EFFECTIVENESS OF A GROUP B STREPTOCOCCUS (GBS) PROTOCOL ON GBS SCREENING AND INTRAPARTUM ANTIBIOTIC PROPHYLAXIS AT KENYATTA NATIONAL HOSPITAL

A RESEARCH STUDY

SUBMITTED BY

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PART FULFILMENT FOR THE

DEGREE OF MASTER OF MEDICINE

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OBSTETRICS AND GYNAECOLOGY

AT THE

UNIVERSITY OF NAIROBI

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DECLARATION

This is to certify that this research is my original work; it has never been presented in any other university and was developed under supervision and approval by senior lecturers and presented to the faculty of obstetrics and gynaecology, school of medicine, University of Nairobi.

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DEDICATION

This is to my family, led by my grandfather Naftali Okola and my Grandmother Zilpa Okola who never reached university but through sheer determination as casual labourers ensured their sons, daughters and grandchildren had an equal chance at getting an education just like any other Kenyan child. To my father Gerald Oyiengo Okola, my mother Joyce Akoth Okola ,my brothers; Wycliffe Okola, Wilfred Okola ,Dan Okola ,sister in law mercy and nephews Baraka and Abel thank you for being patient with me as I pursued this course and for bearing with the demands of my study timelines. To my late maternal grandparents Vitalis Peter Augo and Mama Monegunda Omollo Augo, your existence on earth and love for my mother made it possible I be named after you, to walk eternally in your footsteps. You are truly missed but never forgotten.

LIST OF ABBREVIATIONS

1. ACOG - American college of obstetricians and gynaecologists
2. ANC - Antenatal clinic
3. CDC - Centre for disease control
4. CME – Continuous medical education
5. GBS – Group B streptococcus
6. EOGBS – Early onset group B streptococcal sepsis
7. IAP – Intrapartum antibiotic prophylaxis
8. RCOG – Royal College of Obstetricians and Gynaecologists
9. KNH – Kenyatta National Hospital
10. KOGS – Kenya Obstetricians and Gynaecological Society
10. PPROM – Preterm premature rupture of membranes
11. UK-United Kingdom
12. NAD- No abnormality detected
13. UON – University of Nairobi
14. LMIC- Low and middle income country

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ABSTRACT

Background

Group B streptococcus (GBS; streptococcus agalactiae) is a gram positive coccus carried in the urogenital or lower gastrointestinal tract by approximately 10 – 30% of women worldwide. GBS is an important cause of perinatal morbidity, mortality and a common cause of maternal peripartal infections. There is sufficient evidence that intrapartum antibiotic prophylaxis (IAP) is highly effective at preventing early-onset GBS disease among infants born to colonized women. Although the burden of GBS at Kenyatta National Hospital (KNH) has been estimated from a previous cross sectional study as 25.2% with availability of preferred antibiotics, standardized IAP guidelines have not been developed. Thus it is unknown if developing and implementing a GBS screening and IAP protocol at KNH can increase IAP and its potential in reducing preventable perinatal mortality and maternal morbidity.

Objective

To determine the effectiveness of introducing a GBS screening and intrapartum antibiotic prophylaxis protocol on uptake of GBS screening and antibiotic prophylaxis practice at KNH

Materials and methods

This was a Pre and post intervention quasi- experimental implementation science study conducted in KNH labour ward, antenatal wards and antenatal clinic in two phases. Clinicians providing reproductive health services were interviewed during the first (pre-intervention) phase and then trained on the proposed GBS IAP protocol after which they were re- interviewed in the second (post-intervention) phase. During both phases, data was extracted from the patient files to assess GBS IAP practice. Intervention involved clinician Continuous Medical Education (CME), posters of the protocol mounted in labour ward, antenatal wards and clinics with summary of evidence for the proposed protocol sent through e-mail. The effectiveness of the intervention was assessed using two approaches: First, a data collection form was used to extract relevant information on GBS IAP at both pre-intervention and post-intervention phases. Secondly, consenting reproductive health clinicians (consultants, registrars and nurses) were interviewed using a self-administered questionnaire during the pre-intervention and post-intervention phases to assess accuracy of knowledge on GBS screening and IAP practices. We estimated that a sample size of 39 clinicians and 43 patients pre and post intervention would be sufficient to demonstrate a 30% significant difference in knowledge and practice patterns pre and post introduction of the GBS IAP.

Data was collected using paper questionnaires and double entered into an excel data base and cleaned. Descriptive statistics was conducted for discrete, binary and categorical variables and reported as proportions while continuous variables were described using measures of central tendency and dispersion (mean, mode and median).Chi square test of independence was used for categorical data and t-tests for continuous variables. The strength of the association's was obtained from the effect estimate of p value < 0.05.All analysis was conducted using statistical package for the social sciences (SPSS) version 20

Results

Between 1st of May 2015 and 30th November 2015, 50 and 43 clinicians were interviewed pre-intervention and post-intervention respectively. Majority of the clinicians identified penicillin as the first line antibiotic 42 (84%) before and 32 (74%) post intervention. The intervention resulted in statistically significant proportion of women receiving appropriate GBS IAP (p value < 0.001), this being a significant increase in appropriate IAP from none pre intervention to 20(44%) post intervention. However no patient received GBS screening, 44 (100%) pre intervention and 45 (100%) post intervention and the major barrier was inadequate clinician knowledge 26 (57%) at Post-intervention. Pre intervention majority of the clinicians 40 (93%) did not screen for GBS, the main barrier cited being lack of protocol 37 (77%).More fundamentally, there was near universal recommendation for GBS IAP 47(94%) at pre-intervention and 42 (98%) at post-intervention.

Conclusion

Introduction of a GBS IAP protocol substantially and significantly increased appropriate GBS IAP but not screening practices at KNH. Protocol implementation accompanied by structured and competency based continuous medical education for clinicians may further increase GBS screening and IAP.

1.0 INTRODUCTION

Group B streptococcus (GBS; streptococcus agalactiae) is a gram positive coccus carried by approximately 10 – 30% of women worldwide in their urogenital or lower gastrointestinal tract (1) .GBS is an important cause of perinatal morbidity, mortality and a common cause of maternal peripartal infections. Maternal intrapartum GBS colonization is known to be a major risk factor for early onset neonatal sepsis in infants with an incidence of 1.5 cases per 1,000 live births in the developed countries(2) . Vertical transmission of GBS from mother to foetus primarily occurs after premature rupture of membranes and among women with maternal GBS colonization (3).In Kenya ,GBS is associated with preterm births and is a known cause of neonatal morbidity and mortality (4). However the disease spectrum of GBS is largely still under-recognized in the country with paucity of data countrywide but previously established as a cause of neonatal mortality accounting for about 1 in 3 admissions to new born unit at KNH(5).

1.1 Microbiology

GBS has about 99% of strains showing beta (complete) haemolysis on blood agar plates. Ten serotypes of GBS have been identified by CDC all being isolated on strep B carrot broth (6) , the predominant types causing disease being Ia, Ib, II, III and V. Among genital isolates from pregnant women, the distribution is 38%, 11%, 7%, 26%, and18% for Ia, Ib, II, III and V respectively. Isolates from cases of early neonatal sepsis are very similar to that of genital isolates from pregnant women. However, in late-onset neonatal disease, the isolates are predominantly type III(2).

1.2 Screening and IAP

Screening for GBS involves use of a cotton swab that's inserted into the vagina and the same swab inserted into the rectum and then smeared on Stuarts, Todd-Hewitt or Amies medium and taken for culture and this is done to women between 35 to 37 weeks gestation, those found to be carriers are started on intrapartum antibiotic prophylaxis that involves intravenous antibiotics :Penicillin G, cefazolin, ampicillin, clindamycin or vancomycin(7).Swab collection of specimen can be done by the clinician or the patient and studies have shown non to be superior to the other(8).In Low and middle income countries (LMICS),GBS screening is thought to be costly as compared to high income countries(9). However ,studies indicate significant benefit of GBS screening and IAP even in LMICS ,for example In South Africa ,risk factor based intrapartum antibiotic prophylaxis (IAP) prevents 10% of neonatal cases but when combined with GBS vaccination has been found to be more effective as well as cost effective than vaccination alone(10).Data from Africa on screening practices and IAP is scarce and countries with high incidence of GBS neonatal disease do not have the infrastructure necessary to implement a sustainable GBS screening programme(11)(12). In addition a systematic review and meta-analysis by Edmond et al in 2012 reported no study on use of IAP in the continent(13).

1.3 Guidelines and Protocols

GBS guidelines and protocols for prevention of neonatal disease have been developed by the CDC and RCOG. The ACOG and most European countries have adopted the CDC guidelines which were initially first released in 1996 ,revised in 2002 and 2010 (1)(14).

2.0 LITERATURE REVIEW

2.1 GROUP B STREPTOCOCCUS (GBS) EPIDEMIOLOGY

GBS emerged as a leading infectious cause of neonatal morbidity and mortality in the USA in 1970s with a neonatal mortality incidence of 1.7 cases per 1,000 live births, which led to implementation of prevention measures through national guidelines for intrapartum antibiotic prophylaxis by mid 1990s .The Centre for Disease Control (CDC) estimates the global GBS prevalence to be between 10 -30 % .In the USA, 10 – 35% of pregnant women are asymptomatic carriers of GBS and approximately 50 – 65 % of neonates are born to colonized mothers, others are carriers while up to 2% of these neonates develop invasive GBS disease. Maternal gastrointestinal tract serves as the natural reservoir for GBS and is the likely source of vaginal colonization hence perinatal transmission (1).

In Europe, the reported prevalence of GBS ranges between 10 to 30 %; For example in Germany , Nadia and Elizabeth isolated GBS from among 34(16%) of 210 pregnant women in Aachen and Munich compared to 41(16%) of 250 non-pregnant women(15).

In developing countries the prevalence is no different; For example Schuchat and Stoll reported similar colonization rates : Nigeria – 20 %, Ivory coast – 19%, Togo – 4%, Gambia – 22 %, Mozambique – 1 %(16)(17).An observational cross -sectional based study conducted among one hundred and fifty pregnant women at 35-40 weeks of gestation attending antenatal clinic in Obafemi Awolowo University hospital reported GBS carriage at 11.3%(18) while another cross-sectional study with 200 participants at 24-35 weeks gestation in Enugu state, Nigeria reported GBS prevalence of 18% (19). A similar study done recently in Ghana reported GBS prevalence of 19.1% among 519 participants at gestation of 35 weeks and above from rural Pramso and a similar number in urban town of Kumasi(11). High GBS prevalence rates have also been noted in Tanzania 23% and Malawi 16.5% despite

paucity in data(20) (13).A cross-sectional study conducted among 300 pregnant women at 35 – 37 weeks gestation in Ethiopia in 2014 found a GBS prevalence of 7.2% (positive recto-vaginal isolates in 22 of the 300 participants (9).Similarly a local cross – sectional descriptive study by Salat Mohammed among 322 pregnant women at KNH antenatal clinic reported a GBS prevalence of 25.2%. This study also found significant association between history of still birth and GBS colonization ($p = 0.011$) (4).In summary these studies show that the prevalence of GBS in LMIC is similar to that seen in developed countries. Therefore without routine screening and IAP the maternal and perinatal disease burden in high income countries would be similar to that in low income counties.

