ASSESSMENT OF ADHERENCE TO GUIDELINES FOR THE MANAGEMENT OF ACUTE BACTERIAL MENINGITIS IN CHILDREN ADMITTED TO KENYATTA NATIONAL HOSPITAL

A research dissertation in partial fulfilment for the degree of Masters of Medicine Paediatrics and Child Health, University of Nairobi.

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H58/87782/2016

DECLARATION

This dissertation is my original work and has not been presented for the award of a degree in any other university.

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DEDICATION

To God, for allowing me to come this far and guiding me.

To my dear husband Eric Omani for being there for me and encouraging me.

To my son Jamie Omani for giving me the will to go on and make it.

To my parents Dr. Naftali Oirere and Mrs. Milcah Oirere for believing in me and encouraging me.

To my supervisors Prof. Fred Were and Dr. Jalemba Aluvaala for their continued guidance.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

ABM- Acute bacterial meningitis

CPG- Clinical practice guidelines

CSF- Cerebro-spinal fluid

EBG- Evidence based guidelines

Hib- *Haemophilus influenza* type b

KNH- Kenyatta National Hospital

LP- Lumbar puncture

WHO- World Health Organisation

PAQC- Paediatric admission quality of care

DEFINITIONS

Acute bacterial Meningitis: -Inflammation of the meninges following bacterial infection. It usually develops within a day.

Suspected acute bacterial meningitis: -Any child aged 60days or more with a history of fever and one of the following; coma, inability to drink/ feed, decreased level of consciousness, bulging fontanelle, seizures if age <6months or >6years, partial seizures, agitation/ irritability

Subacute meningitis: -Inflammation of the meninges which develops over a few days or weeks

Chronic meningitis: - Inflammation of the meninges which lasts for more than 4 weeks.

ABSTRACT

Background: Acute bacterial meningitis (ABM) is a disease which if not adequately and promptly managed, can lead to serious adverse effects. Evidence based guidelines in the form of Ministry of Health basic paediatric protocols are available which help in the proper management of the disease. It is important to follow such guidelines in order to improve outcomes.

Objectives: This study was aimed at evaluating the quality of care given to children aged 2 months to 5yrs with ABM, to determine the proportion which gets proper treatment. The study also aimed to find out the outcomes of children who were managed for ABM at Kenyatta National Hospital (KNH).

Methodology: The study was a cross-sectional study, involving children aged 2months to 5years, who were admitted to KNH general paediatric wards between December 2018 and January 2019. The children with suspected acute bacterial meningitis based on the case definition in the guidelines on admission, were identified on discharge and information on the care given to them during the period of admission was extracted from their files using a structured data form.

Data analysis: The data collected was entered into SPSS and analysis was done using SPSS version 23.0. Results were then presented in the form of means and proportions for demographic data and clinical characteristics, as proportions for correct assessment, management and outcomes.

Results and conclusions: Out of 276 patients with suspected ABM, the proportion that was correctly managed was 32.2%. Only 35.9% had a lumber puncture done and 42.8% of the patients received the recommended antibiotics on admission. The proportion of patients who died while receiving treatment was 14.1% and the mean length of hospital stay was 11days.

Recommendations: It was recommended that use of evidence-based guidelines (EBG) in management of patients with ABM should be enforced to health workers in order to improve outcomes.

CHAPTER ONE
INTRODUCTION

1.1 Overview of Acute Bacterial Meningitis

Acute bacterial meningitis (ABM) is a clinical syndrome characterized by inflammation of the meninges. It is a life-threatening infection which has been seen to cause a high rate of morbidity and mortality especially in infancy and childhood.(1) It carries a risk of neurological deficit or death if diagnosis and the starting of treatment are delayed.(2)

Disease caused by the most common causative agents of acute bacterial meningitis is preventable through the use of vaccines. In the pre-vaccination era, the most common bacterial agents which caused acute bacterial meningitis were *Haemophilus influenza*, *Neisseria meningitidis* and *Streptococcus pneumoniae*. However, following the introduction of vaccines against these pathogens, the epidemiology of ABM has changed.(1)

1.2 Epidemiology of Childhood Acute Bacterial Meningitis

Acute bacterial meningitis causes a significant amount of mortality in children. In the Global Burden of Disease study, it was observed that in 2016, meningitis caused a total of 68,000 deaths in children under the age of 5years worldwide, which was a 35.9% drop from the year 2006. A greater reduction in mortality was seen in those aged between one month to one year compared to those between 2 to 4years, with a mortality of 34,300 and 33,600 respectively in 2016. This accounted for a 35.5% and 36.4% drop in mortality respectively, compared to the year 2006.(3)

In an Indian study based on 10 sentinel hospitals, it was found that, out of 19,670 children under 5years who were admitted with fever, 3,104 (15.8%) satisfied the criteria for suspected acute bacterial meningitis.(4) *S. pneumonia* was found to be the most common pathogen causing meningitis in all hospitals except for one in which *H. influenza* type b (Hib) was the commonest. Out of the confirmed cases of acute bacterial meningitis 77.4% occurred in the age group of less than 2 years.(4)

A study done in a Nigerian teaching hospital neurological unit, showed a prevalence of meningitis of 8.16% out of 7,644 patients who were seen between 1st January, 2010 and 31st December, 2012. The study also revealed that long term complications of meningitis occurred

in 15.06% of these patients and the age group which was most affected was between 1 to 5 years, who accounted for 46.81% of those with complications.(5)

In Kenya, a study was done in Kilifi District hospital to determine the effectiveness of including *Haemophilus influenzae* type b (Hib) vaccine into the vaccination program in the year 2002, in preventing bacterial meningitis caused by this organism. It was noted that there was a decrease in the annual incidence of Hib disease among children aged less than 5 years. In the years 2000 to 2001 which preceded the vaccine introduction, the annual incidence of confirmed Hib infection in children aged less than 5 years was 66/100,000 (0.07%), while in those aged less than 2 years, it was 119/100,000 (0.12%). After the introduction of the vaccine, the annual incidence decreased to 47/100,000 (0.05%) in years 2002 to 2003 and 7.6/100,000 (0.01%) in 2004 to 2005, among children aged less than 5 years. In those aged less than 2years, the incidence dropped to 82/100,000 (0.08%) in 2002 to 2003, and 16/100,000 (0.02%) in 2004 to 2005.(6)
Vaccines have been seen to reduce the incidence of acute bacterial meningitis, since the most common causative agents are vaccine preventable, although the disease still causes significant mortality and morbidity.(1,7,8)

1.3 Outcome of acute bacterial meningitis in childhood

Acute bacterial meningitis has a mortality rate of 5-10% for children in developing countries. It has also been reported to have a case fatality rate of 20 to 30%.(9) Out of those who survive the disease, 20-25% may get neurological sequalae, even with the recommended antibiotic treatment. ABM is associated with a high cost to the health sector due to long hospital stay and admission to the intensive care unit.(1,8)

