AUDIT OF QUALITY OF NEONATAL SEPSIS CARE AT KENYATTA NATIONAL HOSPITAL GENERAL PAEDIATRIC WARDS.

DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS OF THE UNIVERSITY OF NAIROBI FOR AWARD OF THE DEGREE OF MASTER OF MEDICINE IN PAEDIATRICS AND CHILD HEALTH.

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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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ABBREVIATIONS.

BPM……Breaths per minute

EBM……Expressed Breast Milk

ETAT+……Emergency Triage Assessment Treatment plus Admission

KNH……...Kenyatta National Hospital

MDG……...Millennium Development Goal

NGT……Nasogastric Tube

NNS……Neonatal Sepsis

WHO……...World Health Organization

DEFINITION OF TERMS.

Neonate: An individual of age between birth and one month.

Neonatal Sepsis: Clinical syndrome characterized by signs and symptoms of infection with or without accompanying bacteremia in the first month of life.

Neonatal Mortality Rate: The probability of dying within the first month of life expressed per 1000 live births.

Quality assessment: It is a continuous process of evaluating processes and procedures in healthcare delivery and support functions and seeking improvements in efficiency, cost-effective care and patient satisfaction.

Clinical audit: Thesystematic and critical analysis of the quality of clinical care

Audit Criteria: are defined as measureable statements about health care that describe its quality and can be used to asses it.

ABSTRACT.

Background: Neonatal sepsis is a major contributor to neonatal deaths, accounting for about 26% of all neonatal deaths in Africa. Studies have shown that clinical outcome for specific conditions, including the risk of death, are correlated with quality of hospital care. Clinical practice guidelines for childhood illnesses, including neonatal sepsis in Kenya are contained in the Ministry of Health Basic Paediatric Protocols. These have been disseminated through Emergency Triage, Assessment and Treatment plus Admission (ETAT+) course since 2007.

Objectives: The study set to assess the process of clinical care given to neonates admitted at Kenyatta National Hospital general paediatric wards with a diagnosis of sepsis and to determine the factors associated with mortality.

Methodology: This was a hospital based descriptive study involving review of medical records of neonates admitted with the diagnosis of neonatal sepsis at the Kenyatta National Hospital general paediatric wards between January 2011 and December 2011. A total of 385 medical records were evaluated. Data were collected by use of an assessment tool and entered into preformed access spreadsheets and analyzed using statistical package for social sciences (SPSS).

Results: Assessment was done based on three domains of care. Total documentation score was 16 (IQR 14-17), recommended first line antibiotic treatment for neonatal sepsis was given in 64.4% and supportive care given at admission was good. Mortality rate was 5.5% with 52.4% deaths occurring within the first 48 hours of admission. Neonates with no change in level of activity, no difficulty breastfeeding and who had no grunting were at a lower risk of dying.

Conclusion: Documentation of some aspects of neonatal history was good, antibiotic choice was good though there were dosing errors and initial supportive care was good though monitoring of vital signs was poor. Mortality was significantly associated with short duration of hospital stay, change in level of activity, difficulty breastfeeding and grunting.

1. BACKGROUND AND LITERATURE REVIEW.

1.1 BACKGROUND.

Globally in 2010, the neonatal mortality was at 3.1 million. Among these, about one third was due to infections. According to World Health Organization (WHO), neonatal deaths account for about 40% of all under-five deaths. The overall neonatal mortality has been declining worldwide. The number decreased from 4.4 million in 1990 to 3.1 million in 2010. There was also a 28% reduction in neonatal mortality rates (NMRs) over the same period, from an estimated 32 deaths per 1000 live births to 23 deaths per 1000 live births. [1]

While neonatal mortality rates were halved in the European and Western Pacific regions, the reduction observed in the African region was only 19%. Nearly 70% of all neonatal deaths were concentrated in just two regions of the world: the African Region and South-East Asia. The vast majority (nearly 99%) of deaths occurred in low and middle-income countries. The risk of a newborn baby dying in low-income countries is about 8 times higher than that of a newborn from a high-income setting. In Africa, the main direct causes of neonatal death are estimated to be preterm birth (28%), sepsis, pneumonia (26%), and intra-partum related (23%). Neonatal tetanus accounts for a smaller proportion of deaths (7%), but is easily preventable. Low birth weight is an important indirect cause of death. [2]

A hospital based cross-sectional study on neonatal sepsis at Muhimbili National Hospital, Dar es Salaam, Tanzania that focused on the etiology, antimicrobial sensitivity pattern and clinical outcome of neonates with sepsis, the overall neonatal mortality was 13.9% (46/330), being higher in neonates with sepsis (24%) as compared to those without (10%).[3]

In Kenya 1 out of 19 children born die before their first birthday with 60% of these deaths occurring before one month of age. According to the Kenya Demographic Health Survey (KDHS) 2008/2009, there has been a marginal decrease in the neonatal mortality rate from 35 per 1000 live births between 1999 and 2003 to 31 per 1000 live births between 2004 and 2008. [4]

A systematic review published in the Lancet series on global, regional, and national causes of child mortality in 2008, the neonatal mortality rate in Kenya was 26.5% with birth asphyxia accounting for 29.1%, pre-term delivery 28.8%, and sepsis 22.9% of the NMR. [5]

In a study done at Kenyatta National Hospital of 308 neonates admitted in general paediatric wards conducted between January and December 2000, to determine the morbidity and mortality predictors among neonates, the commonest diagnosis at admission or discharge was neonatal sepsis at 71% (219) neonates. Sepsis accounted for 37% of neonatal mortality.Other causes of mortality were apneic attacks (74%), hypothermia (74%) and low birth weight (57%).[6]

The United Nations' Millennium Development Goal (MDG) 4 of reducing mortality rate among under-five children by two-thirds from 1990 levels by 2015 cannot be realized without enhanced efforts towards improving neonatal care. Prompt diagnosis, laboratory work up, treatment and follow up of neonates with sepsis in KNH will go a long way towards achieving MDG 4.[7]

1.2 DIAGNOSIS OF NEONATAL SEPSIS.

Neonatal sepsis is a clinical syndrome characterized by signs and symptoms of infection with or without accompanying bacteremia in the first month of life. It encompasses various systemic infections of the newborn such as septicemia, meningitis, pneumonia, arthritis, osteomyelitis, and urinary tract infections. Superficial infections such as conjunctivitis, skin and oral thrush are not usually included under neonatal sepsis. Neonatal sepsis can be classified as either early (from birth to 7 days) or late (after 7 days). [8]

In a literature review and reanalysis of published data of risk factors for early-onset Group B streptococcal sepsis, the most predictive maternal factors for NNS were vaginal colonization with Group Bstreptococcus (GBS) at birth, chorioamnionitis, prolonged rupture of Membranes (PROM) more than 18 hours and intra partum maternal fever > 37.5^0C. Neonatal factors were birth weight <2.5 kg, gestational age <37 weeks and an affected twin or sibling.In this study, group B streptococcal (GBS) positive vaginal culture at delivery had an odds ratio (OR) of 15.4, birth weight < 2500 g (OR 7.37), gestation <37 weeks (OR 4.83), prolonged rupture of membranes (PROM) >18 hours (OR 7.28), intra partum fever >37.5°C (OR 4.05). Chorioamnionitis was reported in most (88%) cases in which neonatal infection occurred despite intra partum maternal antibiotic therapy. Findings of a sibling or twin was seen to be associated with a very high risk of sepsis.[9]