2.2 MATERNAL DISEASE

GBS is associated with significant morbidity. The recognized maternal GBS disease sequelae include:

Urinary tract infections: GBS is causes asymptomatic bacteriuria and is isolated in 5-29 % of cases. It's also known to cause cystitis and pyelonephritis during pregnancy. GBS is also associated with preterm labor and premature birth, hence heavy urinary colonization with GBS in pregnancy with GBS colony count

$\geq$ 100 000 CFU/mL, should be treated with penicillin G (21).

Choriamnionitis: About 0.5-2% of pregnancies are complicated by choriamnionitis characterized by symptoms and signs that include maternal fever, leucocytosis, fetal tachycardia and uterine tenderness; and is a significant cause of preterm labor and premature birth. In addition to GBS, other causative agents include Escherichia coli and anaerobic bacteria. Treatment is usually by broad spectrum antibiotics to address the polymicrobial aetiology and delivery of infant regardless of gestation(22).

Puerperal sepsis: GBS accounts for about 17% of cases of puerperal sepsis which typically usually occurs within 12 hrs of delivery and can manifest with tachycardia, endometritis, fever and abdominal distention(4).

Postpartum endometritis: GBS is implicated in about 28% of cases of endometritis, a polymicrobial disease involving on average, 2-3 organisms. In most cases, endometritis arises from an ascending infection from organisms found in the normal indigenous vaginal flora. Colonization with GBS significantly increases the risk of developing postpartum endometritis. In addition to GBS, other organisms commonly isolated in patients with endometritis include Ureaplasmaurealyticum, Peptostreptococcus, Gardnerella vaginalis, Bacteroides bivius; therefore medical treatment requires broad spectrum antibiotic with anaerobic coverage(4).

2.3 NEONATAL DISEASE

The primary risk factor for early-onset GBS infection is maternal intrapartum rectovaginal colonization with GBS. Other clinical risk factors include gestational age of less than 37 weeks, prolonged rupture of fetal membranes, intra-amniotic infection, young maternal age and black race(23).

Approximately 80% of GBS infant infections occur in the first days of life and are known as early onset disease compared to late onset infections which occur between one week and 2 to 3 months of age. The incidence of early and late onset disease has varied in studies conducted in the United States(24).

Early-onset group B streptococcal sepsis (EOGBS) has been the leading cause of death attributable to infection in new-born infants for nearly 3 decades with more than 6000 cases a

year reported in the United States. GBS has also been documented as the main aetiological agent implicated in cases of neonatal morbidity and mortality in western Europe and Australia(25). Since 1996, there has been a 70% reduction in early-onset neonatal GBS infection attributed to implementation of Guidelines for GBS screening and antibiotic prophylaxis. The sequelae of GBS infection in neonates includes sepsis, pneumonia and meningitis(26). The incidence of EOGBS disease in the UK in the absence of systematic screening or widespread intrapartum antibiotic prophylaxis (IAP) is 0.5/1000 births which is similar to that seen in the USA after universal screening and IAP, despite comparable vaginal carriage rates(14).In Africa ,there seems to be paucity in research on GBS, In Tanzania, as is the case in several other sub-Saharan countries , the rate of GBS colonisation among pregnant women and neonates has not been published and therefore to date no strategies have been formulated to prevent neonatal GBS infection in Tanzania, however a cross sectional study done by Joachim and Mecky involving 300 pregnant women attending antenatal clinic and their newborns delivered at Muhimbili National Hospital (MNH) in Tanzania between October 2008 and March 2009 revealed GBS prevalence in neonates of 8.9% (20). In Kenya a cross sectional study at Kenyatta National Hospital New Born Unit on aetiology of neonatal meningitis by Laving et al found that the highest prevalence of isolates were GBS and Escherichia coli had the highest prevalence of the bacterial aetiological isolates at 26.7% and 46.7% respectively(27).

2.4 PREVENTION OF NEONATAL GBS INFECTION

There is sufficient evidence that GBS screening and Intrapartum antibiotic prophylaxis (IAP) is highly effective at preventing early-onset GBS disease among infants born to colonized women and since introduction resulted in a 70 % decline in incidences of GBS neonatal disease (23).The Centre for Disease Control guidelines on use of IAP for prevention of GBS

disease ,were first issued in 1996 and revised in 2002 and 2010;The guidelines recommended that all women undergo vaginal-rectal screening for GBS colonization at 35-37 weeks' gestation to identify which women should receive IAP(1).

A review of the practice in different settings show that some countries provide risk factor based and others universal GBS screening .For example In Israel, GBS screening and IAP has been documented to lower the incidence of neonatal GBS disease by 40 %; GBS culture screenings for are performed among pregnant women with risk factors i.e. pre-labor rupture of membranes, preterm labor and intra-partum fever. Such women with risk factors are then treated with antibiotics (IAP); however, there are considerations for universal screening of pregnant women using a vaginal-anal culture taken at 35–37 weeks of gestation and not earlier to prevent low positive predictive values that may arise if cultures are taken at less than 35 weeks. Women with a positive culture test would then receive IAP(28).

In the United Kingdom, **Royal college of obstetricians and gynaecologists (RCOG) 2012 green top guidelines** for screening and antibiotic prophylaxis in pregnancy, recommend IAP for eligible women if they have GBS urinary tract infection during pregnancy (evidence level 3) and if GBS is detected on a vaginal swab in the current pregnancy . These guidelines also recommend immediate induction of labour and IAP to all women with prelabour rupture of membranes at 37+0 weeks of gestation or more (evidence level 3) and pyrexia in labour (>38°C)(evidence level 3)(14) .

According to the RCOG guidelines, women should be treated with benzyl penicillin administered as soon as possible after the onset of labour and given regularly until delivery and clindamycin administered to those women allergic to penicillin. Specifically it is recommended that 3 g intravenous benzyl penicillin be given as soon as possible after the onset of labour and 1.5 g 4-hourly until delivery. Alternative drugs include Clindamycin 900

mg 8hourly or vancomycin 1g 12hourly in cases of penicillin allergy. Since benzyl penicillin levels in cord blood exceed the minimum inhibitory concentration for GBS as early as 1 hour after maternal administration, to optimize the efficacy of IAP, the first dose should be given at least 2 hours prior to delivery. Oral IAP are not recommended because of variable absorption during labour(29). Currently in the United Kingdom, there's no evidence of GBS resistance to penicillin ,while clindamycin resistance rates stand at 10% for which vancomycin is an effective alternative IAP(30).

The **2010 Centre for Disease Control (CDC) guidelines** recommend vaginal rectal screening for GBS colonization at 35 – 37 weeks: In addition, the guidelines recommend IAP for: bacteriuria in current pregnancy, GBS positive screening result in current pregnancy, unknown GBS status who deliver at less than 37 weeks gestation, an intrapartum temperature of 100.4 degrees Fahrenheit or greater, or rupture of membranes for 18 hrs or longer. The CDC guidelines recommend penicillin 5 million units I.V at initial dose, then2.5-3 million units 4hourly until delivery ,or ampicillin 2G.I.V as initial dose, then 1G I.V 4 hourly until delivery as the preferred agents and clindamycin 900mg 8 hourly for those with penicillin allergy. Although GBS is susceptible to penicillin, ampicillin and first generation cephalosporin's resistance to clindamycin and erythromycin of 25 to 32 % and 13 to 20 % respectively has been reported in the United States. Therefore vancomycin is recommended as an effective IAP alternative in such cases(1).

The current **American College of Obstetricians and Gynaecologists (ACOG) guidelines** recommend IAP for women with : previous infant with invasive GBS disease,GBS bacteriuria during any trimester of the current pregnancy, positive GBS screening culture during current pregnancy* (unless a caesarean delivery is performed before onset of labor with intact amniotic membranes),unknown GBS status at the onset of labor (culture not done, incomplete, or results unknown) ,delivery at less than 37 weeks of gestation, amniotic

membrane rupture greater than or equal to 18 hours, intrapartum temperature greater than or equal to 100.4°F (greater than or equal to 38 degrees Celsius)(3). Antibiotics use in the protocols mentioned are; the beta lactam antibiotics i.e. penicillin, the cephalosporin cefazolin, clindamycin and vancomycin.

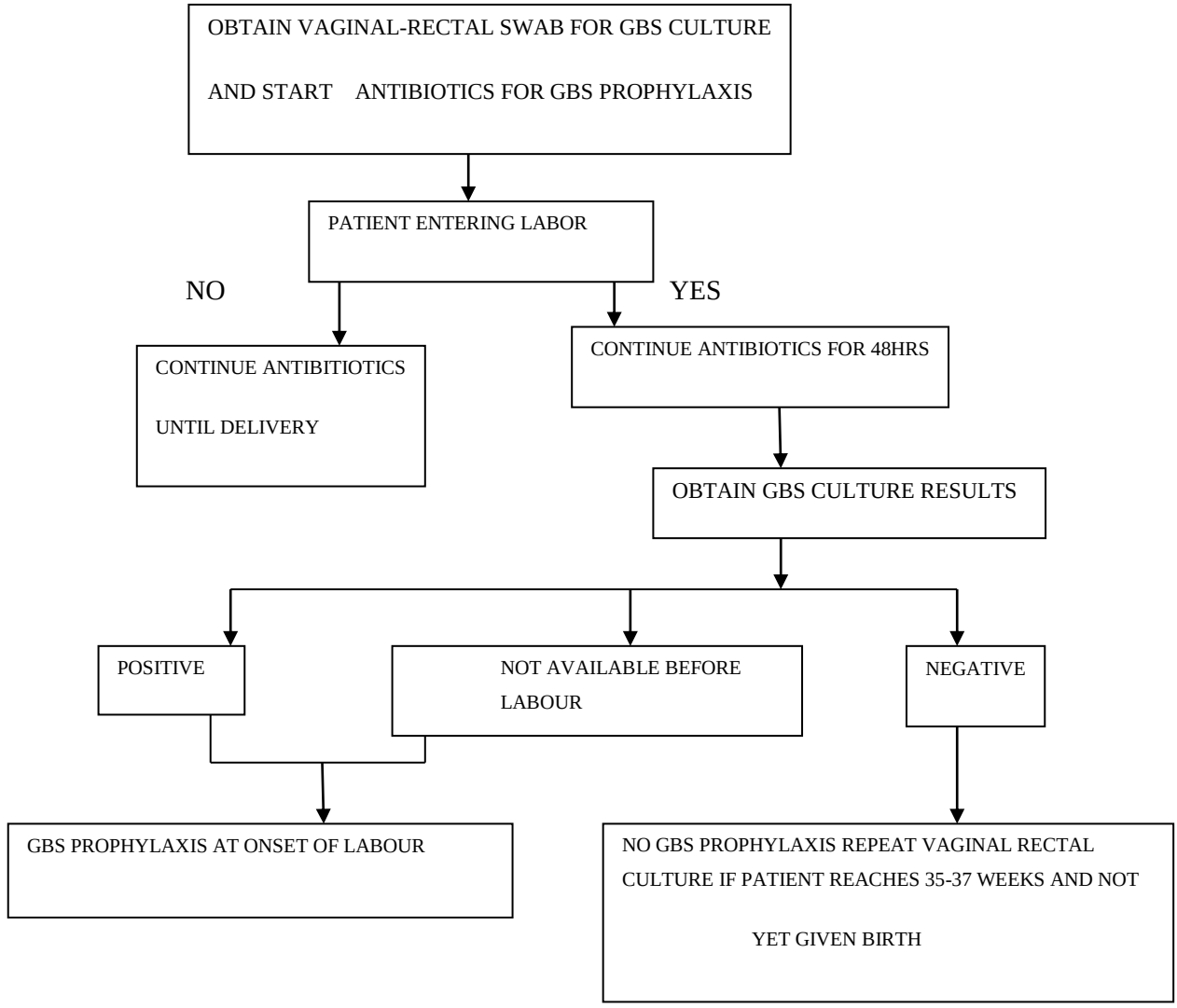
There is paucity of research and guidelines on GBS screening and IAP in low-resource settings. In sub-Saharan Africa Zimbabwe has a documented active research programme on GBS colonization and burden of disease and is currently conducting studies around antibiotic sensitivity patterns of the organism to inform guidelines(19). Currently KNH and Kenya Obstetrician's and Gynaecological Society (KOGS) have no guidelines on GBS screening ,resistance patterns or antibiotic recommendation this could be a major contributory factor early onset neonatal GBS .