Acute bacterial meningitis may result in various adverse outcomes which may be short term or long term. Some of the short-term effects include coma, seizure, hemiparesis, hydrocephalus, aphasia and ataxic gait. This was found during a cohort study by Nyillok (2004), which focused on children aged 2 months to 60 months with acute bacterial meningitis at the Kenyatta National Hospital general paediatric ward and paediatric filter clinic.(10) Brain oedema, subdural effusion and micro-abscesses are also complications which can occur as a result of ABM.(11)

Some long term neurological sequalae which may result following an infection of acute bacterial meningitis include recurrent seizure disorder, cerebral palsy and hearing impairment among other neurological conditions.(5,12) A prospective study done at Kenyatta National Hospital by Karanja et al (2014) to examine the hearing function of children aged between 6 months to 12years admitted with bacterial meningitis, revealed that 43.37% of these children developed sensorineural hearing loss. Out of those children with hearing loss, 26.5% had mild to moderate sensorineural hearing loss while 16.9% had severe or profound sensorineural hearing loss. It was therefore concluded that it is important to screen infants and young children with bacterial meningitis, for hearing loss.(12)

Other long term sequalae which have been described in patients that have survived ABM include reduction in intelligence quotient and developmental delay as seen in a systemic review and meta-analysis by Christie et al (2017). This included 34 studies which provided information on intelligence quotient and 12 studies which provided information on developmental delay in children who survived bacterial meningitis.(13) Roed et al (2013) found that patients who suffered from ABM in childhood had lower educational achievement and economic self-sufficiency compared to people who did not suffer from the disease. This was concluded after a nationwide Danish study which involved adults who had suffered from ABM during childhood before the age of 12 years.(14)

CHAPTER TWO
LITERATURE REVIEW

2.1 Approaches to the assessment of quality of hospital care

The quality of medical care can be improved if evidence-based guidelines (EBG) are followed. Adherence to evidence based guidelines results in better quality of hospital care and hence better outcomes for children.(15,16) Standardized and up to date clinical practice guidelines (CPG) are useful in eliminating uncertainty and variation in the management of patients and hence promote provision of quality medical care.(17)

The World health organization (WHO) recommends that health systems should make improvements in 6 dimensions of quality whereby health care should be effective, efficient, accessible, acceptable, equitable and safe. In order to improve quality, steps have to be taken. These include, analysing the current situation with regards to health care. This is followed by coming up with plans/ strategies which will be used to improve quality of care. Then implementation of these plans and monitoring follows. This process is a continuous cycle since once implementation has been done, analysis then follows and the process continues.(18)

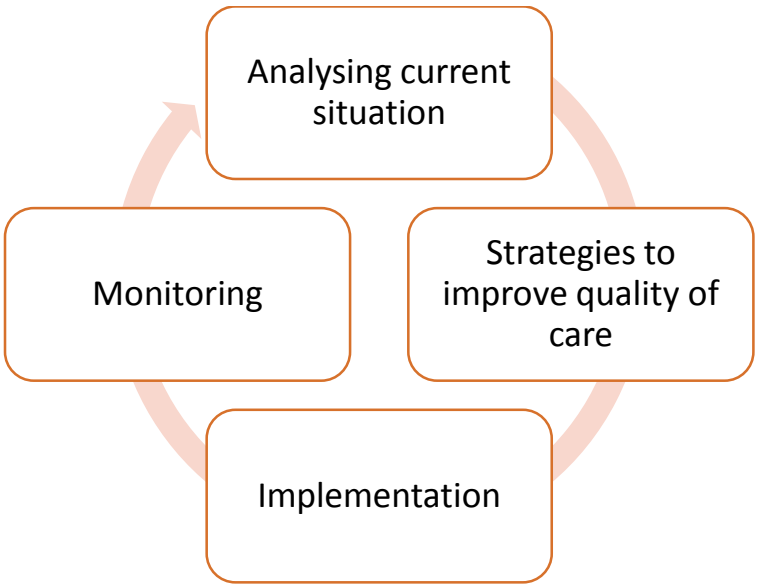

Figure 1:Plan, do study, act cycle (PDSA).

According to Avedis Donabedian, the assessment of the quality of healthcare involves three approaches. These include assessment of: outcome, process and structure.(19) The three approaches may be used together to give wholistic information on the quality of care.

Outcome as a measure of medical care, can be assessed in terms of recovery, restoration of function, or even survival. Process assesses the interaction of the caregiver with the patient. Judgment is based on whether the correct procedure, treatment and other management were done. Assessment of structure involves the study of the setting in which the process of care takes place. This includes the adequacy of facilities and equipment, medical staff availability and their qualifications, among other factors. It is assumed that with the proper structure, good medical care will follow.(19)

In Kenya, the Ministry of Health, developed clinical practice guidelines (CPGs) in the form of the 'Basic Paediatric protocols.' These simple guidelines were aimed at aiding the health provider with evidence based decision making which would help provide optimal care.(20) The guidelines target the common childhood illnesses including meningitis. Along with developing the guidelines, training was done in order to sensitize health providers on how to use them. Therefore, in the assessment of the quality of care in the management of acute bacterial meningitis, these guidelines were used as the standard of care.

2.2 Quality of hospital care for children globally

Several studies have been done to assess the quality of care with regards to various diseases. The assessment of quality of care regularly helps in identifying gaps which may need to be addressed in order to allow better outcomes in health care provision.(21)

Good adherence to evidence based guidelines has been reported in some areas.(22) Some studies however have shown poor adherence to evidence-based guidelines. A study by Lo Vecchio et al (2014) in 31 Italian hospitals to assess the adherence to guidelines for the management of acute diarrhea in hospitalized children, revealed that out of 612 children, only 20.6% were managed in full compliance with the guidelines, while 44.7% were managed in partial compliance.(23)

An Indonesian study by Sidik et al (2013) assessed the quality of hospital care for children by comparing the care given to the national guidelines which were adopted from WHO guidelines. The study was carried out in 6 different geographic regions of Indonesia, where

some hospitals were selected for evaluation. The study focused on the structure and process where an assessment tool was used to assess various hospital services, including; availability of resources, emergency care, case management and patient monitoring, among other parameters. Serious shortcomings were identified in the quality of hospital care for children and this helped in making changes which would help in improvement of the quality of care.(24)

2.3 Quality of care in East Africa

Warille M. (2016) did an audit on the care given to severely malnourished children aged 6 to 59 months at a children's hospital in Juba. The study found that, in more than 70% of the cases, 5 steps of management of malnutrition were correctly followed.(25)