A systematic review on what clinical signs best identify severe illness in young infants aged 0-59 days in developing countries identified history of feeding difficulty, history of convulsions,

temperature (axillary)≥37.5°C or <35.5°C, change in level of activity, fast breathing/respiratory rate ≥60 breaths per minute (bpm), severe chest in drawing, grunting and central cyanosis.[10] In a large WHO multi-center study involving 6 countries, the presence of any one sign or symptom had a sensitivity of 85% and a specificity of 75% in neonates aged 0–6 days. In infants aged 7–59 days any one of these sign or symptom had a sensitivity of 74% and a specificity of 75%.[11.] In one Kenyan study, the presence of any one of these sign or symptom was 94% sensitive and 40% specific for severe disease in neonates 0-6 days and 97% sensitive and 56% specific for very severe disease for infants 7-59 days.[12]. In the grading recommendations, assessment, development and evaluation (GRADE) summary combining quality of evidence and summary of findings, these clinical sign or symptom were classified as moderate or high quality evidence alone or in combination. History of feeding difficulty, history of convulsions, temperature (axillary) ≥37.5°C or <35.5°C, change in level of activity and central cyanosis each were classified as high quality evidence. Fast breathing/respiratory rate ≥60 breaths per minute (bpm), severe chest in drawing and grunting each were classified as moderate quality evidence. [13]

Laboratory studies used to evaluate neonatal sepsis include white cell counts including immature to total lymphocyte count, blood cultures and rapid tests such as C reactive protein (as available) done. Additional tests include lumbar puncture if neonate has change in level of activity, bulging fontanel, history of convulsions or feeding difficulty, other body fluids cultures (as clinically indicated) and radiology (specific organ disease).Other tests that can be used include polymerase chain reaction (PCR), cell surface markers, interleukins and direct antigen detection.[11]

In KNH, the locally adapted clinical guidelines, the Ministry of Health Basic Paediatric Protocols (last revised in September 2010) and the WHO Pocket Book of Hospital Care for Children are widely available. These books are issued to all post graduate students in paediatrics and all undergraduate medical students rotating in the department of paediatrics, who also undergo a five day course for dissemination of these guidelines. The Basic Paediatric Protocol provides guidance in assessment of a sick neonate, illness classification and treatment. It provides guidance on choice of antibiotics and dosage, intravenous fluid and oxygen therapy[16]. The WHO pocket book of hospital care for children and the Basic Paediatric Protocols recommend the use of penicillin and gentamicin as the first line of treatment. Feeds should be maintained per oral or nasogastric tube (NGT). Intravenous fluids should be used only if

respiratory distress or severe abdominal distention. The feeds and fluids should be given at the correct amount and frequency.[14]

1.3 QUALITY OF HOSPITAL CARE.

Quality of hospital care could be significantly improved if knowledge gained from health research is better translated into practice. Previous studies have shown that adherence to such evidence based guidelines is associated with improved health outcomes amongst them reducing the risk of death. Despite the considerable efforts in developing and implementing evidence based guidelines, only a modest impact has been found on clinical practice.Further, the research knowledge has been slow to influence practice or to bridge the know-do gap and a wide range of factors affect the actual ability to improve care[15]

In an effort to improve quality of care of the seriously sick child, the Ministry of Health, Kenya, in collaboration with stakeholders developed and introduced basic paediatricprotocols[1]. The Basic paediatricprotocols were developed based on the best available evidence through literature searches and evidence summaries which were undertaken for all the identified conditions with the exception of infant and child resuscitation. These were undertaken according to the methods suggested by the international child health review collaboration. The protocols are intended to assist the health care provider in evidence based decision making and promote the provision of optimal care in the first 48 hour of hospital admission. These protocols focus on the management of the six common causes of mortality in Kenya, among them neonatal related conditions. They provide guidance on assessment, classification and treatment; both specific and supportive. A five day course, branded as Emergency Triage Assessment and Treatment Plus admission care (ETAT +) was also developed for dissemination of the protocols. The basic paediatricprotocols and the ETAT+ though developed for district hospitals have been embraced in the county and national teaching and referral hospitals in Kenya including Kenyatta National Hospital[12].

1.4 ASSESSMENT OF QUALITY OF CARE.

Pillars of Quality of care include, structure,processand outcome of care[19]. The Donabedian, assessment of care involves assessment of outcome in terms of recovery, restoration and of survival, which has been frequently used as an indicator of the care given. Although outcomes may indicate good or bad care in the aggregate, they do not give an insight into the nature and location of the deficiencies or strengths to which an outcome may be attributed to. Many factors

other than medical care may influence outcome, and precautions must be taken to hold all significant factors other than medical care constant if valid conclusions are to be drawn[16]. Further, basing an assessment on a reduction of paediatric mortality in hospitals in resource limited settings and particularly in Kenya is found to be problematic. There are confounding factors such as, poor recording of deaths that have occurred which give a false picture of the mortality in the health facility. However, if the data management or information systems improve during a study, there may be an increase in recorded mortality. Variation in the severity of disease at presentation may influence mortality. An intervention in a health facility may change outcomes such as mortality.[17]

Another approach to assessment is to examine the process of care itself, rather than its outcomes. This is justified by the assumption that one is interested not in the power of medical technology to achieve results, but in whether what is known to be "good" medical care has been applied. This will be more relevant to the question at hand; whether medicine is properly practiced, in this case whether neonatal sepsis management is per the neonatal sepsis case management guidelines available. This is illustrated in the Ministry of Health Republic of Kenya Basic Paediatric Protocols.Evidence based best practises have been associated with improved outcomes.

A qualitative study was done by Nolan *et al* in 2001 assessing quality of hospital care for seriously ill children in seven less-developed countries in 13 district hospitals and 8 teaching hospitals. 131 newborn records were assessed. Inadequate initial assessment was noted in 41% records, inappropriate antibiotics, feeds or fluids in 61% records, delay in giving appropriate treatment in 18% records and inadequate monitoring 30% records[14].

A two year descriptive study was done in Kenya in 2011 by Gathara*et al* to assess quality of hospital care for sick newborns and severely malnourished children. A total 189 newborn records were assessed. The study showed documentation for neonatal admissions was often very poor at baseline with case records often entirely missing (median assessment score 2/28), inadequate and incorrect prescribing of penicillin and gentamicin were common at baseline (median assessment score 3/28) and prescribing essential feeds appeared almost universally inadequate at baseline.[13]

2. STUDY JUSTIFICATION AND UTILITY.

Globally, 4 million (36%) children die within the neonatal period.[1] Neonatal sepsis contributes 26% of these neonatal deaths[2]. Every year about 46,500 Kenya newborns die. This is as a result of infections (30%), asphyxia (27%) and prematurity (26%).[3] Addressing newborn health is one of the key strategies in reaching Millennium Development Goal 4 (Reduce by two thirds, between 1990 and 2015, the under-five mortality rate).[4] A 50% reduction in neonatal mortality per decade is required in order to achieve this. Reducing the neonatal mortality rate as a result of sepsis will lead to a significant decrease in the neonatal mortality and thus the overall under 5 mortality.[5] Quality of neonatal sepsis care could be significantly improved if knowledge gained from health research is better translated into practice.[8] Previous studies have shown that adherence to such evidence-based guidelines is associated with improved health outcomes, amongst them reducing the risk of death.[9] To reduce neonatal mortality resulting from sepsis, it is important to assess the quality of neonatal sepsis care and information gathered will help in improving quality of neonatal sepsis care and informing process.