It is therefore not surprising that a cross sectional study done at KNH New Born Unit on prevalence of neonatal meningitis found high prevalence of GBS and Escherichia coli at 26.7 % and 46.7% respectively. The antibiotic sensitivity patterns found GBS to be sensitive to ampicillin and the cephalosporin's hence informed potential choice of antibiotic for IAPin preventing early neonatal sepsis(27).

The overwhelming evidence supports routine antenatal maternal GBS screening and IAP at antenatal clinics in resource constrained settings. However, women who miss antenatal screening should undergo a risk based IAP in either case, pregnant women should receive IAP based on risk factors and antenatal GBS culture status. This should be accompanied by development and implementation of a standardized locally relevant protocol. Such studies should therefore not be explorative and descriptive but adopt an implementation science before and after design.

To determine the effectiveness of a GBS screening and IAP protocol in Kenya at Kenyatta National Hospital, we conducted a quasi-experimental before and after study design without a control group. In this study, a sample of participants representing the target population of postpartum women with risk factors and indications for GBS IAP were randomly selected and current practices evaluated including GBS screening practices, (figure1 and figure 2) and antibiotic choices (figure 3) at baseline. After introduction of the intervention (implementation of the proposed GBS protocol), (figure 4) a second representative of the target population of women were randomly selected and evaluated for effectiveness of the intervention. We compared the proportion of women whose risk factors were determined and appropriate IAP antibiotics administered before and after the intervention. We also evaluated the effectiveness of the training on the clinicians by comparing the correct knowledge and practice levels before and after the intervention. To inform scale up, major barriers to GBS IAP were also identified before and after the intervention.

Figure 1: ACOG AND CDC FOR INTRAPARTUM ANTIBIOTIC PROHYLAXIS ALGORITHM FOR WOMEN WITH PRETERM PREMATURE RUPTURE OF MEMBRANES (PPROM)

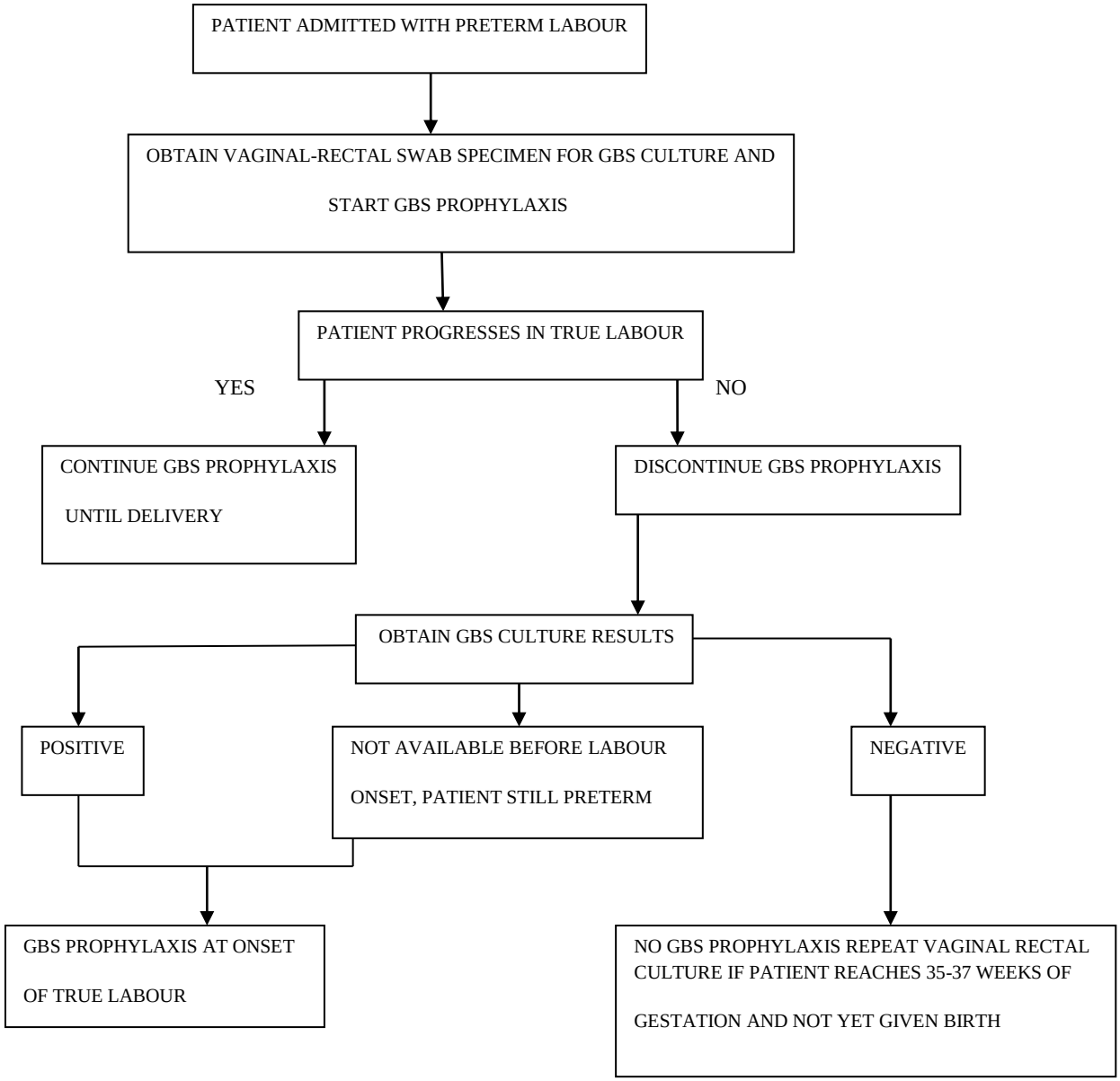


CDC – Centre for Disease Control

ACOG- American College of Obstetricians and Gynaecologists

GBS – Group B streptococcus

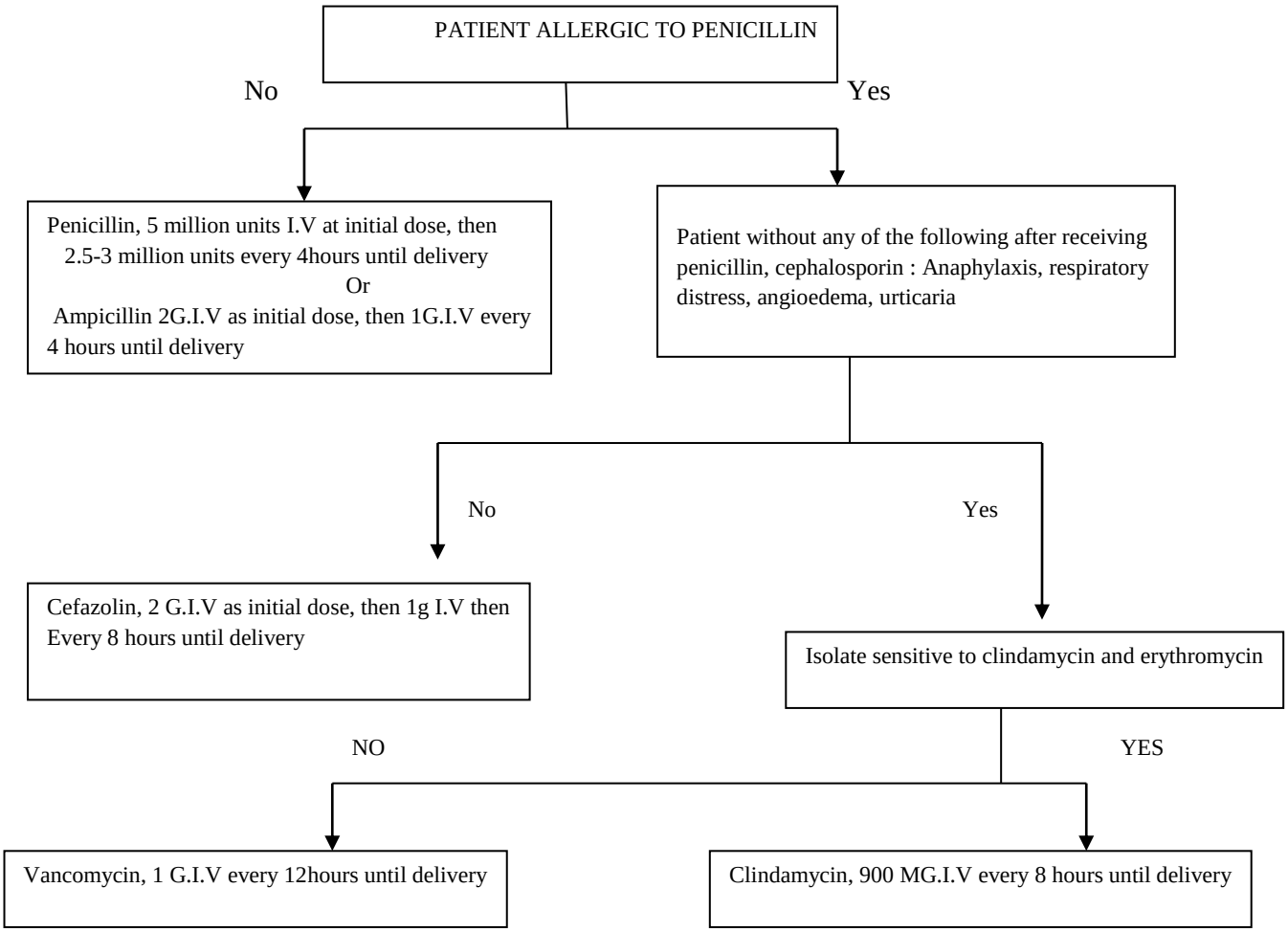
Figure 2: ACOG ALGORITHM FOR GBS PROPHYLAXIS FOR WOMEN WITH PRETERM LABOUR



