3.20), c/sections (OR: 2.29).

These factors are in keeping with the review for low and middle income countries by Hussein J et al, 2012(5).

However this study, unlike in the review by Hussein J et al(5), found no association with anaemia, malnutrition, history of prolonged rupture of membranes or lacerations of the genital tract. This is probably due to increased antibiotic use in patients wiith lacerations and PROM.

In another study by Khaskheli et al, 2011, Pakistan: they identified common risk factors as anaemia, absent membranes and suboptimal personal hygiene as well as improper sterilization(24). In our study, most of those who presented had a haemoglobin level of >10g/dl, which implies other factors playing a larger role amongst the risk factors.

Multiple vaginal examinations also had a significant association with those more than 2 having a higher risk for developing puerperal sepsis. This is in keeping with a study by Dare et al (Nigeria), that showed multiple vaginal examinations was associated with increased risk of puerperal sepsis(25).

Our study revealed that 95% of those that had puerperal sepsis had a normal haemoglobin level and white cell count. 56% of the high vaginal swabs done had a positive culture with a majority being S. aureus and E. coli. In a review of bacteriology by Anne Miller, a wide range of organisms were cultured from swabs from the women with a diagnosis of puerperal sepsis(26). A majority of them cultured sexually transmitted organisms, as well as maternal gut flora. Others had organisms across more than 3 groups and were therefore difficult to classify. As per the classification in this review, our study found organisms within the nosocomial group as well as the maternal gut flora. This points to the aetiology of infection as well as preventive measures that could be taken in order to decrease the incidence of puerperal facility in this setup.

CONCLUSION:

The magnitude of puerperal sepsis at Pumwani was in keeping with data from other countries in Africa and around the world. Antepartum history of foul smelling discharge, multiple (>2) vaginal examinations, prolonged and obstructed labour were found to be significantly associated with risk.

RECOMMENDATIONS:

Prevention, early diagnosis and management of obstructed labour, by proper use of the tools available, like the partograph, would result in a reduction of multiple vaginal examinations.

Vaginal examinations should be kept to a minimum, to be done only when necessary. If more than two vaginal examinations are done, universal precautions and antibiotic prophylaxis should be considered.

Recommended universal measures to reduce puerperal sepsis include(3):

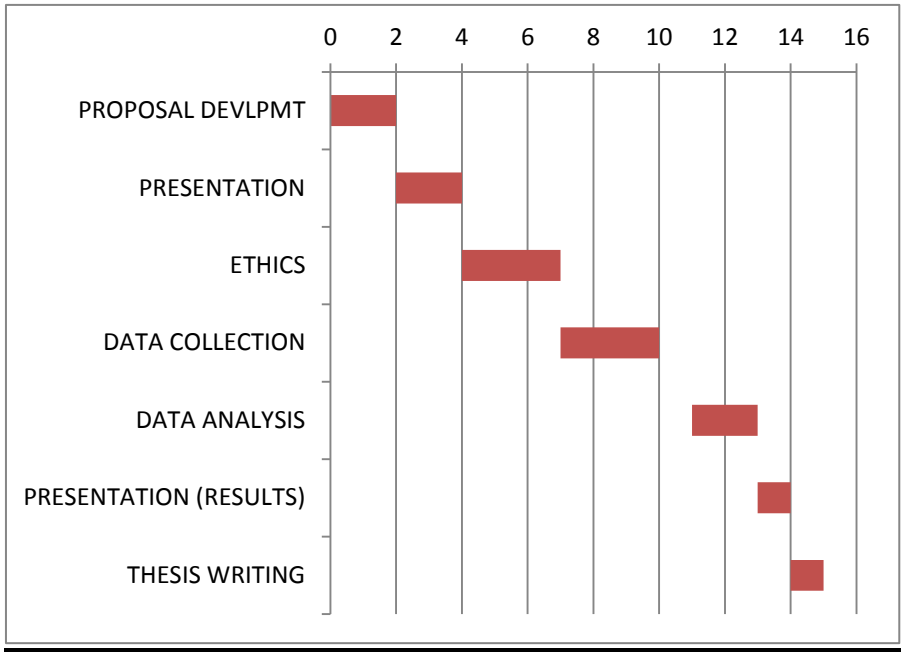
- Routine antibiotic prophylaxis for women undergoing manual removal of the placenta.
- Vaginal cleansing with povidone-iodine immediately before caesarean section.
- For caesarean section, prophylactic antibiotics should be given prior to skin incision.

Further studies may be done to assess the outcomes for different risk factors identified in our setup, for example: adherance to protocols for infection prevention and control, interventional studies in terms of antibiotic use and operative procedures.

TIMELINE:

TITLE: GANNT chart representing the timeline for the study at Pumwani Maternity Hospital 2015.