4.0 OBJECTIVES

4.1 Primary Objective:

To assess the process of clinical care given to neonates admitted with the diagnosis of sepsis at the Kenyatta National Hospital general paediatric wards.

4.2 Secondary Objective:

To determine factors associated with mortality outcome of neonates admitted with the diagnosis of sepsis at the Kenyatta National Hospital general paediatric wards.

5.0 METHODOLOGY

5.1 Study design:

The study was a descriptive study employing review of health records of neonates with an admission diagnosis of sepsis in KNH general paediatric wards.

5.2 Study period:

The study period run for 3 months between September and November 2013.

5.3 Study site:

The study was conducted in Kenyatta National Hospitalgeneral paediatric wards. KNH is a level six hospital, and the national referral hospital in Kenya. Neonates admitted into KNH are admitted either in the New Born Unit (NBU) or in the general paediatric wards. The NBU admits neonates delivered within KNH maternity unit, neonates delivered at another facility or neonates referred from another facility newborn unit. These neonates have several co morbidities that may mimic clinical signs and symptoms of neonatal sepsis, for example, respiratory distress syndrome, meconium aspiration syndrome, prematurity, jaundice, and necrotizing enterocolitis. The newborn unit also has a newborn intensive care unit, which has a capacity of four beds, where the very sick neonates who require mechanical ventilation are admitted. Due to these

several co morbid condition that present in the same way as neonatal sepsis, it is challenging to make a diagnosis of neonatal sepsis as the only primary diagnosis.

The general wards admit children up to the age of 12 years. There are four general wards each with a bed capacity of 60, thought bed occupancy is usually over 100%. Regarding neonates admissions the general wards admit mainly sick neonates who are born at home or who were born in hospital and discharged home. These neonates should weigh more than 1800g and more than 36 weeks gestation. Each ward has a cubical with a capacity of 2 beds (for adults)that are equipped with a radiant heater and oxygen points set aside for the neonates. All admissions are initially reviewed at the Paediatric Emergency Unit before being admitted into the wards. The very sick ones are admitted into the acute room, whereas the others are admitted into the neonatal room. Assessment of care involved the first review done in the ward.

In the year 2010 between January and December, there were a total number of 1556 neonates admitted with a diagnosis of sepsis in the general wards. There were a total number of 255 mortalities due to neonatal sepsis. The mortality rate was 16.4%. [20]

5.4 Study population:

Health records of neonates admitted with a diagnosis of sepsis in the general paediatric wards between January 2011 and December 2011.

5.4.1 Inclusion criteria:

1. All neonate records with an admission diagnosis of sepsis, neonatal infection, bacterial sepsis at KNH general paediatric wards.

5.4.2 Exclusion criteria:

1. Neonate records whose diagnosis of neonatal sepsis was not made at admission.
2. Neonate records referred from another facility with a diagnosis of NNS who had been admitted for more than 24 hours in the referring health facility.
3. Neonate records with other co-morbid conditions such as congenital anomalies, cardiac disease, renal disease, endocrine disease, and jaundice.

5.5 Sample size:

Sample size calculation was based on the primary objective which was to assess process of care of neonates admitted at KNH with a diagnosis of neonatal sepsis.

The calculation is as follows using Fisher's formula:

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

Where: n is the sample size.

Z is statistic for sample size-1.96.

P is the expected proportion of neonates with sepsis.

D is the precision- 5 % (0.05).

$$n = \frac{(1.96)^2\ 0.5\ (1-0.5)}{0.05^2}$$

= 385

5.6 Study procedure.

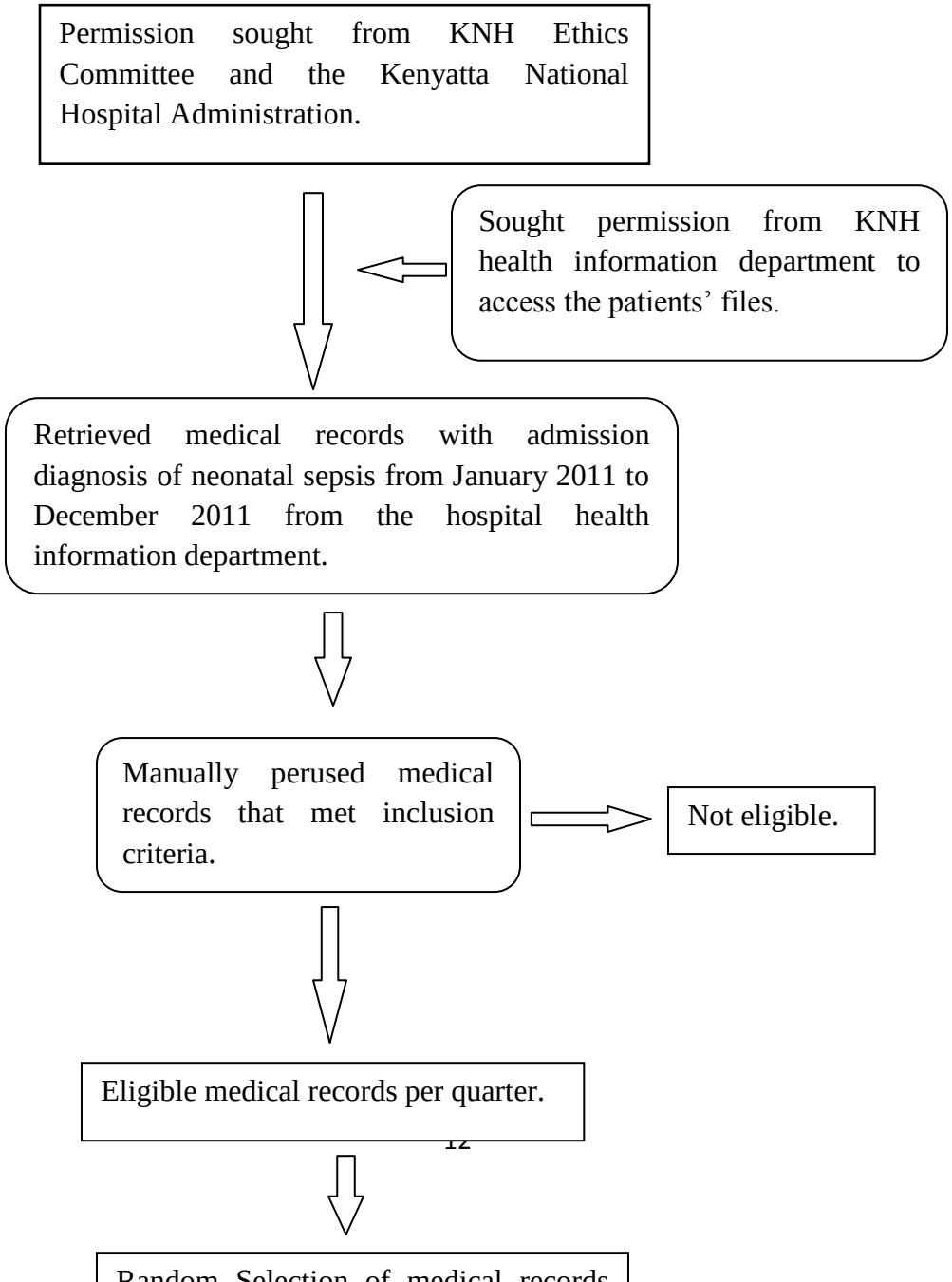
The study was carried out by the principal investigator and trained research assistants.