ACOG- American College of Obstetricians and gynaecologists

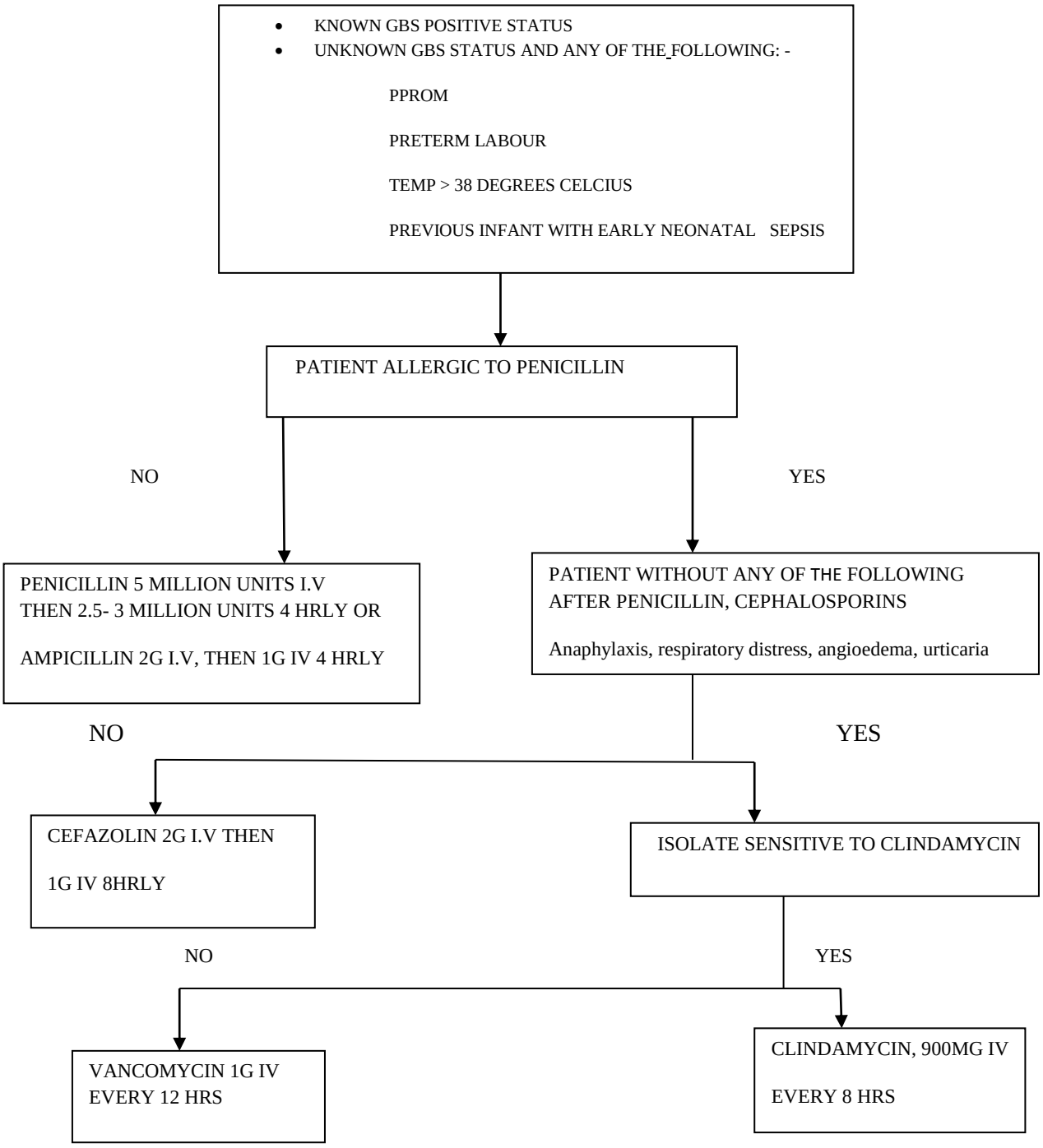
GBS - Group B streptococcus

Figure 3: ANTIBIOTIC CHOICES FOR IAP



IAP – Intrapartum Antibiotic Prophylaxis

Figure 4 Proposed KNH GBS protocol for above 28 weeks gestation



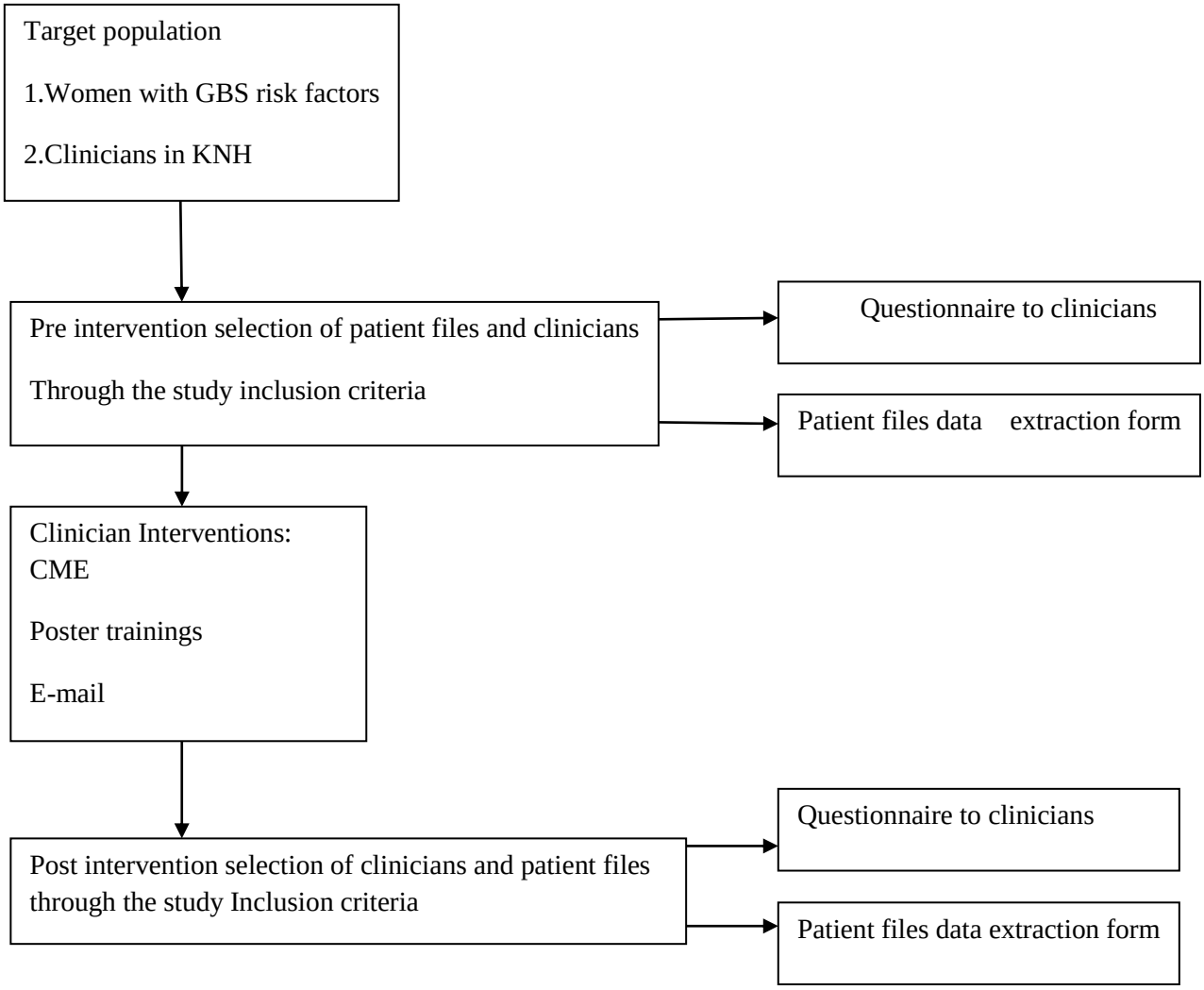
PPROM – Preterm premature rupture of membranes

KNH – Kenyatta National Hospital

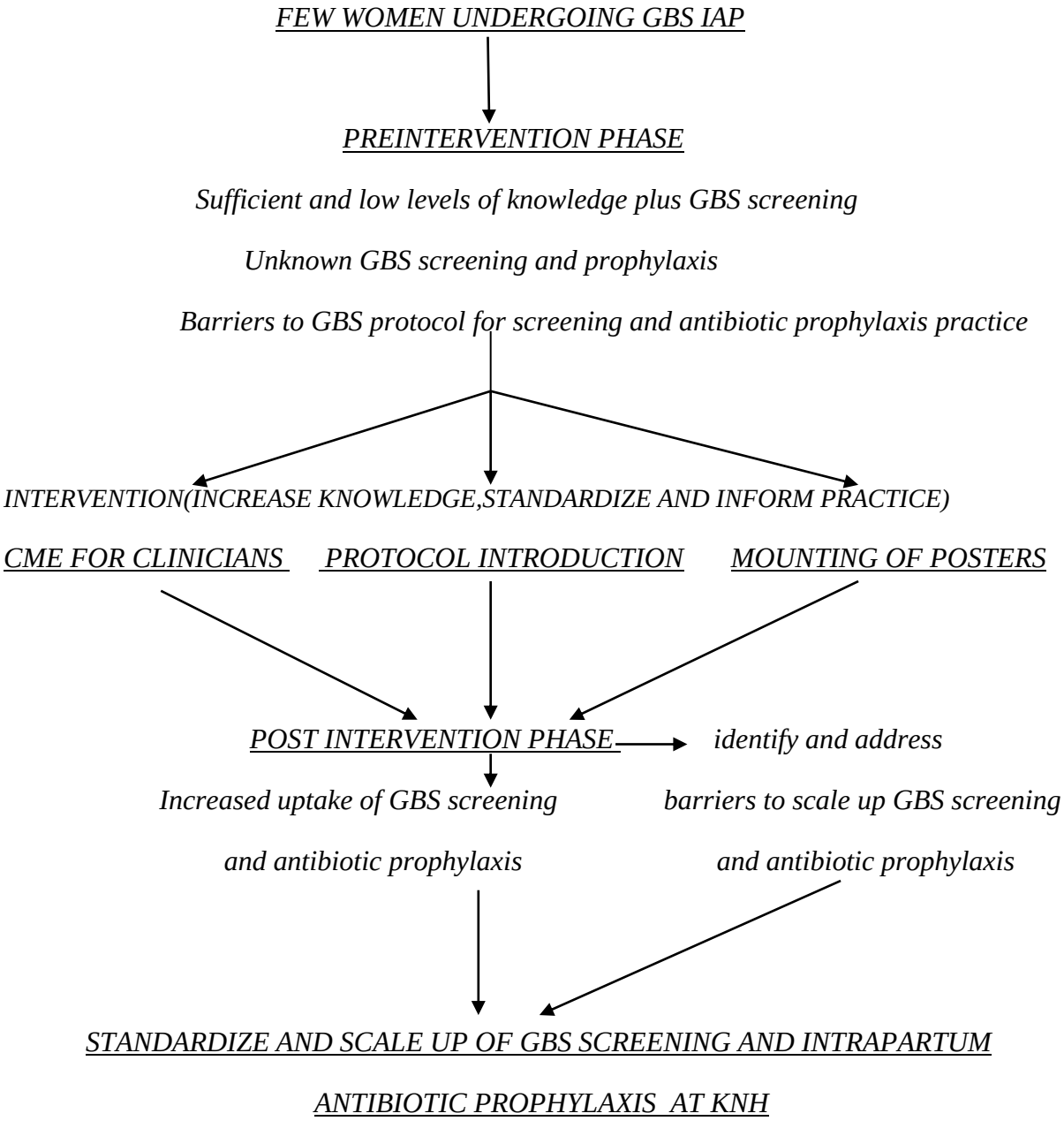
3.0 CONCEPTUAL FRAMEWORK

The basic framework of a quasi-experimental study design involves identification of a particular population of interest that undergoes selection and is subjected to a pre-test evaluation, then introduction of an intervention X with subsequent post-test evaluation, Fig 5.