DURATION IN MONTHS (TIME 0- SEPTEMBER 2014)



BUDGET:

RESEARCH BUDGET AT PUMWANI MATERNITY HOSPITAL:

ITEM	QUANTITY	UNIT PRICE	TOTAL (KSH)
SUPPLIES			
Biro Pens	6	20.00	120.00
Pencils	2	12.00	24.00
Box file	2	150.00	300.00
Spring files	2	120.00	240.00
Pencils sharpener	1	45.00	45.00
White out pen	1	85.00	85.00
Folder	2	120.00	240.00
Staple	1	245.00	245.00
Paper Punch	1	550.00	550.00
Staple Romover	1	235.00	235.00
Note book	2	85.00	170.00
TOTAL SUPPLIES			**2,254.00**
OTHERS			
Printing	30	10.00	300.00
Photocopying	4000	3.00	12,000.00
Final proposal booklet	8	500.00	4,000.00
Ethic comm, Bk	1	2,000.00	2,000.00
A poster	4	2,500.00	10,000.00
TOTAL OTHER			**28,300.00**
Transport	**1**	**10,000.00**	**10,000.00**
Communication	**1**	**5,000.00**	**5,000.00**
Research Assistant	**1**	**50,000.00**	**50,000.00**
Data Statistician	**1**	**20,000.00**	**20,000.00**
Laboratory services	**60.00**	**800.00**	**48,000.00**
TOTAL PERSONNEL			**133,000.00**
TOTAL EXPENSES			**133,554.00**

The total budget amounted to Ksh. 133,554; including lab investigations. The study was sponsored by PRIME –K.

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APPENDICES:

APPENDIX 1: QUESTIONNAIRE FOR THE STUDY(STUDY TOOL)

PUERPERAL SEPSIS STUDY AT PUMWANI MATERNITY HOSPITAL:

This questionnaire is to be filled by the investigator/ research assistant after the patient has given informed consent.

Circle only one of the various options given for each question as per the patient's response.

Ensure the patient has understood the question before filling it out.

PART 1: DEMOGRAPHICS

Patient name (optional):

IP number:

Consent filled: yes/no

Study number:

Contact:

Next of kin:

Contact for next of kin:

Occupation:

Marital status: single- married- divorced- widowed

Education level: none- primary- secondary- tertiary

Weight:

Height : BMI:

LNMP:

GBD:

Parity: Gravida:

ANC profile: Venue

Knowledge of lab results;

Hb-

B/g-

Urinalysis-

HIV- reactive – N/R

HAART use- a)yes b)no

CD4 count a) <200 b)200-350 c)>350

H/o treatment for UTI: a)yes b)no

VDRL- +/-

Regarding antibiotic use: did you receive any antibiotics two weeks prior to delivery?

Yes/ no

If yes,

When:

Which antibiotics

Route of admin: oral, intramuscular, intravenous, rectal, sublingual

Indication: Respiratory, UTI, GIT, others:_____

Any use of local/ herbal applicants in the past two weeks? Yes/ no

Sexual activity in the past two weeks: yes/ no

Any abnormal PV discharge in the past two weeks? Yes/ no

Features of STIs characterized by:

Pain: yes/ no

Discharge: yes/ no

Part 2:

Intrapartum:

Was there drainage of liquor a) yes b)no

Duration/time since drainage a) <12hours, b) 12-24 c) > 24

Colour/smell: clear, meconeum stained, other

Foul smelling: yes/no

No. Of V/Es: a) < 2 b) 2-4 c)>=5

V/Es done at: hospital/home

Was there induction of labour? Yes/ no

If yes, method: PV prostaglandins, SL, IV

Was there augmentation of labour? Yes/ no

Obstructed labour: a) yes b) no

Duration of 2nd stage of labour: <30min, 1hour, >1hour

Outcome:

A) Single b) Multiple

A) Alive b) FSB c) MSB d) Died

Bwt a) <2.5 b) 2.5-3.5 c)>3-5

Sex a) male b) female

Were clots expelled? Yes/no

Episiotomy: a) yes b) no

Perineal tear: a) yes b) no

Antibiotics: did patient receive intra-partum antibiotics? A)yes b) no

Duration of apl: a)<12, b)12-24hrs, c)>24hrs

Vital signs: PR- Temp- RR- BP-

Co-morbidities: a) yes b) no

If yes, A) DM b) ht c) both d) others

Pre eclampsia: a) yes b) no

PPH: a) yes b) no ebl: a) <1000mls b) >1000mls

Did patient receive IV Fluids? Transfusion?