5.6.1 Record management.

Request for access of patient files was done at the coding and indexing office located in the health information department. Retrieval of the patient files was done by a member of staff in this office. The staff member only retrieved the patient files the principle investigator and trained research assistants requested at the time they presented themselves at the health information department. The list given had the total number of neonates admitted between January and December 2011. The data were entered chronologically based on the date of admission. Once the files were retrieved, data collection was done within the health information department. The principal investigator and the research assistants were not allowed to leave the reading room with any patient's file. This reading room acted as a temporary storage for the retrieved files. Once data collection was complete, a member of staff would come into the reading room and confirm that all the patient files provided were available and in good condition and that no patient information other than that in the assessment tool had been obtained. He or she would then collect the files for re-filling before issuing other patient files.

Medical records of the neonates admitted between January 2011 and December 2011 and met the inclusion criteria were manually selected. They were sorted by dates of admission grouping them into quarter categories and each record was given a uniqueserial number that was used to make the sampling frame. The files for the study were then selected by using a blind draw or ballot procedure from each quarter until the sample size was achieved. Random selection of the files were stratified per quarter. Every quarter, 96 medical records with a diagnosis of neonatal sepsis, neonatal infection or bacterial sepsis were randomly selected. The agreed process of care was derived from the Ministry of Health, Kenya Basic Paediatric Protocols.

Figure 1: Study flow chart:



5.7 Assessment Tool:

The total patient records reviewed was 385 health record of neonates admitted with sepsis that met the inclusion criteria. The eligible medical records were perused for documentation of maternal and neonatal history, clinical signs examined, laboratory investigations requested, antibiotics prescribed, dosage and frequency, feeds/fluids prescribed, amount and frequency, evidence antibiotics, feeds and fluids as prescribed were given. The information was abstracted and entered in the assessment tool (Appendix 1).

5.8 Data analysis

Data obtained from the assessment tool was entered into preformed Access spreadsheets and analyzed using Statistical Package for Social Sciences (SPSS) computer package. Three main domains of care were analyzed: documentation of neonatal assessment, treatment of neonatal sepsis and supportive care and outcome of care. To evaluate documentation of core clinical signs and symptoms of neonatal illness an assessment score was calculated based on 22 features of neonatal illness including: information on maternal history (n = 6 features) maternal history of fever, vaginal discharge, chorioamnionitis, affected twin or sibling, duration of rupture of membranes and gestational age; neonatal history (n = 4 symptoms) birth weight, change in level of activity, difficulty breastfeeding and abnormal movements or convulsions; neonatal clinical examination (n = 7 signs) temperature, respiratory rate, grunting, cyanosis, ability to breastfeed, severe chest in-drawing and bulging anterior fontanel; and laboratory investigations indicated for neonatal sepsis (n = 5 investigation) complete blood count, immature to total lymphocyte count, blood culture, lumbar puncture and random blood sugar. The score ranged from 0 (documentation completely absent) to 22 (perfect documentation).A univariant analysis was conducted for each variable in the data set and appropriate data statistics reported. Continuous variables were summarised using means (Standard Deviation) and medians (range). Categorical variables were presented as frequency distributions using tables or graphs. The main outcome

was calculated as a binary variable representing the percentage of children managed according to the Basic Paediatric Protocols. The chi square test was used to compare categorical variables across two groups by level of guideline adherence. The students' T test was used for comparison of the means of normally distributed continuous variables.

6.0 ETHICAL CONSIDERATIONS

1. Approval to carry out the study from KNH Ethics and Research Committee.
2. Confidentiality of information obtained from the health records.
3. The data collected were kept in a safe place.
4. Patients were identified by unique study number.

7.0 RESULTS.

Admission and inpatient case records for a total of 385 neonates admitted to KNH with neonatal sepsis over a period of twelve months between January 2011 and December 2011 were reviewed. The retrieval rate of sampled medical records was high (100%) with no variations noted in retrieval rates across the twelve months covered by the study.

Patient characteristics.

Table 1 showscharacteristics of the neonates whose medical records were reviewed. Of the 385 admission, 186 (48.3%) were male and 191 (49.6%) were females giving a male: female ratio of approximately 1:1. The median age was 8 days (IQR 5–14) and 46.8% of the admissions were aged between 1 day and 7 days. Most (85.7%) deliveries were SVD with most newborns reported to have cried at birth (79.2%) and 88.1% of births were hospital deliveries. The median duration of hospital stay (IQR) was 6(4-9) days. The mortality rate of the study population was 5.5%.

Table 1: Characteristics of neonates admitted to KNH with neonatal sepsis.

Characteristic	**Frequency n=385**
Age group	
Less than 7 days	180(46.8%)
8 – 28 days	205(53.2%)
Gender	
Male	186(48.3%)
Female	191(49.6%)
Not documented	8(2.1%)
Place of delivery	
Hospital	339(88.1%)
Home	28(7.3%)
Not documented	18(4.7%)
Mode of delivery	
SVD	330(85.7%)
C/S	45(11.7%)
Not documented	10(2.6%)
APGAR Score	
Cried at birth	305(79.2%)
No cry at birth	25(6.5%)
Not documented	55(14.3%)
Outcome	
Median duration of hospital stay (IQR)	6(4 -9)
Discharge	364(94.5%)
Mortality	21(5.5%)

Domains of care.

Three main domains of care were analyzed: documentation of neonatal assessment, treatment of neonatal sepsis and supportive care and outcome of care.

Domain 1 - Documentation of neonatal assessment.

To evaluate documentation of core clinical signs and symptoms of neonatal illness an assessment score was calculated based on 22 features of neonatal illness including: information on maternal history (n = 6 features), neonatal history (n = 4 symptoms), neonatal clinical examination (n = 7 signs), and laboratory investigations indicated for neonatal sepsis (n = 5 investigation). The score ranged from 0 (documentation completely absent) to 22 (perfect documentation).

Table 2 shows the median (IQR) number of tasks documented.Overall, the median number of tasks documented for neonatal sepsis out of the 22 required tasks was 16 (IQR 14-17), Out of the four areas of documentation, performance was good for neonatal history, laboratory investigations and clinical examination. The median number of features of neonatal illness documented from history was 4 (out of a total of four required features). For laboratory investigations a median of 5 of the six guideline recommended investigations for neonatal sepsis were documented and similarly a median number of 6 out of the 7 features of neonatal illness were documented. Documentation of maternal history was poor (median = 2, IQR 1-2).

Table 2: Median (IQR) number of tasks documented in clinical records of neonatal sepsis admissions to KNH.