Figure 5 BASIC FRAMEWORK FOR A QUASI EXPERIMENTAL WITHOUT A CONTROL GROUP



3.1 STUDY CONCEPTUAL FRAMEWORK



3.2 STUDY CONCEPTUAL NARRATIVE

1. **Unknown GBS screening and antibiotic prophylaxis**; at the beginning of this study, the GBS screening practices and antibiotic prophylaxis was unknown despite evidence of high GBS prevalence at KNH. It was hypothesized that this could have led to few women undergoing GBS IAP.

2. **Pre-intervention**; This part of the study involved data extraction from the clinicians and patient files. From the patient files we extracted information to ascertain baseline GBS screening and antibiotic choices for patients who presented with risk factors for GBS colonization and neonatal sepsis. Clinicians were interviewed on their knowledge on GBS screening and IAP through structured questionnaire. This phase of the study was to establish knowledge and identify barriers to implementation of the GBS protocol.

3. **Introduce intervention and expected increased knowledge on GBS screening and antibiotic practice**; This part of the study involved use of continuous medical education meetings to create awareness on the GBS protocol to be adopted and used by clinicians, reading materials were also sent to clinicians on e-mail, posters were then mounted in antenatal clinics, labour ward and the antenatal wards to provide easy access to read information on the GBS IAP protocol (figure 1-4).It is hypothesized that among busy clinicians this approach would be more successful at reaching more clinicians and providing quick references when needed.

4. **Post intervention increased standardized GBS screening and antibiotic prophylaxis.** This part of the study involved use of a similar structured questionnaire used at pre-intervention administered again to the clinicians and data extraction forms used pre intervention used to extract data from patient files. Clinicians' knowledge on GBS after

intervention was assessed and patient files were used to confirm the same in practice and to identify the patients who had received IAP and screening for GBS. We also identified barriers to inform future scale up of the intervention.

4.0 STUDY RATIONALE

GBS is an important cause of preventable maternal morbidity and perinatal mortality. The burden of GBS disease in low resource settings is similar to that in high income settings. The prevalence of GBS is high. In 2009, a cross-sectional study conducted at KNH by Salat estimated the GBS prevalence of GBS amongst 322 ANC attendees to be 25.2%, which is comparable to the global prevalence documented by CDC as 10- 30 %(4). Similarly, a cross sectional study on aetiology of neonatal meningitis at the KNH New Born Unit Laving et al found high prevalence of GBS(26.7%) and Escherichia Coli (46.7%) (27). While Implementation of national guidelines for intrapartum antibiotic prophylaxis resulted in an approximate 80% reduction in the incidence of early onset neonatal sepsis due to GBS, no similar guideline or practice has been documented in resource constrained settings where many neonates die from early neonatal sepsis(3). There is an urgent need to provide evidence and introduce GBS guidelines and protocols in this setting. Also despite awareness of GBS burden, availability of the appropriate antibiotics and the need to reduce the high preventable maternal morbidity and perinatal mortality, there is no national standard protocol for GBS IAP in Kenya and at KNH.

This study therefore seeks to implement and evaluate a protocol that can be used in a resource constrained setting and to increase clinician competency and identifying some of the barriers to implementation of a GBS screening and intrapartum antibiotic prophylaxis before and after introduction of the protocol. It's hoped that in addition to other protocols, this study and

protocol will standardize and improve care of pregnant women at risk of neonatal and maternal GBS disease at KNH and nationally.

5.0 RESEARCH QUESTION

What is the effectiveness of introduction of a Group B streptococcus (GBS) screening and intrapartum antibiotic prophylaxis protocol on uptake of GBS screening and antibiotic prophylaxis practice in Kenyatta National Hospital (KNH) labour ward?

6.0 HYPOTHESIS

6.1 NULL HYPOTHESIS

Introduction of a GBS screening and IAP protocol is not associated with changes in uptake of a GBS screening and Intrapartum antibiotic prophylaxis at KNH.

6.2 ALTERNATE HYPOTHESIS

Introduction of a GBS screening and IAP protocol is associated with changes in uptake of a GBS screening and Intrapartum antibiotic prophylaxis at KNH.

7.0 OBJECTIVES

7.1 BROAD OBJECTIVE

To determine the effectiveness of introducing a GBS screening and intrapartum antibiotic prophylaxis protocol on uptake of GBS screening and antibiotic prophylaxis practice at KNH.

7.2 SPECIFIC OBJECTIVES

1. To determine if introduction of a GBS screening and intrapartum antibiotic prophylaxis protocol at KNH is associated with change in proportion of women receiving appropriate GBS screening and intrapartum antibiotic prophylaxis.

2. To evaluate if introduction of a GBS screening and intrapartum antibiotic prophylaxis protocol at KNH is associated with change in proportion of clinicians providing appropriate GBS screening and intrapartum antibiotic prophylaxis.

3. To compare the changes in proportions of factors identified as barriers to implementation of a GBS screening and intrapartum antibiotic prophylaxis before and after introduction of protocol.

8.0 METHODOLOGY

8.1 STUDY DESIGN

This was a pre and post intervention quasi- experimental implementation science study carried out between May 2015 and October 2015.

8.2 STUDY AREA / SETTING

The study was undertaken at KNH labor ward, antenatal ward and antenatal clinic. KNH hospital is the main referral hospital in the country, its wards and clinics are run by consultant doctors, resident postgraduate doctors, medical officer interns and nurses. The antenatal clinic attendance in the hospital is between 1,000 and 2,500 patients per month, with an average 1,000 to 1,500 live deliveries per month of which about 5 percent of the live births in the hospital are admitted with neonatal sepsis(31). The GBS prevalence in the hospital has been previously estimated at 26% among antenatal clinic attendees(4).

8.3 STUDY POPULATION

The study population deferred by aims. For aim 1 and 3 the study population consisted of clinicians i.e. consultant obstetrician gynaecologists, nurses and post graduate doctors working in the division of reproductive health. For aim 2, the study population was pregnant women at 28 weeks or greater gestational age who were at risk of GBS disease according to predetermined inclusion criteria.

8.4 INCLUSION CRITERIA

i. Participating women (Gestation of above 28 weeks)

1. Known or unknown GBS positive status.

2. Preterm prelabour rupture of membranes (PPROM)

3. Preterm labour (less than 37 weeks gestation.)

4. Intrapartum temperature of 38 degrees Celsius and above.

5. Previous infant with known invasive GBS disease or early neonatal sepsis.

6. Prolonged prelabour rupture of membranes (> 18hrs)

ii. Clinicians

1. Directly providing intrapartum care
2. Consultant Obstetrician Gynaecologists
3. Residents in Obstetrics & Gynaecology
4. Nurse midwives

8.5 EXCLUSION CRITERIA

1. Patients at more than 37 weeks gestation and GBS negative.

2. Clinicians who have high turnover in labour ward i.e. clinical officers, medical officer interns and student nurses

8.6 SAMPLE SIZE DETERMINATION

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

P 1 – baseline GBS IAP

P 2 – Post intervention GBS IAP

P1 – baseline staff knowledge on IAP

P2 – post intervention staff knowledge on IAP

Z beta – 0.84 (Z 1- alpha /2) – 1.96

Due to lack of regional studies in a similar population, we based our sample size calculation on the findings from Kathy L. McLaughlin et al that assessed adherence to GBS screening at mayo clinic, Rochester USA on GBS guidelines through paired electronic reminder and education intervention .In this study post intervention rates of quality-improved screening increased from 30 to 62 % with a sample size of 129 patients pre intervention and 126 patients post intervention. (P<.001)(32).

AIM 1 SAMPLE SIZE CALCULATION: Assuming baseline appropriate GBS IAP of 30% (p1) and Post intervention GBS IAP 60% (p2) and 10% addition for incomplete records we estimated that a minimum sample size of 43 women with risk factors and need for GBS IAP at baseline and post intervention would be needed.

AIM 2 SAMPLE SIZE CALCULATION: Assuming baseline appropriate staff knowledge on GBS IAP of 50% (p1) and post intervention 80% (p2) and a 10% addition for lack of response from staff we estimated a minimum sample size of 39 clinicians handling women with risk factors and need for GBS IAP at baseline and post intervention.

8.7 SAMPLING TECHNIQUE AND DATA COLLECTION

For aim 1; the study participants comprised of postpartum women who had risk factors requiring GBS IAP .A data extraction form was used to extract information from patient files to assess GBS screening practices, the use of appropriate antibiotics for patients with risk factors to GBS colonization and disease at pre intervention and post intervention. Patient files eligible for inclusion into the study were subjected to consecutive sampling until desired sample size for both pre and post intervention was achieved.

For aim 2; the study participants comprised of consultants, registrars and nurses providing reproductive health services at Kenyatta National Hospital (KNH). The institutions labour ward is run by three units that rotate every week, each having consultants and registrars in obstetrics and gynaecology working with the team of nurses /midwives in labour ward. All three units were represented. The principle investigator and research assistants used the weekly duty rota and consecutively selected from 3 units and three cadres of clinicians from the pool of consultants, registrars and nurses in the duty rota until the sample size was achieved. Consenting providers recruited into the study were given a self-administered structured questionnaire to fill in at the start of the study to assess baseline knowledge on GBS. Protocol training was then conducted for consultants, registrars and nurses in efforts to create awareness on the proposed GBS screening and antibiotic prophylaxis protocol implemented at the institution. For the consultants and registrars the training was via continuous medical education in the department of obstetrics and gynaecology, University of

Nairobi and information disseminated through e-mail. Additionally for all clinician's, posters of CDC, ACOG algorithms' and proposed protocol (fig1-4) were mounted in labour ward, antenatal wards and clinics. The principal investigator and research assistant conducted poster trainings for clinicians, for the nurses this was done in the morning during handing over time. A similar structured questionnaire administered at start of the study was then administered again after intervention to the study participants to assess changes in practice and barriers to implementation of the GBS protocol.

8.8 DATA MANAGEMENT

The data extraction forms and questionnaire were stored under lock and key before and after data entry. The questionnaires had codes and not names hence protecting identity of the consenting clinicians, the data extraction forms also had coded identities known only to the principle investigator .There was no use of in or out patient file numbers or names on the filled extraction forms.

8.9 STATISTICAL ANALYSIS

Data was collected using paper questionnaires and double entered into an excel data base and cleaned. Descriptive statistics was conducted for discrete, binary and categorical variables and reported as proportions while continuous variables were described using measures of central tendency and dispersion (mean, mode and median).Chi square test of independence was used for categorical data and t-tests for continuous variables. The strength of the association's was obtained from the effect estimate and considered significant at p value < 0.05.All analysis was conducted using statistical package for the social sciences (SPSS) version 20.