Kithinji (2014) assessed the quality of care given for patients with neonatal sepsis in Kenyatta National Hospital general paediatric wards between January to December2011. She found that the recommended first line antibiotics were given in 64.4% of 385 cases. She also noted that there was a mortality rate of 5.5% and that 52.4% deaths occurred within the first 48 hours of admission.(26)

In a study to determine the adherence of health workers to new born resuscitation guidelines in Garissa Provincial General Hospital, Otido (2013) found that out of 136 resuscitations, only 26.5% resuscitations were performed appropriately. It was noted that the reason for this was lack of the required equipment and that some of the health workers lacked training on new born resuscitation.(27)

Irimu et al (2012) carried out a study to assess the performance of health workers in the management of seriously ill children at Kenyatta National Hospital. The study looked at how patients were managed prior to introduction of basic paediatric protocols containing clinical practice guidelines (CPGs) and compared this to how they were managed after their introduction. Quality of care indicators were used to assess performance. These indicators included assessment, classification, treatment and follow up care within 48 hours of admission. Following the introduction of CPGs and training of health care workers on their use, it was noted that there was a 20% increase in performance of 7 out of 15 key indicators, while a 50% increase was seen in 3 indicators.(28)

In relation to this study, another was done by Irimu et al (2014) to determine barriers to implementation of CPGs. Some of the barriers included lack of communication, limited objective ways for monitoring and evaluating clinical care, among other factors.(29,30) These clinical practice guidelines which were developed included guidelines for the management of ABM.

A study by Opondo et al (2016) aimed at developing a paediatric admission quality of care (PAQC) score to assess the compliance of clinicians with recommended steps in clinical guidelines found in the basic paediatric protocols. The study focused on various domains in the process of care during admission of children with three common diseases. The domains included assessment of patients, diagnosis and initial treatment. Summing up scores in these domains gave an overall score which pointed towards the quality of care offered on admission. It was noted that following the introduction of the PAQC score, there was an improvement in the documentation of primary symptoms of disease and severity. However, further work was required to determine the validity of this tool.(31)

2.4 Case Management of suspected Childhood Acute Bacterial Meningitis in Kenya

Early diagnosis and treatment are important to avoid the adverse effects of ABM. This may pose a challenge owing to the fact that ABM may present with non-specific clinical signs which may overlap with other diseases such as malaria and encephalitis as seen in other studies such as one by Gichina (2010).(32,33) However, there are guidelines in the basic paediatric protocol which aid in the identification and treatment of ABM. These guidelines were adopted from the WHO guidelines which are outlined in the 'WHO pocket book for hospital care for children.' This is what is used in Kenya as the standard of care.

The diagnosis of ABM is through clinical evaluation and laboratory investigations.(7) According to the guidelines, a child above 2 months of age who has fever and any of the following symptoms, should be suspected to have, and hence evaluated for acute bacterial meningitis. The symptoms include; coma or decreased level of consciousness, inability to drink or feed, stiff neck, bulging fontanelle, seizures, agitation or irritability.(34) A study by Berkley et al (2004), done at Kilifi District Hospital, to determine the indicators of acute bacterial meningitis in children and another by Best et al (2007) to identify the clinical features of bacterial meningitis, found that similar signs and symptoms as those in the basic paediatric protocol were associated with the disease.(32,35)

Once the suspicion of ABM has been made, a lumbar puncture (LP) should be performed and CSF analysis done. However, the LP can be deferred if the patient requires cardiopulmonary resuscitation, has a poor pupillary response to light or has a skin infection at the site where the LP should be done.(34) CSF analysis is the gold standard test for diagnosing ABM.(2) The CSF analysis shows the inflammatory response to the infection and detect the causative agent through gram stain, culture, antigen assay and molecular detection.(7)

The treatment of acute bacterial meningitis should be started as soon as possible once a clinical suspicion has been made, even before getting the results of the Lumber puncture. If a lumber puncture has not been done but there is clinical suspicion of ABM, treatment should still be started immediately.(36) Empirical antibiotics are used depending on local drug sensitivities.

WHO, recommends high dose 3rd generation cephalosporins (ceftriaxone or cefotaxime) as the drug of choice for the treatment of acute bacterial meningitis for ten to fourteen days. This was after assessing studies which compared the use of these 3rd generation cephalosporins and chloramphenicol-based antibiotics. There was no significant difference in terms of efficacy and safety. However, the most common causative agents of ABM were found to be resistant to chloramphenicol-based antibiotics. Ceftriaxone had an advantage in rapid sterilization of CSF after 48hours of treatment. It was also more acceptable due to the single daily dose compared to the chloramphenicol 6 hourly dose.(37)

2.5 Quality of Hospital Care for suspected acute BM in Children

Few studies have assessed the quality of hospital care for acute bacterial meningitis. Turel et al (2014), assessed if the diagnosis and treatment of childhood ABM in Turkey was evidence based. The study was carried out in 11 tertiary hospitals in Istanbul and involved children aged 1month to 5 years with a diagnosis of ABM. It was found that out of 283 patients, 68%, 87% and 13% had a blood culture, CSF studies and CSF Gram stain done respectively. It was also found that in 90% of the cases, a 3rd generation cephalosporin was the drug of choice.(38)

A study done by Gathara et al (2015), focused on assessing the quality of care of common childhood diseases including malaria, diarrhea/dehydration, pneumonia, malnutrition and meningitis. This study followed the Donabedian approach of assessment of quality of care,

whereby there is assessment of the structure, process and outcome. Various internship centers across Kenya were assessed on the structure and process of healthcare. The study evaluated the availability of resources required to manage the conditions, the process of care in terms of documentation and disease specific management in comparison to the Kenyan national guidelines. The study found that guideline recommended disease severity grading was followed in 44%, 73% and 92% cases of malaria, pneumonia and dehydration respectively. Also, treatment recommended guidelines were followed in 74% of malaria cases and 25% of malnutrition cases.(21) This study however, did not assess some aspects of the management of acute bacterial meningitis, including the use of empirical antibiotics for treatment.