Documentation score (range)	**Median score**	**IQR**
Maternal history (0-6)	2	1-2
Neonatal history (0-4)	4	3-4
Clinical examination (0-7)	6	5-7
Laboratory investigations (0-5)	5	5-5
Total documentation score (0-22)	**16**	**14-17**

Table 3 shows documentation of maternal history.For all the six features of maternal history on admission documentation was incomplete in at least one-half of all neonatal sepsis admissions (range 55.3% to 90.9%). The most commonly documented aspect of maternal history was gestational age (5.2% below 37 weeks and 39.5% above 37 weeks) and duration of rupture of membranes (39.7% less than 18 hours and 1.8% with PROM). History of vaginal discharge (present 9.2% and absent 8.3%) and chorionamnionitis (present 1.3% and absent 7.8%) were rarely documented.

Table 3: Documentation of maternal history among neonates admitted to KNH with sepsis.

Characteristic	**Documented**		**Not Documented**
Fever	≥37.5^{0}C	15(3.9%)	330(85.8%)
	<37.5^{0}C	40(10.4%)	
Vaginal Discharge	Present	9(2.3%)	344(89.4%)
	Absent	32(8.3%)	
Chorioamnionitis (foul smelling liquor)	Present	5(1.3%)	350(90.9%)
	Absent	30(7.8%)	
Affected twin or sibling	Yes	6(1.6%)	258(67.0%)
	No	121(31.4%)	
Duration of RoM	<18 hours	153(39.7%)	225(58.4%)
	≥18 hours	7(1.8%)	
Gestational age	≤37 weeks	20(5.2%)	213(55.3%)
	>37 weeks	152(39.5%)	

Table 4 shows documentation of neonatal history. Abnormal movements and birth weight was complete in the case records of 84.9% and 77.9% neonatal admissions, respectively. Of these most neonates were had birth weight>2500g (69.1%) and 77.9% had no abnormal movements or convulsions. Details regarding neonates' activity level and difficulty in feeding were documented in 64.7% and 57.8% of patients with 38.4% presenting with difficulty feeding and 27.3% with change in activity level.

Table 4: Documentation of neonatal history among admissions to KNH with neonatal sepsis

Characteristic	**Documented**		**Not Documented**
Birth weight	<2500g	33(8.6%)	86(22.3%)
	≥2500g	266(69.1%)	
Change in level of activity	Yes	105(27.3%)	136(35.3%)
	No	144(37.4%)	
Difficulty breastfeeding	Yes	148(38.4%)	64(16.7%)
	No	173(44.9%)	
Abnormal movements/convulsions	Yes	27(7.0%)	58(15.1%)
	No	300(77.9%)	

Table 5 shows documentation of neonatal examination findings. Documentation was completed in most case records. Between 10.8% and 47.5% of case records did not contain documentation on whether any one of the seven features of neonatal sepsis was examined or not. Among the signs of neonatal sepsis the presence or absence of grunting, severe chest indrawing, cyanosis and ability to breastfeed were most commonly documented.

Table 5: Documentation of neonatal examination findings among neonates admitted at KNH with neonatal sepsis.

Characteristic	**Documented**		**Not Documented**
Temperature	>37.5^{0}C	193(50.1%)	86(22.3%)
	35.5-37.5^{0}C	96(24.9%)	
	<35.5^{0}C	10(2.6%)	
Respiratory rate	≥60bpm	130(33.8%)	183(47.5%)
	<60bpm	72(18.7%)	
Grunting	Present	32(8.3%)	42(10.9%)
	Absent	311(80.8%)	
Cyanosis	Present	9(2.3%)	49(12.7%)
	Absent	327(85.0%)	
Severe chest in drawing	Present	57(14.8%)	40(10.8%)
	Absent	288(74.8%)	
Ability to breastfeed	Present	246(63.9%)	52(13.5%)

	Absent	87(22.6%)	
Bulging anterior fontanel	Present	6(1.6%)	130(33.8%)
	Absent	249(64.7%)	

The fourth sub-domain for documentation of neonatal illness was investigations for neonatal sepsis. Table 6 shows performance in this sub-domain was better than in the other sub-domains. The most documented investigation was a complete blood count at 98.4%, whereas the least documented was a lumbar puncture at 95.8%. Most case records contained requests for these investigations but reported documentation did not reflect availability of the results of investigations.

Table 6: Documentation of requests for investigations for neonatal sepsis at KNH

Item	**Documented**	**Not Documented**
Complete blood count	379(98.4%)	6(1.6%)
Immature to total lymphocyte count	371(96.4%)	14(3.6%)
Blood culture	378(98.2%)	7(1.8%)
Lumbar puncture	369(95.8%)	16(4.2%)
Random blood sugar	376(97.7%)	9(3.4%)

Domain 2 – Treatment.

Selected treatment procedures were selected for evaluation of the quality of care for neonatal sepsis. These included antibiotic prescribing and dosing practices.

Antibiotic prescription

Guideline recommended first-line treatment for neonatal sepsis is crystalline penicillin and gentamycin administered in combination. Table 7 shows overall antibiotic prescription. Approximately 248(64.4%) of admissions received gentamycin and penicillin and 88 (22.9%) were treated using ceftriaxone and the rest were prescribed crystalline penicillin alone or amikacin and ceftriaxone combination as first line of treatment. Out of the 248 neonates receiving gentamycin and penicillin combination 245 (98.8%) were prescribed the drugs at the correct frequency (i.e. crystalline penicillin given 12 hourly in age less than 7 days and 6 hourly in age more than 7 days; gentamicin given 24 hourly irrespective of age).

Antibiotic dosing

Table 7 shows out of the 248 neonates receiving gentamycin and penicillin combination, 93 (37.5%) had an antibiotic dosing error (i.e. crystalline penicillin dose below 40,000 or above 60,000 IU per kg and gentamicin below 3mg/kg (2.4-3.6mg/kg) in age less than 7 days and less than 2 kg, 5mg/kg (4-6mg/kg) in age less than 7 days and more than 2kg and 7.5mg/kg (6-9 mg/kg) in age more than 7 days irrespective of weight. Ceftriaxone dose is 50mg/kg (maximum dose) given 24 hourly. Most errors in crystalline penicillin and ceftriaxone dosing were

administration of under doses, reported in 28.3% and 46.6% of neonates, respectively. For gentamycin, over dosing was more common than under dosing. This was seen especially in neonates less than 7 days and less than 2kg 104(73.4%) compared to those less than 7 days and more than 2kg 44(31.4%) and those who were more than seven days 56(39.2%).

Table 7: Overall antibiotic prescription.

	Age	Dailydose recommended innational guidelines	Under dose	Correct dose	Overdose
Crystalline penicillin	1-28 days	50,000IU/Kg	70 (28.3%)	155 (62.5%)	15 (6.1%)
Gentamicin	≤7 days <2kg	3mg/kg	10 (7.1%)	26 (18.6%)	104 (74.3%)
	≤7 days ≥2kg	5mg/kg	39 (27.9%)	57 (40.7%)	44 (31.4%)
	>7 days	7.5mg/kg	23(16.4%)	65(46.4%)	56(39.2%)
Ceftriaxone	1-28 days	50mg/kg	41 (46.6%)	31 (35.2%)	7 (8.0%)

Domain 3 - Supportive care.