8.10 RESEARCH ETHICAL CONSIDERATIONS

Ethical approval was obtained from the University of Nairobi/Kenyatta National Hospital (UON/KNH) Ethics committee and the department of Obstetrics and Gynaecology, University of Nairobi. The proposed GBS screening and IAP Protocol approval was obtained from Kenyatta National Hospital Department of Reproductive Health .Participation in the study was voluntary and no incentives were given for participation and Informed consent was obtained from participating clinicians and all information obtained treated in confidentiality.

9.0 STUDY STRENGTHS

This was an implementation science study, one of the first of its kind here to identify likely challenges of introducing a GBS protocol. This is a non-randomized quasi experimental trial; that accurately depicts inherent weaknesses and strengths of introducing a protocol in a system with different cadres and large number of staff and patients. The study was done where support systems are readily available for example KNH drug formulary has all the required antibiotics for implementation of the GBS protocol and the laboratory both at KNH and UON microbiology confirmed capacity to isolate GBS.

10.0 STUDY LIMITATIONS

This study relied on clinician informed consent which was within their rights to decline an interview and declined consent meant that any valuable information from that particular clinician may have been withheld and therefore not captured in the study. The study had no interaction with the patients and relied on data already recorded in the files and therefore a question previously not asked by the clinician attending to the patient and may have been of interest to this study, may not have been recorded in the file seen. Further cultures are not routinely and electively performed: thus we couldn't evaluate resistance patterns. However,

in general in a low resource setting like this guideline is unlikely to recommend routine culture and sensitivity

11.0 RESULTS

Between May 2015 and November 2015 we retrieved a total of 110 patient files from KNH records department. A total of 89(81%) met the inclusion criteria; 44(49%) files for the pre intervention phase and 45(51%) files for the post intervention phase. 21(19%) files did not meet the inclusion criteria and were therefore not included in the study.

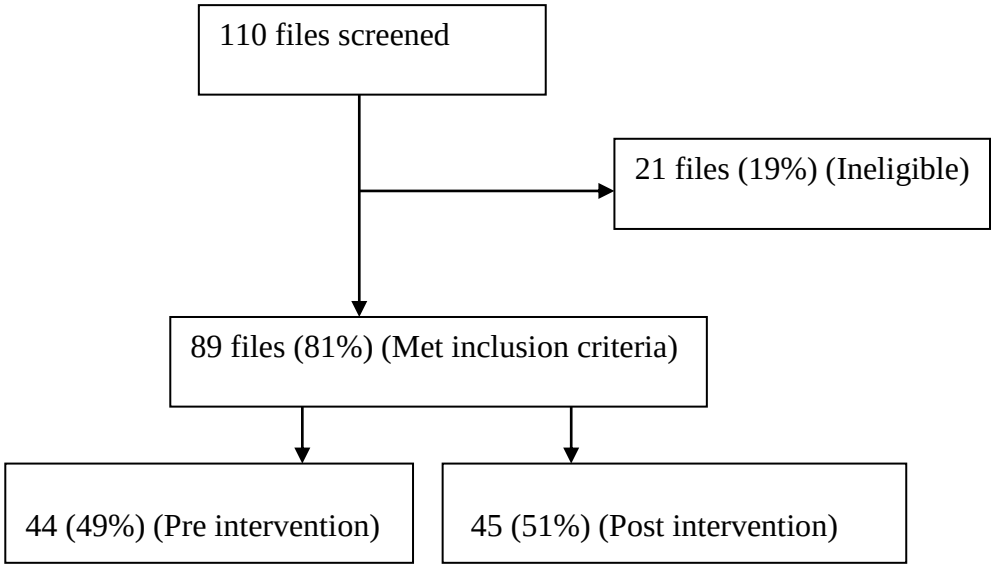
We approached 103 clinicians; 22(21%) consultants, 36(35%) registrars and 45(44%) nurses/midwives of whom 10(10 %) declined to participate; 4(40%) consultants, 3(30%) registrars and 3(30%) nurses. Out of the 93(90%) clinicians who gave informed consent, 50(54%) were interviewed during the pre-intervention phase and consisted majorly of those who had worked at KNH for more than 6 years, 19(38%) and those who had worked for less than 2 years 19(38%).During the post intervention phase 43(46%) clinicians were interviewed and majority consisted of those who had worked at KNH between 2 to 6 years 18(42%) , (Table 4). In total there were 10(9.7%) refusals, 3(30%) declined in the pre intervention phase and 7(70%) at post intervention; only 2(20%) out of the 10 clinicians cited lack of time as a reason for not participating in the study.

During both pre intervention and post intervention phases, patients had similar sociodemographic characteristics (table 1).Mean age was at 26 years, majority were married 37(84%) at pre intervention and 33(73%) at post intervention, employed 27(61%) and 33(73%) and with tertiary level education 26 (59%) and 23(51%) at pre and post intervention respectively. Mean gestation was 35 weeks, with majority of the patients having one or two previous live births, 22(50) at pre intervention and 25(55.6) at post intervention and with no previous history of abortion, 36(81.8) and 32(71.1) (Table 2).

Regarding antibiotic use the prescription of appropriate antibiotics for GBS IAP by clinicians increased from none at pre intervention to 20(44%) at post intervention (Table 3) ,with majority identifying penicillin as first line antibiotic of choice both at pre and post intervention,42(84) and 32(74) .Majority of clinicians were aware of existence of GBS protocols in use worldwide, 26(52) and 23(54), CDC protocol being the most identified by clinicians at both pre and post intervention , 9(32) and 9(37) .Most clinicians offering intrapartum services do not however routinely screen and offer intrapartum antibiotic prophylaxis for GBS , 46(92%) at pre intervention and 40(93%) at post intervention (Table 4) . The main barrier to routine screening and GBS IAP was lack of a protocol at KNH accounting for 37 (77%) of the clinician responses at pre intervention which decreased to 18(39%) post intervention. At post intervention, inadequate clinician knowledge was the main barrier accounting for 26 (57%) of the responses post intervention (Figure 6). None of the patients had evidence of rectovaginal swab culture or antibiotic sensitivity pattern for GBS both at pre intervention 44(100%) and post intervention 45(100%), (Table 3).

11.1 STUDY FLOW CHART

11.1.1 PATIENT FILES SELECTION FLOW CHART



11.1.2 CLINICIAN SELECTION FLOW CHART

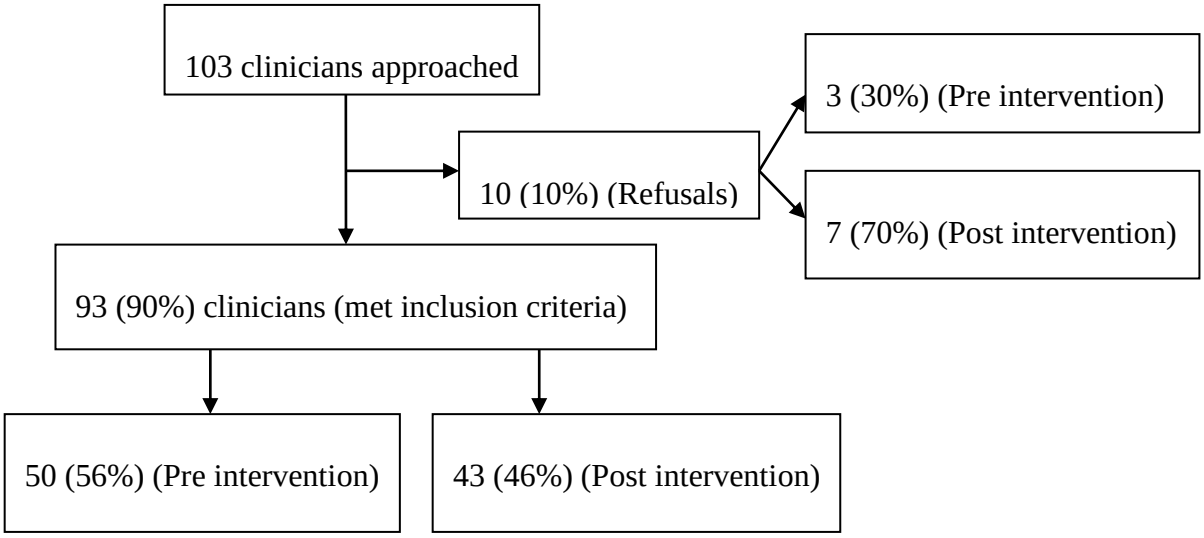


Table 1: Patient sociodemographic characteristics

Characteristics	Pre intervention (n=44)	Post intervention (n=45)	P-value
Mean Age in years (SD)	26.61 (5.2)	26.91 (4.9)	0.783
Age in categories(yrs.)			
18-23	13(29.5)	13(28.9)	0.657
24-29	20(45.5)	20(44.4)	
30-35	8(18.2)	10(22.2)	
36-41	3(6.8)	1(2.2)	
42-47	0(0.0)	1(2.2)	
Marital Status (%)			0.1216
Married	37 (84)	33 (73)	
Single	7 (16)	12 (27)	
Occupation (%)			0.228
Employed	27 (61)	33 (73)	
Unemployed	17 (39)	12 (27)	
Level of education (%)			0.225
Primary	2 (5)	7 (16)	
Secondary	16 (36)	15 (33)	
Tertiary	26 (59)	23 (51)	

As shown in table 1 The sociodemographic characteristics were similar .Majority of study participants were aged between (24-29) years with a mean age of 26 years, employed with tertiary level education; Age 44.5% and 44.4% , 84% and 73% married,61% and 73% employed with 59% and 51% having tertiary level education this being noted at pre and post intervention respectively.

Table 2: Patient history and physical examination finding

History and physical exam findings	Pre intervention (n=44)	Post intervention (n=45)	P-value
Mean gestation in weeks(SD)	35.16 (4.0)	35.18 (3.7)	0.982
Previous live births (%)			0.867
0	20(45.5)	18(40)	
1-2	22(50)	25(55.6)	
3-4	2(4.5)	2(4.4)	
Prior Still births (%)			0.778
0	39(88.6)	39(86.7)	
1-2	5(11.4)	6(13.3)	
Previous abortions (%)			0.234
None	36(81.8)	32(71.1)	
> 1	8(18.2)	13(28.9)	
Previous child with early neonatal sepsis (%)			
None	42(95.5)	0(0)	
> 1	2(4.5)	0(0)	
Per vaginal discharge (%)			
No	44 (100)	45 (100)	
Drainage of liquor (%)			< 0.001
Yes	22 (50)	40 (88)	
No	22 (50)	5 (12)	
Duration of liquor drainage (%)			< 0.001
>18 hrs.	22 (50)	40 (88)	
Not indicated in file	22 (50)	5 (12)	
Labour pain (%)			0.561
Yes	34 (77)	37 (82)	
No	10 (23)	8 (18)	
UTI treatment in pregnancy (%)			0.921
Yes	14 (32)	16 (36)	
No	12 (27)	11 (24)	
Not recorded	18 (41)	18 (40)	
Temperature > 38 (%)			0.879
No	14 (32)	15 (33)	
Not recorded	30 (68)	30 (67)	
Mean fundal height in weeks (SD)	34.2 (3.1)	33.9 (3.3)	0.693
Mean cervical dilation in cm (SD)	2 (2.4)	3.86(2.2)	0.005
Speculum exam for drainage of liquor (%)			0.169
Confirmed drainage of liquor	21 (48)	28 (62)	
Not recorded	23 (52)	17 (38)	

As shown in table 2 the risk factors associated with increased risk of GBS diseases were prevalent in this study population. For example Rupture of membranes > 18hrs, previous child with early neonatal sepsis. Most obstetric characteristics were similar between pre intervention and post intervention phases except for mean gestation by dates and clinical clinician fundal height finding which were statistically slightly different.