2.6 Conceptual framework

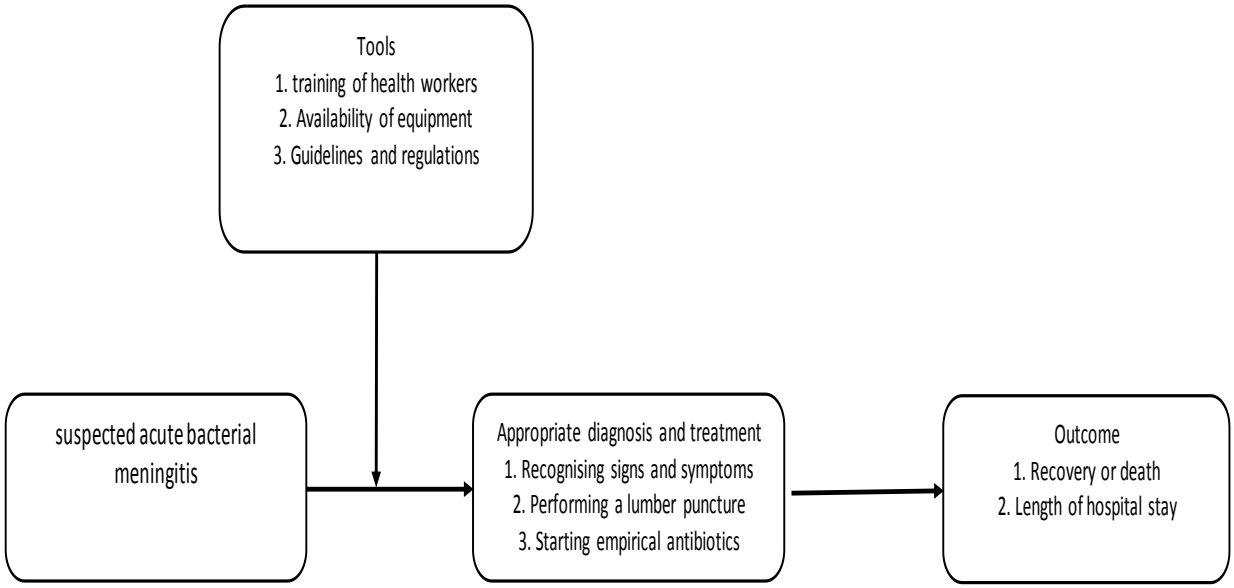

Figure 2:Conceptual framework

In order to have quality care for acute bacterial meningitis, there have to be adequate resources or equipment to perform procedures, the staff has to be trained on the type of care being given and they need to have guidelines and regulations on how to provide this care, depending on their cadre. This will influence the ability of the health worker to recognize the clinical features of ABM, the ability to do a lumber puncture and making the decision to start empirical treatment. Ultimately, this will influence the outcome of the patients who are managed by the health workers, in terms of whether they will recover or not and in terms of the length of hospital stay.

2.7 Study Justification

Acute bacterial meningitis is a common disease which if not promptly and properly managed, can lead to serious morbidity and mortality.(3) However, no studies at Kenyatta National Hospital have been done to assess the process of care against the set guidelines, which would in turn reveal any gaps in the management of the disease. This study will therefore help identify such gaps and sensitize health workers on the importance of following evidence-based guidelines in order to get better patient outcomes. This is also important as it will encourage antimicrobial stewardship since with proper assessment and investigation, there should be proper use of empiric antibiotics which will help to avoid antimicrobial resistance.

2.8 Study Question

What proportion of children aged 2 months to 5 years with suspected acute bacterial meningitis received the correct management during the period of admission at Kenyatta National Hospital in the general paediatric wards?

2.9 Objectives

2.9.1 Primary objective

To determine the proportion of children aged 2 months to 5 years with suspected acute bacterial meningitis who received correct management in Kenyatta National Hospital general paediatric wards.

2.9.2 Secondary objective

To describe the outcomes of children 2 months to 5 years managed for acute bacterial meningitis in Kenyatta National Hospital general paediatric wards.

CHAPTER THREE
METHODOLOGY

3.1 Study Design

The study was a cross-sectional study. Files belonging to patients who were suspected to be having acute bacterial meningitis on admission were identified once the patients were discharged. Data on the management of the patients was extracted from these files using a structured data extraction form. The principle investigator and research assistant were not actively involved in the management of patients in the study, but only got data on how the patients had been managed.

3.2 Study Site

The study was carried out in the Kenyatta National Hospital general paediatric wards. KNH is a National teaching and referral hospital. It has four general paediatric wards where neonates and children aged up to 12 years are admitted. Each of these wards has a bed capacity of 60 beds although most of the time the admissions are more than the capacity. Patients are first seen at the paediatric filter clinic and those who require admission are transferred to the general paediatric wards, apart from neonates who require to be admitted to the new-born unit. On average, about forty patients with confirmed acute bacterial meningitis are admitted to the general paediatric wards in a month. However, those with suspected acute bacterial meningitis are usually more than the confirmed cases.

3.3 Study population

The study targeted children aged 2months to 5 years, who were admitted into the KNH general paediatric wards with suspected acute bacterial meningitis.

3.4 Inclusion criteria:

Paediatric patients aged 2months to 5years with suspected ABM on admission. That is, any child aged 60 days to 5 years with a history of fever and one of the following; coma, inability to drink/ feed, decreased level of consciousness, bulging fontanelle, seizures if age <6months or >6 years, partial seizures, agitation/ irritability.

3.5 Exclusion criteria:

1. Patients with subacute or chronic meningitis (symptoms for more than a week) and those referred from other facilities after management for any condition.
2. Patients who were readmitted following recent discharge from the hospital.
3. Patients with other pre-existing neurological conditions such as convulsive disorder.

3.6 Study period

The study was carried out between December 2018 and January 2019.

3.7 Quality of care measures

The following outcomes were expected to be achieved by the study:

- The proportion of patients who received correct management. That is:
    1. Correct assessment in terms of complete documentation of signs and symptoms of suspected ABM. The symptoms included fever and any of the following: coma, inability to drink/ feed, decreased level of consciousness, bulging fontanelle, seizures if age <6montns or > 6years, partial seizures, agitation/irritability.
    2. An LP was done following identification of features of suspected ABM, where no contraindication existed plus
    3. Appropriate Empiric treatment was started following the lumber puncture. The empirical treatment according to the basic paediatric protocols was high dose ceftriaxone given at 50mg/kg 12hourly or 100mg/kg given 24hourly.
- The outcome of patients managed for ABM in terms of:
    1. In-hospital mortality
    2. Length of stay in hospital

3.8 Sample size determination

Sample size was calculated using the Fisher's formula.(39)

$$n = \frac{Z^2 P (1-P)}{d^2}$$

$$n = \frac{(1.96)^2 \times 0.206 \times (1 - 0.206)}{(0.05)^2}$$

$$n = 251$$

Where:

n- sample size

Z- 1.96 (95% confidence interval)

P- Estimated proportion with the correct management= 20.6%

d- Margin of error = +/- 5%

An extra 10% of the sample size was added to cater for missing or incomplete information.

10/100 x 251= 25.1

251 + 25 = 276

Therefore **276** was used as the sample size

p value was determined from a study by Lo Vecchio et al which revealed that only 20.6% of children were managed in full compliance with the guidelines.(23)

3.9 Sampling procedure

Files of patients who were suspected to have acute bacterial meningitis from the clinical presentation on admission were identified at the point of discharge by the principle investigator and research assistant. Information from each of these patient files was collected by consecutive sampling until the required sample size was achieved. Approximately forty patients with confirmed acute bacterial meningitis were admitted to the general paediatric wards per month. However, the number of those with suspected acute bacterial meningitis was higher.