Table 8 shows supportive care given.A total 248(64.4%) neonates were prescribed for feeds or fluids. Feed were prescribed in 154(62.1%) and fluids in 94(37.9%). 61(40%) of the records documented the type, amount, mode and frequency of feed. 95(61.7%) were prescribed expressed breast milk, 32(2.1%) commercial feeds. The most common route of feeding was through the nasogastric tube 149(90.7%) compared to cup and spoon at 14(9.3%).

Neonates whose fluids were prescribed, 23(24.4%) had the type, amount and frequency of fluid documented. The most commonly prescribed fluid type was 10% dextrose 45(47.9%) whereas the least fluid prescribed was half strength darrow's/5% dextrose at 4(4.7%). Other fluids prescribed were half strength darrows 5(5.3%), normal saline 27(28.7%) and ringer's lactate 13(13.8%).

A total 337(87.5%) records had a vital signs chart. Of these, temperature at admission was recorded in 304(90.4%), respiratory rate and pulse rate in 264(78.4%). Only 16% of the records had vital signs recorded every 6 hourly within the first 24 hours of admission.

Table 8: Supportive care.

Item	**Recorded**	**Not recorded**
Feeds	60(40%)	90(60%)
Fluids	21(24.4%)	64(75.6%)

Temperature	305(90.4%)	32(9.6%)
Respiratory rate	264(78.4%)	73(21.6%)
Pulse rate	264(78.4%)	73(21.6%)

Domain 4 - Outcome of care.

Twenty-one (5.5%, 95% CI 3.2-7.7%) deaths occurred during hospitalization among admissions with neonatal sepsis and the median (IQR) duration of in-patient stay was 6 days (4-9). Outcome of admission was significantly associated with length of hospital stay ($p < 0.001$) with most deaths occurring earlier during admission (median length of stay = 2 days [IQR = 1-4]). There were no significant differences in the characteristics of neonates with sepsis who died during hospitalisation and those who were discharged alive with regards to: age ($p = 0.611$), place of delivery (health facility versus home deliveries, 5 versus 10.7%, respectively; $p = 0.213$), or mode of delivery ($p = 0.314$). The odds of neonatal in-patient death were not significantly different in neonate with positive maternal history of PROM ($p = 0.165$) or chorioamnionitis ($p = 0.652$). There were no deaths among neonates with gestation age < 37 weeks and there were 4 (2.6%) deaths in neonates with a gestation age > 37 weeks. Neonates with no history of changes in activity level ($p = 0.004$) or difficulty breastfeeding ($p = 0.002$) were at lower risk of in-patient death compared to admissions with positive history for these signs of severe illness. Absence of grunting on physical examination was associated with lower risk of death ($p = 0.026$), while cyanosis, cheat in-drawing and inability to breastfeed were not significant predictors of in-patient mortality.

Factors associated with mortality.

Neonatal admission information.

Table 9 shows the associations between neonatal characteristics and outcomes of neonates admitted at KNH. There were no significant differences in the characteristics of neonates with sepsis who died during hospitalisation and those who were discharged alive with regards to: age (p = 0.611), place of delivery (health facility versus home deliveries, 5 versus 10.7%, respectively; p = 0.213), or mode of delivery (p = 0.314).

Table 9: Neonatal characteristics and outcome.

	Died			
	Yes	**No**	**OR**	**P value**
Median age in days (IQR)	7(6-10)	9(4-19)	NA	0.611
Place of delivery				
Health facility	17(5.0)	322(95.0)	1.00	
Home	3(10.7)	25(89.3)	2.27	0.213
Not documented	1(5.6)	17(94.4)	1.11	0.919
Mode of delivery				
SVD	20(6.1)	310(93.9)	1.00	
C/S	1(2.2)	44(97.8)	0.35	0.314
Not documented	0(0.0)	10(100.0)	NA	
Cried at birth				
Yes	20(6.6)	285(93.4)	1.00	
No	0(0.0)	25(100.0)	NA	
Not documented	1(1.8)	54(98.2)	0.26	0.198

Maternal history

Table 10 shows the maternal admission information and outcome. The odds of neonatal in-patient death were not significantly different in neonate with positive maternal history of PROM (OR = 0.44, 95%CI 0.05-5.39; p = 0.165) or chorioamnionitis (OR = 0.65, 95%CI 0.19-14.74; p = 0.652). Documentation of gestation age was done in less than one- half of admissions

(44.7%); there were no deaths among neonates with gestation age < 37 weeks and 4 (2.6%) deaths in neonates with a gestation age > 37 weeks.

Table 10: Maternal admission information and outcome.

	Died			
	Yes	**No**	**OR**	**P value**
Chorioamnionitis				
Yes	1(20.0)	4(80.0)	1.00	
No	3(10.0)	27(90.0)	0.44	0.524
Not documented	17(4.9)	333(95.1)	0.20	0.165
Duration of membrane rupture				
<18 hours	14(9.2)	139(90.8)	1.00	
≥18 hours	1(14.3)	6(85.7)	1.65	0.652
Gestation age				
<37 weeks	0(0.0)	20(100.0)	------	N/A
≥37 weeks	4(2.6)	148(97.4)	------	N/A

Neonatal History.

Table 11 shows neonatal symptoms and outcome. Based on admission history, neonates with no history of changes in activity level (p = 0.004) or difficulty breastfeeding (p = 0.002) were at lower risk of in-patient death compared to admissions with positive history for these signs of severe illness. The risk of in-patient death was 78% lower in children with no changes in activity level (OR = 0.22, 95% CI 0.08-0.61) compared to those presenting with changes in activity levels. Similarly the risk of mortality was 86% lower in children with no difficulty in breastfeeding compared to those admitted with difficulty in breastfeeding (OR = 0.14; 95%CI 0.04-0.47).

Table 11: Neonatal symptoms and outcome.

	Died			
	Yes	**No**	**OR**	**P value**
Birth weight				
<2500 grams	1(3.0)	32(97.0)	1.00	
≥2500 grams	14(5.3)	252(94.7)	1.78	0.584
Change in level of activity				
Yes	15(14.3)	90(85.7)	1.00	
No	5(3.5)	139(96.5)	0.22	0.004
Not documented	1(0.7)	135(99.3)	0.04	0.003
Difficulty breastfeeding				
Yes	17(11.5)	131(88.5)	1.00	
No	3(1.7)	170(98.3)	0.14	0.002
Not documented	1(1.6)	63(98.4)	0.12	0.043
Abnormal movement				
Yes	3(11.1)	24(88.9)	1.00	
No	17(5.7)	283(94.3)	0.48	0.268
Not documented	1(1.7)	57(98.3)	0.14	0.096

Neonatal examination.

Table 12 shows neonatal examination findings and outcome. Absence of grunting on physical examination was associated with lower risk of death (p = 0.026), while cyanosis, cheat in-drawing and inability to breastfeed were not significant predictors of in-patient mortality. The odds of in-patient death were 71% lower in neonates with no grunting (OR = 0.29, 95%CI 0.1-0.86) compared to neonates who had grunting.

Table 12: Neonatal examination findings and outcome.