Table 3: Group B streptococcus screening and antibiotic prophylaxis

Management and outcome	Pre intervention (n=44)	Post intervention (n=45)	P-value
Vaginal bacteriological swab culture done (%)			
No	44 (100)	45 (100)	
Antibiotic sensitivity done (%)			
No	44 (100)	45 (100)	
Antibiotic use (%)			0.904
Yes	25 (57)	25 (56)	
No	19 (43)	20 (44)	
***Appropriate antibiotic given as per GBS protocol (%)**			< 0.001
Yes	0 (0)	20 (44)	
No	44 (100)	25 (56)	
Antibiotic route of administration (%)			0.001
Intravenous	7 (16)	20 (44)	
Oral	19 (43)	6 (14)	
Not recorded	18 (41)	19 (42)	
Pregnancy outcomes (%)			0.325
Live birth	26 (60)	26 (58)	
Still birth	2 (4)	0 (0)	
Conservative	16 (36)	19 (42)	

*Appropriate antibiotic – Cefazolin, Penicillin, Ampicillin, Clindamycin or Vancomycin given Intravenously.

GBS – Group B streptococcus

Table 3 above shows the GBS screening and IAP practices as extracted from patient files. Appropriate antibiotic was given as per GBS protocol at post intervention phase in comparison to pre intervention with a statistically significant P-value < 0.001.However none of the files screened had any GBS culture or antibiotic sensitivity done.

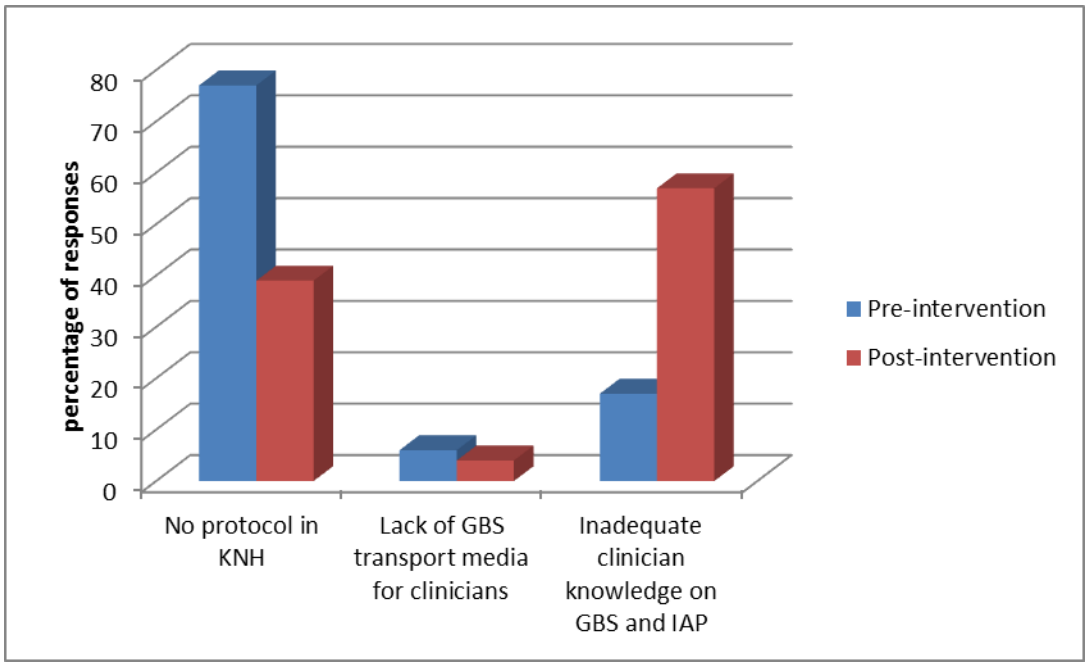
Table 4: Clinician characteristics and competency on GBS screening and Intrapartum antibiotic prophylaxis

Clinician responses	Clinician responses pre-intervention (n=50)	Clinician responses post-intervention (n=43)	P-value
Current qualification (%)			0.783
Consultant	11 (22)	7 (17)	
Registrar	17 (34)	16 (37)	
Nurse	22 (44)	20 (47)	
Years of practice (%)			0.138
<2 years	19 (38)	15 (35)	
2–6 years	12 (24)	18 (42)	
>6 years	19 (38)	10 (23)	
Approximate GBS prevalence in ANC attendants at KNH (%)			0.196
10-15%	14 (28)	19 (44)	
16-20%	10 (20)	9 (21)	
21-26%	3 (6)	4 (9)	
Don't know	23 (46)	11 (26)	
Awareness on existence of GBS protocol (%)			0.886
Yes	26 (52)	23 (54)	
No	24 (48)	20 (46)	
Protocol known to the clinician (%)			0.812
ACOG	4 (14)	3 (9)	
RCOG	9 (32)	6 (23)	
CDC	9 (32)	9 (37)	
All	6 (22)	8 (31)	
Antibiotics recommended as first line GBS IAP (%)			0.279
Clindamycin	3 (6)	7 (16)	
Penicillin	42 (84)	32 (74)	
Don't know	5 (10)	4 (9)	
Antibiotic recommended as 2nd line GBS IAP (%)			0.314
Clindamycin	29 (58)	17 (40)	
Penicillin	3 (6)	4 (9)	
Don't know	16 (32)	18 (42)	
cephalosporin's	2 (4)	4 (9)	
Routine screening for GBS by clinician in KNH (%)			0.852
Yes	4 (8)	3 (7)	
No	46 (92)	40 (93)	
If answered no, why (%)			< 0.001
No protocol in KNH	37 (77)	18 (39)	
Lack of GBS transport media for clinicians	3 (6)	2 (4)	
Inadequate clinician knowledge on GBS and IAP	8 (17)	26 (57)	
Prescription for IAP in current pregnancy if has previous history of neonatal sepsis (%)			0.497
Yes	34 (68)	32 (74)	
No	16 (32)	11 (26)	
Recommendation for use of GBS screening & IAP protocol in KNH (%)			0.384
Yes	47 (94)	42 (98)	
No	3 (6)	1 (2)	

GBS- Group B streptococcus IAP – Intrapartum antibiotic prophylaxis

The clinician characteristics and practices summarised in table 4 show that majority were nurses and the characteristics were similar between the two study phases .Majority were aware of existence of GBS protocols ,however they did not screen routinely and give Intrapartum antibiotics , main barrier to GBS screening and IAP identified by clinicians pre intervention was no protocol in place at the institution(77%) ,while at post intervention the main barrier accounting for 57% of clinician responses was inadequate clinician knowledge on GBS and IAP with a statistically significant P value <0.001

Figure 6: Barriers to implementation of a GBS screening and IAP protocol



As shown in figure 6, the main barrier to use of a GBS screening and IAP protocol at baseline was no protocol in place at KNH (77%), this improved post intervention (39%) while at Post intervention inadequate clinician knowledge on GBS screening and IAP (57%) was identified as the main barrier to GBS screening and IAP.

12.0 DISCUSSION

The proportion of patients receiving appropriate GBS IAP from risk based approach after introduction of protocol in our study significantly increased indicating compliance ,a finding comparable to other similar GBS protocol interventions in America & Australia; In one cohort study in Australia two hospitals had IAP compliance of up to 78% and 76% after introduction of GBS protocols, similar compliance has been noted in American studies of up to 65% and 50%(33)(34)(35). Majority of clinicians correctly chose penicillin as first line for IAP with a lower percentage correctly choosing clindamycin, cephalosporin's as second line both before and after intervention, this finding comparable to a survey done on members of ACOG between January & July 2014;(penicillin 71% , cefazolin 51% & clindamycin 36%)(36). These findings in our study of use of clinician education to change prescription practice are in keeping with a 2015 systematic review survey and Cochranes effective practice of care recommendation (2002) that use of clinician education interventions have been proven to promote positive professional behaviour change among clinicians(37).

In this study we found that the proportion of patients undergoing screening for GBS did not change despite intervention, a contradiction to findings in other settings that reveal increased screening after intervention; In a randomized control trial conducted in Porto Alegre Brazil, mail and follow up education of obstetricians was noted to be a more effective intervention compared to mailing only and this increased GBS screening from 17% to 25% (38) .Several North American studies have shown increased GBS screening from 30% to 62% and 48% to 85% with use of clinician computer reminders, academic meetings and posters training as was the intervention in our study pointing out the crucial role that educative interventions play in terms of change in clinician prescription practice and attitude change towards GBS screening and IAP (32)(39). In addition to these findings it is evident that majority of clinicians in KNH do not routinely screen for GBS and subsequently give IAP a finding that

is comparable to Israel in 2005 when a telephone questionnaire conducted for all 27 delivery units in the country revealed only 2 of them adhered to CDC guidelines ,same findings were noted in the United Kingdom(UK) after two national surveys conducted between 1999 and 2001 revealed that no delivery unit conducted any screening and IAP as per CDC recommendations and this was until countrywide circulation of protocols in UK in 2003,yet documented reports from the country still indicate little impact of the protocols as of the year 2013(40) (41)(42). Currently there seems to be no supportive data published regionally and locally suggestive of clinician screening practices and compliance to GBS screening and IAP protocol despite known high prevalence rates(4) .These findings in our study could be attributed to inadequate clinician knowledge on GBS screening and IAP , the minimal contact time clinicians have with patients in KNH labour ward in active labour waiting for a GBS screening result and lack of readily available swabs and transport media in antenatal wards and clinics.

The main barrier to protocol implementation in this study was inadequate clinician knowledge accounting for majority of the responses post-intervention as opposed to no protocol in place at pre- intervention (Figure 6). This is similar to findings in America, Israel and areas such as Italy and Finland that have already implemented the screening protocol after national adoption of CDC guidelines, but still collecting suboptimal samples for laboratory evaluation as a result of inadequate clinician knowledge; in Emilia-Romagna Italy more than 86% of the women at term had been screened in good time,97% had a documented result at delivery but what was noted in this study was that health facilities with fewer deliveries were more likely to screen appropriately for GBS this had tremendous impact on laboratory isolations of the organism because greater than 50% of collected samples were suboptimal since they were only collected from vaginal site only as opposed to the CDC recommended rectovaginal swab collection and this was linked to the various cases

of early onset neonatal GBS disease. Although the incidence of early onset GBS disease in Finland is relatively low, current prevention practices have been documented to be suboptimal with data indicating that most mothers of neonates in Finland with early onset GBS disease did not receive prophylactic antibiotics and there is wide consensus even from the 1980s when the organism had already been identified as the causative agent of majority of early onset neonatal disease in the country ,currently there's some push towards a need to establish national guidelines to prevent GBS neonatal disease. A similar study to ours done in Israel in 2005 revealed the lack of an antenatal screening approach program for GBS with half of the senior obstetricians interviewed not aware of the incidence of GBS in their respective hospitals and in Israel ,this important finding was noted to be the main barrier to the acceptance of CDC guidelines as part of antenatal screening of women for GBS (40)(43)(44) (45) .