3.10 Data collection

Data was extracted from the selected patient files using a structured data extraction form (see appendix IV). This data form was derived from a study by Gathara et al (2015) and therefore pretesting was not required as it had been used previously. (20) A research assistant was trained on how to identify the patient files belonging to patients with suspected acute bacterial meningitis once discharged and trained how to fill in the data extraction form using data from the selected patient files. The research assistant was a registered clinical officer who had previously rotated in paediatrics and participated in data collection in other studies. The following information was noted down:

1) Clinical features.
2) Whether or not a lumbar puncture was done.
3) Treatment given

4) Outcome of the patient on discharge i.e. whether dead or alive and the length of hospital stay.

3.11 Data analysis and management

Data obtained from the file was coded, verified and entered into SPSS and analysis done thereafter using SPSS version 23.0.

The study population was described by summarizing demographic characteristics in terms of means and medians for continuous data and in terms of proportions for categorical data.

Correct assessment, lumbar puncture and empiric treatment was analyzed and presented as proportions.

Outcomes were analyzed and mortality presented as a proportion, and length of hospital stay presented as median.

3.12 Control of Errors and Bias

In order to avoid errors, the data collected was double checked before and after entry. Information bias was avoided by not informing the involved health workers that the clinical records were being assessed to determine the quality of care. Data was extracted from the files at a secluded place in the ward and at a time when most of the involved health workers were away, usually from 4.pm, to prevent them from knowing what kind of information was being extracted. Access to the data extraction form was limited to the researcher and research assistants. Selection bias was avoided by including all patients with suspected acute bacterial meningitis within the age group of 2 months to 5 years during the study period until the required sample size was achieved.

3.13 Data quality control measures

The research assistant was trained adequately on how to use the standard data extraction form to get data from the patient files before commencing the study. After using each patient file, a note with a reference number was placed on it to avoid using one file more than once for data collection. Following collection of data, every data extraction form was checked by the principle investigator for completeness. The data was then entered into SPSS and crosschecked by the principle investigator to verify on completeness, correctness and consistency of data entry. A qualified statistician assisted in vetting of the data extraction form, guided in designing of a database and also provided guidance on proper analysis of the data.

The completed data extraction forms were locked up safely by the principle investigator and the computer used for data entry and analysis was password protected to avoid access by anyone other than the principle investigator.

3.14 Ethical Considerations

Before carrying out the study, approval was sought from the Kenyatta National Hospital and the University of Nairobi ethics research committee. This was done by submitting copies of the written proposal to the committee, including the tools that were required for the collection and analysis of data. Ethical approval was provided by the ethics research committee for the proposal number P535/07/2018.

Authorization was then obtained from the KNH administration to carry out the study in the paediatric wards. Data collection and analysis then commenced. Informed consent was not required since data on care of patients was obtained from the patient files. However, confidentiality was maintained by not including patient names in the data collection forms. Following the completion of the study, conclusions were drawn and recommendations given to the health workers involved in the management of children with suspected acute bacterial meningitis.

3.15 Dissemination of findings

The results were presented to the health workers involved in managing children with suspected acute bacterial meningitis at the Kenyatta National Hospital and the University of Nairobi, to help improve the management of the disease. The findings from the study were also made available to the paediatrics department and library at the University of Nairobi and submitted for possible publication.

CHAPTER FOUR
RESULTS

4.1 Introduction

The findings of the study are presented in this chapter. The main objective of the study was to determine the proportion of children aged 2 months to 5 years with suspected acute bacterial meningitis based on the basic paediatric protocols, who received correct management in the Kenyatta National Hospital general paediatric wards. That is, patients with features of suspected ABM who were correctly assessed, had a lumbar puncture performed and were started on ceftriaxone. A total of 276 children were examined between the months of December 2018 to January 2019.

4.2 Patient characteristics

This section describes the children aged 2 months to 5 years with suspected acute bacterial meningitis who were managed in the Kenyatta National Hospital general pediatric wards. Most of the children were below 2 years and were 205 (74.3%) out of 276 patients. The mean age was 16.9 months (SD 13.3), while the median age was 12 months. There were more males in the study 145 (52.5%) as compared to females.

Table 1:Age and gender of Patients with suspected ABM

Age (months) Median age 12 (IQR=18)	**No. of patients (%) n=276**
2 – 24	205 (74.3)
25 – 60	71 (25.7)
Gender	**No. of patients (%) n=276**
Male	145 (52.5)
Female	131 (47.5)

4.3 Clinical Features of Patients with Suspected Acute Bacterial Meningitis

This study looked at how patients with suspected ABM were assessed in terms of documentation of clinical features suggestive of the disease. The level of documentation ranged from 97.5% to 100% for the various clinical features. Consciousness level and presence of convulsions were documented for all the patients, while presence or absence of a bulging fontanelle was the least documented feature at 97.5%. The most common clinical

features at admission were fever 99.3% and inability to drink/ feed 95.7%. The least common clinical feature was bulging fontanelle which occurred in only 4 (1.4%) patients.

Table 2: Clinical Features of Patients with ABM on Admission

Clinical features	**Number Documented (Yes/No) (%)**	**Clinical feature Present (%) n= 276**
Fever (Temperature >37.5^{0}C)	275 (99.6)	274 (99.3)
Coma/Decreased level of consciousness	276 (100.0)	112 (40.6)
Inability to drink/ feed	275 (99.6)	264 (95.7)
Bulging fontanelle	269 (97.5)	4 (1.4)
Convulsions	276 (100.0)	92 (33.3)
Stiff neck	274 (99.3)	72 (26.1)

4.4 Investigations Done on Patients with Suspected ABM

Table 3 below shows the investigations which were done on patients admitted with features suggestive of suspected ABM. A lumbar puncture was done on only 99 (35.9%) of these patients. The most commonly done investigations included a full blood count and HIV test which were done on 273 (98.9%) and 269 (97.5%) of patients respectively.

Table 3:Investigations Done

Investigation	**No. of patients (%) n= 276**
Lumbar puncture	99 (35.9)
Full blood count	273 (98.9)
HIV test	269 (97.5)
Malaria test	220 (79.7)
Random blood sugar	189 (68.5)
Others	5 (1.8)

4.5 Diagnosis of Patients with Suspected ABM

Table 4 below shows the diagnoses which the clinicians came up with during admission of patients with features of suspected ABM. Meningitis was diagnosed in only 96 (34.8%)

patients with features of suspected ABM, while the most common diagnosis was pneumonia in 145 (52.5%) patients.