	Died			
	Yes	**No**	**OR**	**P value**
Grunting				
Yes	5(15.6)	27(84.4)	1.00	
No	16(5.1)	295(94.9)	0.29	0.026
Not documented	0(0.0)	36(100.0)	NA	
Cyanosis				
Yes	1(11.1)	8(88.9)	1.00	
No	20(6.1)	307(93.9)	0.52	0.548
Not documented	0(0.0)	45(100.0)	NA	
Severe chest wall in-drawing				
Yes	5(8.8)	52(91.2)	1.00	
No	16(5.6)	272(94.4)	0.61	0.358
Not documented	0(0.0)	34(100.0)	NA	
Inability to breastfeed				
Yes	18(7.3)	228(92.7)	1.00	
No	3(3.4)	84(96.6)	0.45	0.213
Not documented	0(0.0)	45(100.0)	NA	

8.0 DISCUSSION.

Quality of neonatal sepsis care given to neonates admitted at Kenyatta National Hospital general paediatric wards was good overall. Documentation of neonatal assessment was good especially documentation of core clinical signs and symptoms of neonatal illness and documentation of laboratory investigations requested. However, documentation of maternal history was poor. This is possibly because most mothers do not remember to carry their ante natal clinic cards when bringing their neonates to the hospital, and most do not recall the circumstances surrounding the pregnancy and delivery that are important as several risk factors for neonatal sepsis are identified from maternal history. Some of the neonates are not brought to the hospital by the mother. The clinicians may also not focus much on the maternal history.

Documentation of neonatal assessment was better in Gathara's[18] study. This could be because his study was conducted immediately post ETAT+ training and introduction of structured neonatal admission records. In this study, though most health care providers have undergone the ETAT+ training, not all are trained at the same time and some period had elapsed between the training and period the study was carried out. In most records, documentation was not done in a structured neonatal admission record, possibly because it was not was not available at the time of clerkship.

Though documentation of laboratory investigations requested was good, it is important to carry out further studies to determine whether the tests requested were done, availability of the results in the patient's records and the turnaround time between admission, specimen collection and having the results ready in the patient's records.

Clinical guidelines recommend use of crystalline penicillin and gentamicin in combination as the first line in management of neonatal sepsis[14, 15]. Recommended first line antibiotics were given in 64.4% of neonates, with 37.5% of them having a dosing error. The rest had either ceftriaxone, ceftazidime, amikacin or meropenem documented as first line. Choice of other antibiotics as first line could be based on clinicians' assessment on the severity of illness.

The most common antibiotic dosing error for crystalline penicillin was under dosing and that for gentamicin was over dosing. Gentamicin overdosing was more common in neonates less than 7 days and less than 2kg compared to those less than 7 days and more than 2kg and those more than 7 days irrespective of the weight. Gentamicin over dosing especially in those less than 7 days and less than 2kg could be because the dosage was calculated based on weight more than 2kg or dose for more than 7 days. There was a delay in giving the first antibiotic dose (within one hour of admission) in a few neonates. This dosing errors could have contributed to prolonged hospital stay; under dosing leading to a slower response to treatment, or could have contributed to mortality. These antibiotic dosing errors compare to Gathara's[18] where crystalline penicillin was almost half the recommended dose, and the most common dosing error for gentamicin was over dosing especially in those neonates less than 7 days and less than 2kg.

Breastfeeding was the preferred mode of feeding for most of the neonates. Appropriate mode, route, amount and frequency of feed and fluid prescription was accurately documented in

patient's records where other feeds (other than breast milk) or fluids were indicated. However, feed and fluid charts were not available in the records and the mode, route, and frequency of feed or fluid given was documented in the clinicians' notes and the nursing care notes.. This could be because of unavailability of feed and fluid charts. A vital signs chart was available in most of the records. Admission temperature, respiratory rate and pulse rate were well documented in most of the records. However, 6 hourly vital signs monitoring and charting was not done in most of the records. Poor monitoring of vital signs could have been as a result of high in patient numbers in the general paediatric wards in KNH and few members of staff. Poor monitoring could have contributed to mortality as neonates who deteriorated may not have been identified early and prompt intervention given.

The total mortality was 21(5.5%). Mortality occurred mainly in neonates with a duration of hospital stay less than 48 hours. Neonates who did not have change in level of activity, who were able to breastfeed and did not have grunting were at a lower risk of dying. These neonates did not have signs of severe illness, thus their better outcome. Mortality occurring within 48 hours of admission was in those neonates who were severely ill.

9.0 STUDY LIMITATIONS.

1. Due to poor documentation, tasks may be done and not documented, thus the results may be affected.
2. Storage of mortality records is done separately. This may have affected the total number of mortality records assessed, giving an impression of a lower mortality. The mortality was 16.4% from the health information records while the mortality was 5.5% in this study.

10.0 CONCLUSION.

1. Documentation of neonatal history, neonatal examination and laboratory investigations requested was good.

2. Documentation especially of maternal history and some aspects of neonatal history and examination was poor.Prescription for feeds and fluid, prescription of antibiotics and monitoring of vital signs was also poor.

3. Mortality occurred mainly in neonates with a duration of hospital stay less than 48 hours who had change in level of activity, difficulty breastfeeding and grunting.

11.0 RECOMMENDATIONS.

1. Regular audits should be carried out and feedback given to the health care workers and any other relevant people involved in neonatal care.
2. Documentation can be improved by introducing structured neonatal admission records.

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13.0 APPENDICES.

ASSESSMENT OF QUALITY OF NEONATAL SEPSIS CARE AT KENYATTA NATIONAL HOSPITAL GENERAL PAEDIATRIC WARDS.

Appendix 1: Assessment Tool

Study number: _____

Date: _____

Neonate admission information

Date of admission: _____

Date of discharge/Death:_____

Length of stay (in days): _____

Outcome: Discharge Dead

Age in days: _____

Sex: Male Female No information

Place of delivery: Hospital HomeOther facility (specify) _____ No information

Mode of delivery: SVD C/S Other mode (specify) _____ No information

Apgar score: Cried at birth _____ No information

Maternal History

Maternal age (years)	_____		No information
Fever	Present	Absent	No information
Vaginal discharge	Present	Absent	No information
Chorioamnionitis	Present	Absent	No information
Duration of rupture of membranes (hours)	_____		No information
Duration of labour(hours)	_____		No information
Gestational age (weeks)	_____		No information

Neonatal History

Birth weight (grams)	_____		No information
Length of illness (days) (if many select oldest complaint)	_____		No information
Change in level of activity	Yes	No	No information
Difficulty feeding	Yes	No	No information

Abnormal movements/convulsions	Yes	No	No information
Affected twin/sibling	Yes	No	No information

Examination

Admission weight (grams)	_____		No information
Temperature (^{0}C)	_____		No information
Respiratory rate	_____		No information
Pulse rate	_____		No information
Grunting	Present	Absent	No information
Cyanosis	Present	Absent	No information
Severe chest wall in drawing	Present	Absent	No information
Ability to breastfeed	Present	Absent	No information
Budging fontanel	Present	Absent	No information

Laboratory Investigations

Were the following tests ordered?			
Complete blood count	Yes	No	No information

Immature to total lymphocyte count	Yes	No	No information
Blood culture	Yes	No	No information
Lumbar puncture	Yes	No	No information
Blood sugar	Yes	No	No information
Other Investigations (specify): 1. 2. 3.			