Placenta delivery: a) manual b) cct

Mode of delivery: a) vaginal b) breech c)assisted vaginal d) cs

Was patient discharged/ died? A) discharged b) died

Prolonged hosp stay:

1)> 24hours- vaginal a) yes b)no

2) >3days- cs a) yes b)no

Readmission: yes/no

Part 3

Postpartum:

Hob/fever: a)yes b) no

Pelvic pain: a)yes b)no

Foul smelling pv discharge: a)yes b)no

Urinary symptoms: a)yes b)no

Exam:

Vital signs

Abd tenderness: a)yes b)no

Subinvolution: a)yes b) no

Foul lochia: a)yes b)no

Cervix open: a)yes b)no

Tender adnexa/ cervical motion tenderness: a)yes b)no

Episiotomy site infection: a)yes b)no

Caesarian section site infection: a) yes b) no

FBC results:

A: haemoglobin:

a) <5g/dl
b) 5.1-8 g/dl
c) 8-10 g/dl
d) >10g/dl

B: white cell count

1) 4000-11000
2) >11,000

HVS results

Microscopy: organism ----------

Culture a) positive b) negative

Baby:

Is baby breastfeeding? Yes/ no

Any malformations? Yes/ no

Jaundice, discharge in the eyes, cataracts?

Was baby readmitted? Yes/ no

What was the indication?_____

Cord/ stump? Infected, clean.

THANK YOU.

APPENDIX 2:

Consent Form for Participation in a Research Study

The University of Nairobi

Title of Study: MAGNITUDE OF PUERPERAL SEPSIS IN WOMEN DELIVERING AT PUMWANI MATERNITY HOSPITAL.

Introduction:

My names are Dr. Naima A. Shatry, a student of the University Of Nairobi. I am pursuing my Masters degree in Masters of Medicine, Obstetrics and Gynaecology.

This research project is done as a part of the requirements for the award of the masters degree mentioned above.

Description of the research and participation

I would like to invite you to participate in this research study. The purpose of this research is to identify the level and causes of infections after delivery in our facility. This will help us be able to better manage infections after delivery. It will also help our staff to come up with ways of preventing these infections.

Your participation will involve:

1. Helping us fill a questionnaire at the time of admission and at follow up visits.
2. Full examination at admission and at subsequent visits.
3. Some lab tests will be done. These will include: A blood test(Full blood account) and a sample from the vagina (high vaginal swab).

Risks:

There are no known risks associated with this research.

Potential benefits

There are no known benefits to you that would result from your participation in this research. This research may help us to understand the magnitude to which this condition affects our population and eventually be able to tackle one of the factors of maternal mortality in Kenya.

Protection of confidentiality

We will do everything we can to protect your privacy. Any data collected will be stored carefully and only those involved in the study will be permitted access. Your identity will not be revealed in any publication resulting from this study.

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

If found to have this infection, you will be treated as per the current guidelines regardless of whether you opt to participate or not.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact

Dr. Naima Shatry

Department of Obstetrics and Gynaecology,

College of Health Sciences,

University of Nairobi at

Tel: 0737667728.

If you have any questions or concerns about your rights as a research participant, please contact the Kenyatta National Hospital Ethics and Research committee:

Prof M. L Chindia

Secretary KNH/UoN

Ethical and Research Committee

Tel: 0720726300-9

Consent

Participant:

I have read this consent form, understood it fully and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature_____ Date:_____

Person conducting the consenting process:

I have provided adequate information and have ensured patient's understanding of the study and all that it entails as discussed in the consent form.

Signature_____ Date:_____

A copy of this consent form should be given to you.

APPENDIX 3: KNH ETHICS AND RESEARCH COMMITTEE APPROVAL AND RENEWAL:

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 12 FEB 2015 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

Ref: KNH-ERC/A/51

12th February, 2015

Dr. Naima A. Shatry
Dept of Obstetrics & Gynaecology
School of Medicine
University of Nairobi

Dear Dr. Shatry

Research Proposal: Incidence and Risk Factors for Puerperal Sepsis in women delivering at Pumwani Maternity Hospital P725/12/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 12th February 2015 to 11th February 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.erc.uonbi.ac.ke**

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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH- ERC/R/82

7th June, 2016

Dr. Naima Shatry
Reg. No. H58/69529/2013
Dept. of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Shatry,

Re: Approval of Annual Renewal – Magnitude of Puerperal Sepsis in Women Delivering at Pumwani Maternity Hospital (P725/12/2014)

Your communication dated May 31st , 2016 refers.

This is to acknowledge receipt of your study progress report and hereby grant you annual extension approval for ethical research protocol P725/12/2014.

The study renewal dates are 12th February 2016 – 11th February 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study.
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine, UoN
The Chair, Dept. of Obstetrics and Gynecology, UoN
Supervisors: Prof. Guyo Jaldesa, Dr. Kizito Lubano,