Table 4: Diagnosis at Admission

Diagnosis	**No. of patients (%) n=276**
Meningitis	96 (34.8)
Pneumonia	145 (52.5)
Dehydration	98 (35.5)
Diarrhea	87 (31.5)
Anaemia	25 (9.1)
Malnutrition	14 (5.1)
Malaria	14 (5.1)
HIV/AIDS	2 (0.7)
Pulmonary tuberculosis	2 (0.7)

4.6 Initial Treatment

This study evaluated the treatment which was initiated on admission for patients with features of suspected ABM. Ceftriaxone which is the recommended empirical antibiotic was given to 118 (42.8%) patients, while the most commonly given treatment was a combination of penicillin and gentamicin, which was administered to 127 (46%) patients.

Table 5: Initial Treatment

Antibiotic	**Frequency (%)**
Ceftriaxone	118 (42.8)
Penicillin/Gentamicin	127 (46.0)
Penicillin	16 (5.8)
Meropenem	13 (4.7)
Others	2 (0.7)

4.7 Management of Patients with Suspected ABM

The following Table 6 shows the proportion of patients who received the correct management. That is;

1. Correct assessment was done by documentation of clinical features of suspected ABM. These features included fever and any of the following: coma, inability to drink/feed, decreased level of consciousness, bulging fontanelle, seizures if age <6 months or > 6years, partial seizures, agitation/irritability.
2. An LP was done following identification of features of suspected ABM, where there was no contraindication, plus
3. Appropriate empirical treatment was started based on the basic pediatric protocol following the lumbar puncture. That is, ceftriaxone was given at 50mg/kg 12hourly or 100mg/kg 24hourly.

The proportion of patients who were correctly managed was 32.2% (CI, 0.27-0.38)

Table 6: Management

Management	**Frequency n (%) n= 276**
Correct management	89 (32.2)
Incorrect management	187 (67.8)

4.8 Association between Clinical Features and Management of Patients with Suspected ABM

The Chi square test was used to determine the association between the clinical features of the patients and the management which they received. This was an exploratory inferential analysis. It was found that patients with convulsions were more likely to be correctly managed OR 546.4 (CI, 155.7-1917.3). Those with stiff neck were also more likely to be correctly managed OR 94.8 (CI 36.7-245.2).

Table 7: Association between clinical features and management

	Correct Management	Incorrect Management	Total	p-value	OR (95%CI)
Fever					
Yes	89 (100.0)	185 (99.5)	274 (99.6)	1.000	-
No	0 (0.0)	1 (0.5)	1 (0.4)		
Coma/Decreased level of consciousness					
AVPU= A	54 (60.7)	110 (58.8)	164 (59.4)	0.770	1.1 (0.6-1.8)
AVPU< A	35 (39.3)	77 (41.2)	112 (40.6)		
Inability to drink/feed					
Yes	77 (87.5)	187 (100.0)	264 (96.0)	<0.0001	-
No	11 (12.5)	0 (0.0)	11 (4.0)		
Bulging fontanelle					
Yes	4 (4.6)	0 (0.0)	4 (1.5)	0.010	-
No	83 (95.4)	182 (100.0)	265 (98.5)		
Convulsions					
Yes	85 (95.5)	7 (3.7)	92 (33.3)	<0.0001	546.4 (155.7-1917.3)
No	4 (4.5)	180 (96.3)	184 (66.7)		
Stiff neck					
Yes	66 (75.9)	6 (3.2)	72 (26.3)	<0.0001	94.8 (36.7-245.2)
No	21 (24.1)	181 (96.8)	202 (73.7)		

4.9 Outcomes of Patients with Suspected ABM

This section presents the outcome of patients with suspected acute bacterial meningitis in terms of in-hospital mortality and length of hospital stay. The proportion of children who died was 14.1% (CI, 0.11-0.19), while 237 (85.9%) were discharged alive. Most of the patients 185 (67%) had a length of hospital stay of 14 days or less. The median (IQR) for length of hospital stay was 11 (7-17) days.

Table 8: Outcome of Patients

Outcome	**Frequency (%) n=276**
Alive	237 (85.9)
Died	39 (14.1)
Length of stay	**Frequency (%) n=276**
≤14 days	185 (67.0)
>14 days	91 (33.0)

4.10 Association between management outcome of patients with suspected acute bacterial meningitis

The Chi square test was used to determine the association between the management and outcome of patients with acute bacterial meningitis. This was an exploratory inferential analysis. It was found that patients who were discharged alive were more likely to have been managed correctly, although this was not statistically significant [OR 1.5, 95% CI (0.7-3.1), p-value 0.341]. Patients who stayed in hospital for 14 days or less were more likely to have received correct management as compared to those who stayed longer. This was also not statistically significant [OR 1.1, 95% CI (0.6-1.8), p-value 0.925].

Table 9: Association between management and outcome

		Correct Management	**Incorrect Management**	**Total**	**p-value**	**OR (95%CI)**
Outcome	Alive	79 (88.8)	158 (84.5)	237 (85.9)	0.341	1.5 (0.7-3.1)
	Died	10 (11.2)	29 (15.5)	38 (14.1)		
Length of hospital stay	≤14 days	60 (67.4)	125 (66.8)	185 (67.0)	0.925	1.1 (0.6-1.8)
	>14 days	29 (32.6)	62 (33.2)	91 (33.0)		

CHAPTER FIVE
DISCUSSION, CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

5.1 Discussion

Following this study, it was found that a third of children were correctly managed for suspected ABM. This included patients who were correctly assessed in terms of documentation of clinical features of suspected ABM, followed by performance of a lumbar puncture, then administering of the recommended empirical antibiotic which is ceftriaxone. The in-hospital mortality was found to be 14.1%, while the median length of stay was 11 days.

The children who were included in this study were aged between 2 months and 5 years and it was noted that most of them were below 2 years. This is comparable to a study done in Kilifi in 2002 to determine the effectiveness of vaccines on the reduction of meningitis, whereby the prevalence of meningitis was found to be higher in children less than 2years.(6)

The clinical features which were used in the study to classify patients as having suspected acute bacterial meningitis were derived from the guidelines in the basic paediatrics protocols. To be included in the study, the patient had to have fever or elevated temperature of above 37.5^0C and any of the following: coma or decreased level of consciousness, inability to drink/feed, bulging fontanelle, convulsions, irritability.(34) These clinical features are similar to those found in other conditions such as encephalitis and cerebral malaria. A study by Gichina (2010) focused on encephalitis in children, and similar clinical features were used for the case definition as those used in this study including fever, seizures and altered consciousness.(33) However, this study focused on the care for suspected acute bacterial meningitis and not on the other conditions presenting in a similar way.

A lumbar puncture is recommended in the guidelines once a patient has features suggestive of suspected acute bacterial meningitis. In this study, only 99 (35.9%) patients had a lumber puncture done. This proportion was quite low compared to a study by Turel et al (2014) which assessed if treatment of ABM was evidence based in Turkey, and 87% of the patients had CSF studies done.(38) The guidelines state contraindications to doing a lumber puncture. These include: if a patient requires cardiopulmonary resuscitation, has poor pupil response to light or a skin infection at the LP site. However, this study was retrospective and dependent

on documentation of the clinician, therefore, the reason for not performing an LP was not readily available. The study did not include taking of an inventory of equipment required for a lumbar puncture, therefore the lack of equipment could not be excluded as a reason for not doing the procedure.