Treatment

Antibiotic choice	Dose/kg	Frequency/24 hours	Route	Number of doses in 1st 24 hours
Penicillin				
Gentamicin				
Ceftriaxone				
Other drugs				
1				
2				
3				

Supportive care

Were supplementary feeds or fluids prescribed for the baby? Yes

No

If yes, feed prescribed: Expressed Breast Milk

Commercial Formula

Cow's milk

Other (specify): _____

Time of starting feeds in hours (after admission): _____

Not indicated

Route of feeding: NG tube

Cup and Spoon

Not indicated

Feed volume per feed prescribed (mls) _____

Not indicated

Feed volume per feed recorded as given (mls) _____

Not indicated

Number of feeds recorded as given in 24 hours: _____

Not indicated

Was the neonate given IVF? Yes

No

If yes, fluid prescribed: Half Strength Darrows

Half Strength Darrows with 5% Dextrose

10% Dextrose

Normal Saline

Ringers' lactate/Hartmanns

Other (specify) _____

Fluid volume prescribed in 24 hours (mls) _____

Not indicated

Is there a vital signs chart? Yes

No

Is temperature recorded? Yes

No

Frequency of temperature charting in first 48hrs: _____

Is Respiratory rate recorded? Yes

No

Frequency of respiratory rate charting in first 48hrs: _____

Is pulse rate recorded? Yes

No

Frequency of pulse rate charting in first 48hrs: _____

Is there a treatment sheet? Yes

No

After how long was treatment given after admission (hours)?_____

How many times in the 1st 48 hours of admission is treatment given filled? _____

Appendix 2: Consent form.

ASSESSMENT OF QUALITY OF NEONATAL SEPSIS CARE AT KENYATTA NATIONAL HOSPITAL.

Investigator's statement

I am Dr. Bridget Kithinji a postgraduate student at the University of Nairobi – Department of Paediatrics and Child Health. I am asking you to allow me to carry out this research study in this institution. The purpose of this form is to give you information you will need to help you decide whether you will allow me to access the patient records that I require to conduct my research.

Brief description of Study

The Ministry of Health has adopted and implemented clinical guidelines to assist health workers in managing major paediatric illnesses including neonatal sepsis. The study aims to assess care of neonates with sepsis admitted at Kenyatta National Hospital in order to determine areas of care that need improvement and thus better the outcome for such neonates.

The results of this study will help health workers in this facility to improve care given to all neonates with sepsis. It will also provide information on the current management of sepsis and the steps that can be taken to improve management of sepsis.

Once you allow me to access patient records, I will peruse through a minimum of 385 records and enter the information against an assessment tool. All the information obtained will be held in strict confidentiality. Any information that may identify the patients or the health workers involved in the patient management will not be published or discussed with any unauthorised persons. Patient records will not be carried out of the Health Information Department. I will adhere to all the rules and regulations that will be stipulated to me.

If you have any questions about the study, you can contact the principal investigator, Dr. Bridget Kithinji **0720667447**.

If you have any questions on your rights as an institution, you can contact the Kenyatta National Hospital Ethics and Research Committee (KNH- ERC) by calling (**254-020**) **2726300** Ext. **44355**

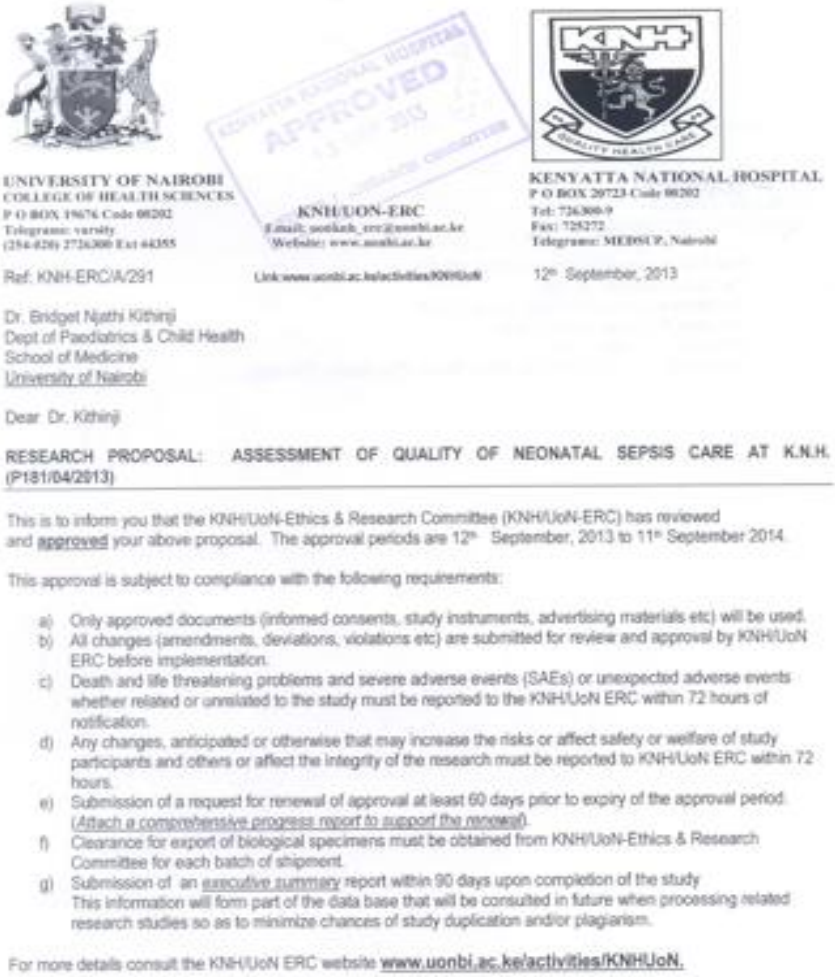
Thank you.

Investigator's Signature..... Date.....

Head, Department of Health Information KNH

Signature….. ……. Date ……

Appendix 3: Approval letter.



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Ref: KNH-ERC/A/291

Link:www.uonbi.ac.ke/activities/KNH/UoN

12th September, 2013

Dr. Bridget Njathi Kithinji
Dept of Paediatrics & Child Health
School of Medicine
University of Nairobi

Dear Dr. Kithinji

RESEARCH PROPOSAL: ASSESSMENT OF QUALITY OF NEONATAL SEPSIS CARE AT K.N.H. (P181/04/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 12th September, 2013 to 11th September 2014.

This approval is subject to compliance with the following requirements:

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

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

Yours sincerely

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

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
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AD/Health Information, KNH
Supervisors: Dr. Grace Irimu, Dr.Admir Bashir, Prof. Aggrey Wasunna

Appendix 4: Budget.

ITEM	QUANTITY	UNIT PRICE	TOTAL
Biro pens	10	20	200
Pencils	10	10	100
Box file	2	100	200
Printing and photocopying	1	15,000	15,000
Final proposal booklet	1	10,000	10,000
Poster	1	3,000	5,000
Data statistician	1	20,000	20,000
Research assistant	2	10,000	20,000
Miscellaneous			20,000
TOTAL			90,500