These barriers can be overcome by continuous clinician trainings and patient GBS information awareness. Clinician education through trainings such as CME ,mailing system and posters have been shown in systematic reviews of educational interventions to have some promising results similar to those found in our study of better prescription practice, compliance to protocol and as shown in figure 6 a decline post-intervention in the no protocol response as the main barrier to GBS protocol implementation pre intervention(37)(46)(47),more over patient awareness booklets on GBS have proven to be very effective in involvement of patients in Ireland, the country has GBS screening and IAP information booklets that have been approved for use in their antenatal clinics and this has shown tremendous gains according to an online survey done that revealed that out of 2,200 women in early pregnancy to mothers with a youngest child aged 2 years ,nearly 3 in 5 women were aware of GBS -42% from a pregnancy book,21% from a friend or mother,20% found out from a midwife and majority responded that they should be made more aware of

GBS and be offered a test during pregnancy or the option to pay for it and this accounted for 56% of the participants (48) .

13.0 CONCLUSION

Introduction of a Group B Streptococcus (GBS) protocol is associated with increase in appropriate GBS intrapartum antibiotic Prophylaxis (IAP) prescription but not increase in screening practices. The main barriers identified to protocol implementation were lack of a protocol in KNH at pre -intervention and inadequate clinician knowledge on GBS at post-intervention.

14.0 RECOMMENDATIONS

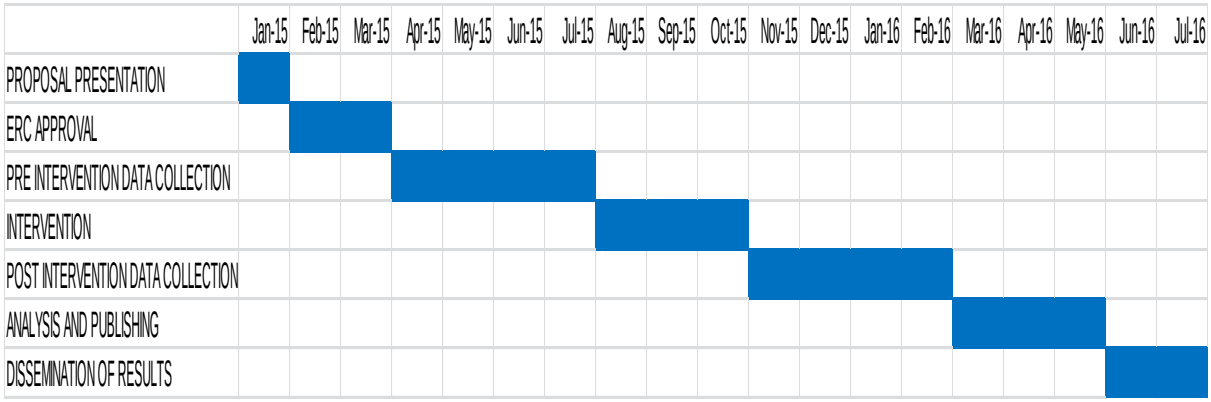
1. We recommend Group B streptococcus (GBS) screening and intrapartum antibiotic prophylaxis at Kenyatta National Hospital (KNH).

2. Eliminate barriers for Group B streptococcus (GBS) screening by :

- Continuous clinician trainings via continuous medical education(CMEs) on protocol adherence

- Putting posters of GBS protocols in clinics and wards

15.0 TIMELINES



16.0 BUDGET FORM

Components	Unit of Measure	Duration/ Number	Cost (kshs)	Total (Kshs)
Personnel				
Research Assistant	1	4	1,500	6,000
Statistician				30,000
Participants				
Printing				
Consent Form	1	2	10	20
Assent Form				
Questionnaires	1	2	10	40
Final Report	1	100	10	1,000
Photocopying				
Consent Form	50	2	3	300
Assent Form				
Questionnaires- Clinician	50	2	3	300
Data extraction form-data collection	50	4	3	600
Final Report	5	100	3	1,500
Final Report Binding	6	1	500	3,000
Laboratory Cost				
Other costs				
ERC Fees				2,000
posters	30	1	500	15,000
Total				59,780

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APPENDIX 1: QUESTIONNARE TO CLINICIAN

QUESTIONNAIRE NUMBER ☐

1. Please tick as appropriate your current qualification

☐ Consultant ☐ registrar ☐ nurse

2. Please tick as appropriate the number of years of practice in current position in KNH?

☐ <2yrs ☐ 2-6yrs ☐ >6yrs

3. From your local literature reviews what do you think is the approximate prevalence of GBS (group B streptococcus) in antenatal mothers at KNH?

☐ 10-15% ☐ 16%-20% ☐ 21%-26% ☐ don't know

4. Are you aware of the existence of any GBS (Group B streptococcal) screening and antibiotic prophylaxis protocols used worldwide?

☐ YES ☐ NO

5. If yes, which protocol are you familiar with?

☐ CDC (centre for disease control)

☐ RCOG (royal college of Obstetrics and gynaecology)

☐ ACOG (American college of obstetrics and gynaecology)

☐ All mentioned protocols

6. Which group of antibiotics is recommended as first line for GBS intrapartum antibiotic prophylaxis?

☐ Clindamycin ☐ penicillin's ☐ don't know

☐ Others, specify _____

7. Which is the recommended antibiotic as second line for GBS intrapartum antibiotic prophylaxis?

☐ Clindamycin ☐ Penicillin's ☐ don't know

☐ Others, specify _____

8. Do you routinely do GBS screening and IAP at KNH for patients with risk factors for GBS?

☐ Yes ☐ No

9. If No, why

☐ No protocol in place at KNH ☐ lack of GBS transport media for clinicians use

☐ Inadequate clinician knowledge on GBS screening and IAP

☐ other ,please specify _____

10. In a patient with history of previous infant with early onset neonatal sepsis, would you prescribe Intrapartum antibiotic prophylaxis for GBS in current pregnancy?

☐ Yes ☐ No

11. Would you recommend GBS screening and intrapartum antibiotic prophylaxis at KNH?

☐ Yes ☐ No

APPENDIX 2: PATIENT FILE DATA EXTRACTION FORM

FORM NUMBER ☐

SOCIODEMOGRAPHIC CHARACTERISTICS

1. Age of patient in years ☐

2. Marital status

1. Married ☐
2. Single ☐
3. Divorced / separated ☐
4. Widowed ☐
5. Not recorded ☐

3. Occupation status

1. Employed ☐
2. Unemployed ☐
3. Not recorded ☐

4. Level of education.

1. Primary ☐
2. Secondary ☐
3. Tertiary ☐
4. Not recorded ☐

CURRENT OBSTETRIC HISTORY

5. Gestation in weeks ☐

6. Number of previous live births ☐

7. Number of previous still births ☐

8. Number of abortions ☐

9. Number of previous births with early neonatal sepsis ☐

10. History of per vaginal discharge

☐ Yes ☐ No

11. History of drainage of liquor

☐ Yes ☐ no

12. Duration of drainage of liquor?

☐ < 18hrs ☐ > 18hrs ☐ Not recorded

13. History of lower abdominal pains characteristic of labour?

☐ Yes ☐ No

14. History of treatment for UTI in current pregnancy

☐ Yes ☐ No ☐ not recorded in file

CLINICAL EXAMINATION

15. Temperature > 38 degrees centigrade

☐ Yes ☐ no ☐ not recorded in file

16. Fundal height exam ☐ weeks

17. Initial recorded cervical dilatation ☐ centimetres. ☐ not recorded

18. Speculum exam findings in patients presenting with history of drainage of liquor.

☐ Confirmed drainage of liquor ☐ speculum exam not recorded

INVESTIGATIONS

19. Urinalysis done

☐ Yes ☐ No

20. If yes, results of urinalysis

☐ NAD (no abnormality detected) ☐ leucocytes

☐ Proteins ☐ pus cells

21. Urine culture done

☐ Yes ☐ No

22. If yes, GBS isolated?

☐ Yes ☐ No

23. Bacteriological vaginal swab culture done

☐ Yes ☐ No

24.if yes, was GBS (group B streptococcus) cultured?

☐ yes ☐ No

25.Antibiotic sensitivity done?

☐ yes ☐ No

26.if antibiotic sensitivity done,sensitivity patterns of isolates to penicillin,erythromycin.

☐ penicillin sensitive ☐ penicillin resistant

☐ clindamycin sensitive ☐ clindamycin resistant

TREATMENT

27. Were antibiotics prescribed for the patient?

☐ yes ☐ No

28.Did the patient receive appropriate intraparturm antibiotic prophylaxis regimen as per GBS protocol?

☐ yes ☐ No

29. antibiotics route of administration?

☐ Oral ☐ Intravenous

30. Outcome of patient management in KNH

☐ live birth ☐ Still birth

APPENDIX 3: INFORMED CONSENT FOR CLINICIAN

Consent number ☐

TITLE OF STUDY: EFFECTIVENESS OF A GROUP B STREPTOCCOCUS (GBS) PROTOCOL ON GBS SCREENING AND INTRAPARTUM ANTIBIOTIC PROPHYLAXIS AT KENYATTA NATIONAL HOSPITAL

PRINCIPLE INVESTIGATOR: Dr Vitalis okola – PART II registrar in obstetrics and gynaecology, university of Nairobi.

Before consenting to this study, please read through the information provided below and understand the purpose of this study.

INTRODUCTION: Group B streptococcus (GBS; streptococcus agalactiae) is a gram positive bacteria. It's an important cause of perinatal morbidity, mortality and a common cause of maternal peripartal infections. Maternal intrapartum GBS colonization is known to be a major risk factor for early onset disease in infants.

OBJECTIVES OF STUDY: To determine the effectiveness of introduction of a GBS screening and intrapartum antibiotic prophylaxis protocol on uptake of GBS screening and antibiotic prophylaxis practice in KNH labour ward**.**

BENEFITS OF THE STUDY: we expect this study to improve on your knowledge, attitude and screening practices as pertains to GBS screening and intrapartum antibiotic prophylaxis. Kenyatta National Hospital, department of reproductive health also stands to benefit from vital information provided by you as a key health care provider at the institution as pertains to barriers to GBS protocol implementation that will go a long way in implementation of the study protocol and assisting the institution in line with its vison of being a world class patient centred specialized care hospital.

RISKS: No adverse events are anticipated.

STUDY PROCEDURE: you will be requested to fill in a structured questionnaire that will take approximately 10 minutes of your time.

CONFIDENTIALITY OF RESEARCH RECORDS: your response to the questionnaire will be completely anonymous; information obtained in hard copy shall be kept under lock and key by the principle investigator.

REVIEW FOR THE PROTECTION OF PARTICIPANTS: This study has been reviewed by the KNH/UON ethics committee.

RESEARCH PARTICIPANTS RIGHTS: By consenting to this project, you are confirming that you have read through the above information and are voluntarily accepting to be a participant in the study.

I _____ have read the above provided Information and hereby give voluntary consent to be a participant of this study.

SIGN _____ DATE _____

PRINCIPLE INVESTIGATOR / RESEARCH ASSISTANT: NAME _____

SIGN _____

DATE _____