In terms of the assessment of patients with features of suspected ABM, documentation of clinical features ranged from97.5% to 100%. Level of consciousness and presence/ absence of convulsions were documented for all patients, while presence or absence of bulging fontanelle was the least documented feature. The most common clinical feature at admission was fever 99.3% and inability to drink/feed 95.7%. The least common clinical feature was a bulging fontanelle which only occurred in 4 (1.4%) of the patients. Only 96 (34.8%) patients were diagnosed by the clinicians as having suspected acute bacterial meningitis on admission, despite all patients in the study having features of the disease. Other diagnoses which were made included pneumonia (53.5%), malaria (5.1%), among others. The reason for the missed diagnosis of suspected ABM may have been that the clinical presentation of suspected ABM is similar to that of other conditions including encephalitis, as seen in the study by Gichina (2010).(33)

Ceftriaxone which is the drug of choice for suspected acute bacterial meningitis was given to only 118 (42.8%) patients with features of suspected ABM on admission. This was low compared to the study by Turel (2014), whereby 90% of 283 patients being managed for ABM were given a 3rd generation cephalosporin.(38) The proportion was also low compared to a study by Gathara et al (2014) where treatment recommendations were followed in 74% of malaria cases, but higher compared to malnutrition treatment where only 25% of the cases received recommended treatment.(21)

This study however did not look at subsequent change or duration of treatment during the hospital stay since the focus was on the initial management on admission. It would have however been important to do this in order to give more insight on patient outcomes. The format of this study was similar to a study by Opondo et al (2016), whereby he developed the paediatric admission quality of care (PAQC) score based on the process of care at admission. The study used various domains such as assessment of patients, diagnosis and initial treatment to come up with an overall quality of care score for 3 main diseases affecting children.(31)

The proportion of patients who were correctly managed in this study was found to be 32.2%. This proportion included those who were assessed correctly, had a lumbar puncture performed and were treated using ceftriaxone. This proportion was high compared to a study by Lo Vecchio et al (2014) in Italy, whereby only 20.6% of hospitalized children with acute diarrhea were managed in full compliance with guidelines.(23) It was also higher compared to a study by Otido (2013) in Garissa Provincial General Hospital, where out of 136 neonatal resuscitations, only 26.5% were performed according to the guidelines.(27) However, considering the seriousness of the suspected ABM and the morbidity and mortality caused by it, this proportion was of correctly managed patients was low.

On univariate analysis, it was found that patients with convulsions were more likely to be correctly managed OR 546.4 (CI, 155.7-1917.3). Those with stiff neck were also more likely to be correctly managed OR 94.8 (CI 36.7-245.2).

The outcome of patients with acute bacterial meningitis was reported in terms of in-hospital mortality and length of hospital stay. Outcome in terms of neurological function of those who survived was not assessed in this study, but a previous study by Nyillok (2014) assessed this.(10) The proportion of patients who died was 14.1%. This proportion was high compared to the mortality of 5-10% reported in children with acute bacterial meningitis in developing countries but low compared to the case fatality rate of 20- 30%.(1,8,9) This could not be attributed to the quality of care noted in this study whereby only 32.2% of patients with suspected ABM were correctly managed, since this outcome may have been out of chance as shown by the p value of 0.341.

In terms of length of hospital stay, the majority of patients 185 (67%) stayed in hospital for 14 days or less. The median length of stay was 11 days, which is expected since the length of treatment for acute bacterial meningitis is 10 to 14 days. It was found that patients who were discharged alive were 1.5 times more likely to have been managed correctly, although this was not statistically significant.

5.2 Limitations

1. This study did not include taking of an inventory to determine if all the required equipment and antibiotics were available to facilitate proper management of patients with ABM.
2. Being a retrospective study, extraction of information was highly dependent on documentation therefore information on reasons for not following the correct procedure could not be obtained.
3. The study focused on the management of suspected ABM and therefore information about the management of other conditions with a similar presentation was not explored.

5.3 Conclusion

1. Patients who were correctly managed for suspected ABM were 32.2% of the study subjects.

2. Patients who had a lumbar puncture done were 35.9%, while those who received ceftriaxone once ABM was suspected were 42.8%.

3. Patients who died while receiving treatment were 14.1%, while the median (IQR) for length of stay was 11 (7-17) days.

5.4 Recommendations

1. Use of evidence-based guidelines in management of patients with suspected ABM should be enforced to the health workers in order to improve the outcomes.
2. A follow up qualitative study should be done to evaluate reasons why some of the procedures for management of suspected ABM were not being followed.

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APPENDICES

Appendix I: Time frame

the study was carried out during the following period:

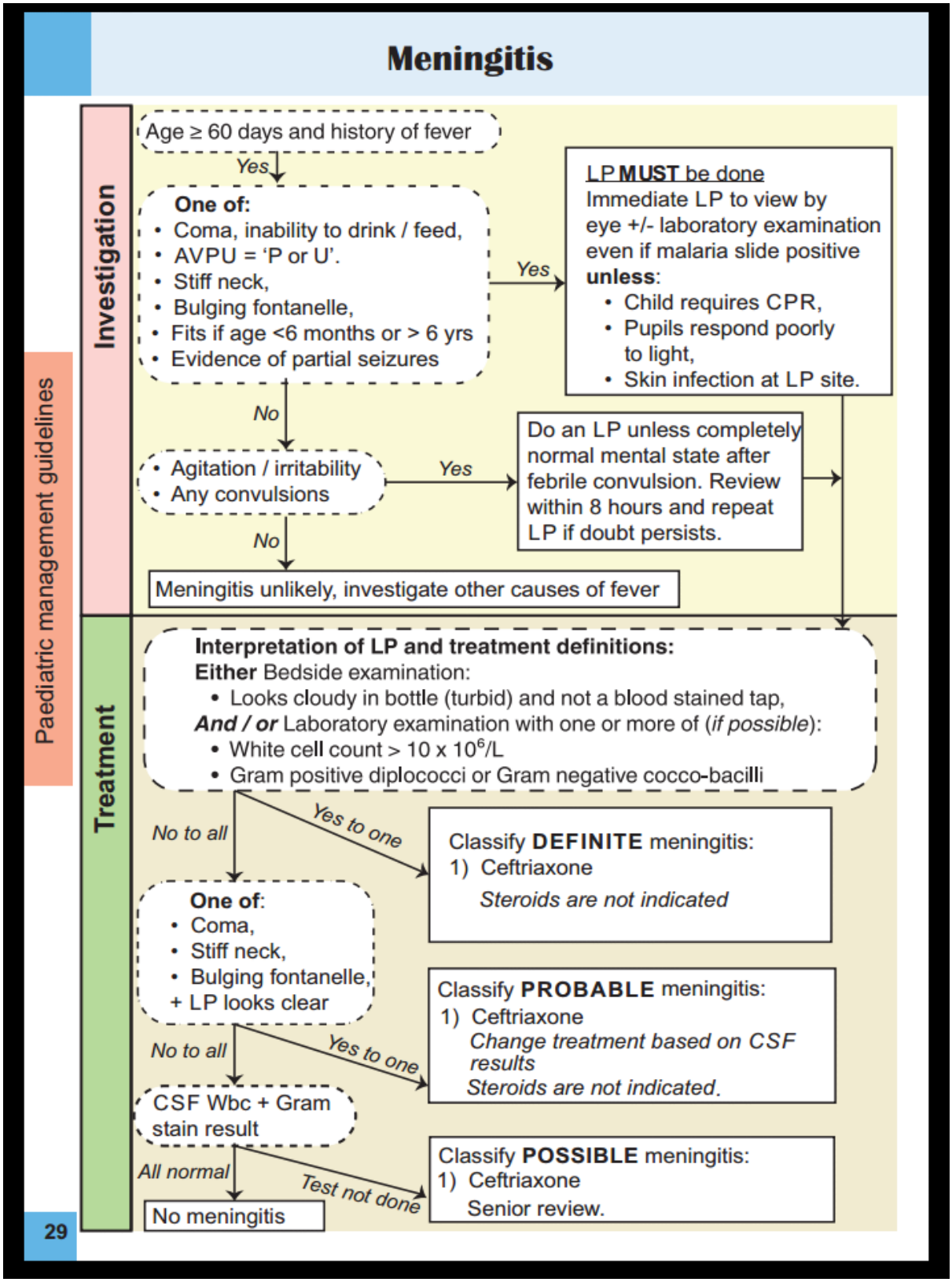
	Activity	Estimated Time
1.	Development of Proposal and presentation	January to July 2018
2.	Proposal Submission for ethical approval	July 2018
3.	Proposal corrections	September to November 2018
4.	Obtaining permission from KNH administration	November 2018
5.	Data Collection	December 2018 to January 2019
6.	Data Analysis	February 2019
7.	Thesis Writing	February to March 2019
8.	Results Presentation	April 2019
9.	Thesis Submission	May 2019

Appendix II: Budget

For this study, the budget catered for the initial proposal development, data collection with the help of a research assistant, data analysis done with the assistance of a statistician and development of the final thesis. The estimated budget for the study was therefore as follows:

ITEM	QUANTITY	UNIT PRICE	TOTAL
Proposal copies	185 pages	5	925
Proposal binding	5 books	150	750
Data extraction forms	850 pages	5	4250
Research assistant	2	10000	20000
Statistician	1	35000	35000
Poster printing	1	3000	3000
Thesis drafts	100 pages	5	500
Thesis draft binding	2 books	150	300
Final booklet	1	5000	5000
Miscellaneous			10000
Total			79,725

Appendix III: Protocol for diagnosis and management of acute bacterial meningitis



Appendix IV: Data Extraction Form

Serial Number				Age		Yrs	Mths
Adm Date	/ / 20	Wt (kg)		Ht (cm)		WHZ	
Sex	M / F / E	Temp (^{0}C)		Vaccines	*PCV10 X...../E*	*M'sles* Y / N / E	*DTP/ Penta X...../E*

History			
Length of illness	Days		
Fever	Y		E
Cough	Y	N	E
Cough > 3 weeks	Y	N	E
Difficulty breathing	Y	N	E
[redacted]			
Diarrhoea	Y		E
Diarrhoea > 14d	Y	N	E
Diarrhoea bloody	Y	N	E
Convulsions	Y	N	E
If yes, no of fits			
Partial / focal fits?	Y	N	E

Examination						
Airway	Clear	Stridor	Needs active support to open	E		
Breathing	Respiratory Rate	/min / E				
	Oxygen saturation	_ _ % SpO2				
	Central Cyanosis	Y	N	E		
	Indrawing	Y	N	E		
	Grunting	Y	N	E		
	Acidotic breathing	Y	N	E		
	Wheeze	Y	N	E		
	Crackles	Y	N	E		
Circulation	Pulse	Weak	Norm	E	/min	
	Cap Refill	X	<2	2-3	>3	E
	Skin temp	Not cold	hand	forearm	elbow	E
	Pallor / Anaemia	0	+	++ +	E	
Dehydration	Sunken eyes	Y	N	E		
	Skin pinch (sec)	0	1	2	E	
Disability	AVPU	A	V	P	U	E
	Can drink / breastfeed?	Y	N	E		
	Bulging fontanelle	Y	N	E		
	Stiff neck	Y	N	E		

					General / Nutrition	Jaundice	0	+	++ +	E
Difficulty feeding	Y	N	E			Visible severe wasting			Y	N	E
						Oedema	none	foo t	knee	face	E

Admission Diagnoses			
Malaria	□ Severe □ Non-sev□ No classif'n	*Anaemia*	□ Sev □ Non-sev
Pneumonia	□ V. Sev □ Sev□ Non-sev	*Meningitis*	
Diarrhoea	□ Non-bloody□ Bloody		
Dehydration	□ Shock□ Sev□ Some □ No classif'n		
HIV / AIDS	□ previous diagnosis□ Clinical suspicion		
Malnutrition	□ Kwash□ Marasm□ M. Kwash		
Other 1			

Investigations ordered			
	Ordered?	Results documented on same day	Result (give units)
Malaria Slide	Y / N	Y / N / E	**Pos / Neg**
Hb / HCT / PCV	Y / N	Y / N / E	
HIV test	Y / N	Y / N / E	**Pos / Neg**
Glucose	Y / N	Y / N / E	
Lumbar Puncture	Y / N	Y / N / E (microscopy)	**Pos / Neg**
Other tests			

Treatment – Record only the initial treatment prescribed for the admission episode						
	Was drug prescribed?	Drug prescription				
		Route	Dose	Units	Freq	Days

Antibiotics						
Penicillin	Yes / No	iv /im		mg /iu		
Gentamicin	Yes / No	iv /im		Mg		
Amoxicillin	Yes / No	po		mg / mls / tabs		
Ceftriaxone	Yes / No	iv /im		mg / mls / tabs		
Meropenem	Yes / No	iv /im				
Other						
Supportive Care						
Paracetamol	Yes / No	im / po		mg / mls / tabs		
Others						

Discharge information

Is there a discharge/Death summary in the case record? Y ☐ N ☐			
Discharge Date	/ /201	Outcome	Alive / Dead / Refer'd / Absc'd