DISSERTATION SUBMITTED IN PART FULFILMENT FOR THE DEGREE OF MASTER OF MEDICINE IN PAEDIATRICS AND CHILD HEALTH UNIVERSITY OF NAIROBI

TITLE:

EFFECT OF STRUCTURED NEWBORN CLINICAL EVALUATION BY PAEDIATRIC RESIDENTS AT KENYATTA NATIONAL HOSPITAL ON RE-HOSPITALIZATION RATES WITHIN THE FIRST MONTH OF LIFE

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DECLARATION

I, **Dr. Veronica A. A. Obunga,** declare that the work contained herein is my original idea and has not been presented at any other place in Kenya to the best of my knowledge.

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DEDICATION

To my parents and family whose support, guidance and unconditional love have brought me this far.

To the residents and consultants of the Paediatrics and Child Health Department, University of Nairobi, who I have been privileged to work with.

To Dr. Jasper Muruka, for the love and support and forever being my unconditional cheerleader.

Table of Contents

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

GBS – Group B Streptococcus

GEE- Generalized Estimating Equations

ICU – Intensive Care Unit

KDHS – Kenya Demographic and Health Survey

KNBS – Kenya National Bureau of Statistics

KNH – Kenyatta National Hospital

MDGs – Millennium Development Goals

NBU – New Born Unit

PEC – Paediatric Emergency Centre

SPSS – Statistical Products and Service Solutions

Under-5 – Less than 5 years of age

UON – University Of Nairobi

WHO – World Health Organization

1. ABSTRACT

Background: Neonatal morbidity and mortality continues to significantly contribute towards under-5 morbidity and mortality despite significant improvement seen worldwide within this population. Studies at Kenyatta National Hospital have revealed that well-appearing neonates are potentially being discharged with their mothers only to be readmitted with significant illness. This study aimed to define the re-hospitalization rates of neonates delivered at KNH after postnatal discharge, while comparing the effect of two different modes of management.

Objectives: To determine the effect of structured newborn clinical evaluation by paediatric registrars at Kenyatta National Hospital on re-hospitalization rates within the first month of life.

Methods: Randomized Controlled Study. 600 neonates were recruited from the Kenyatta National Hospital's maternity unit. Following consideration of the inclusion and exclusion criteria, an informed consent was obtained followed by simple randomization of neonates. A questionnaire was then administered to the study participants and neonates in the intervention group underwent structured clinical evaluation. The control group on the other hand was managed and discharged as per the current standard modes employed within the maternity unit. Upon discharge, the two groups were followed up via mobile phone, at 7, 14 and 30 days. 246 and 273 neonates completed follow-up in the control and intervention groups respectively. Re-hospitalization, age at re-hospitalization and outcome of re-hospitalization were recorded during follow-up. Univariate analysis was used for categorical variables and descriptive statistics used for continuous variables. Bivariate analysis was used to investigate associations between the two modes of management and the outcomes in terms of re-hospitalization and vital status.

Results: Of the neonates who completed the 30-day follow-up period, 19.5% of the control group and 11% of the intervention group were re-hospitalized within the first month of life following birth hospitalization. The calculated Odd's Ratio was 0.5093 (p=0.0073, 95% Confidence Interval 0.3110-0.8340) indicating a risk reduction for re-hospitalization of up to 50% within the intervention group.

Conclusion: Structured evaluation of neonates following delivery resulted in a reduction of re-hospitalization of these neonates.

2. INTRODUCTION

The Kenyatta National Hospital (KNH) located in Nairobi, Kenya is the biggest referral hospital in East and Central Africa. This translates to its being a busy hospital with frequently overstretched resources, which is further exacerbated by the fact that it is located in a relatively poor resource country. The maternity and paediatrics departments are among those that function beyond their capacity, predictably more since the implementation of free maternity healthcare in 2013.

On average, the maternity staff conducts 37 deliveries daily.[1] Majority of these neonates do not get assessed by residents undergoing training in paediatrics or by the paediatric specialists. The paediatrics team mainly gets involved in the event of a difficult delivery or in case a neonate requires active resuscitation following delivery. The well-appearing babies are then roomed-in with their mothers. However, if the neonates exhibit any symptoms or signs of concern to the mother and the maternity staff, then a paediatrics resident is consulted.

Once the mothers are declared healthy by the maternity staff, they are allowed home from the maternity wing together with their babies. A majority of neonates delivered at KNH are deemed healthy and are therefore discharged without having had any contact with any medical personnel from the paediatrics unit. A number of these newborns then end up being hospitalized in various facilities, including in KNH, with signs and symptoms of omphalitis, neonatal sepsis, dehydration, neonatal jaundice, among others.[2]

Neonatal admissions into the general paediatric wards at Kenyatta National Hospital make up a significant number of daily ward admissions. Data from the statistics department of KNH reveals that on average, 22 children are admitted into the hospital's paediatric general wards per day.[1]Out of this number, an estimated 4 neonates are admitted daily.

Neonates admitted in the general paediatric wards at KNH generally do not meet the criteria for admission into the newborn unit (NBU) and include home deliveries, those discharged home from health facilities following delivery, and direct referrals from various peripheral health facilities. This group of neonates therefore tends to be older and with relatively different causes of morbidity and mortality in comparison to babies admitted into the newborn unit.[2,3]A proportion of these neonatal admissions are those hospitalized following delivery at the KNH

maternity unit. This population had not been previously defined by various preceding studies done at the hospital.

This study therefore aimed to assess the re-hospitalization rates of neonates born at KNH, and the effect of clinical evaluation by paediatric residents, while defining the outcomes following re-hospitalization.

3. EPIDEMIOLOGY

The fourth Millennium Development Goal (MDG4) statement is to reduce under-5 child mortality by 2 thirds between 1990 and 2015.

The WHO states that 6.6 million children under the age of 5 years died in 2012. Of these deaths, 75% were reportedly attributed to 6 conditions namely neonatal causes, pneumonia, diarrhoea, malaria, measles, and HIV/AIDS.[4]

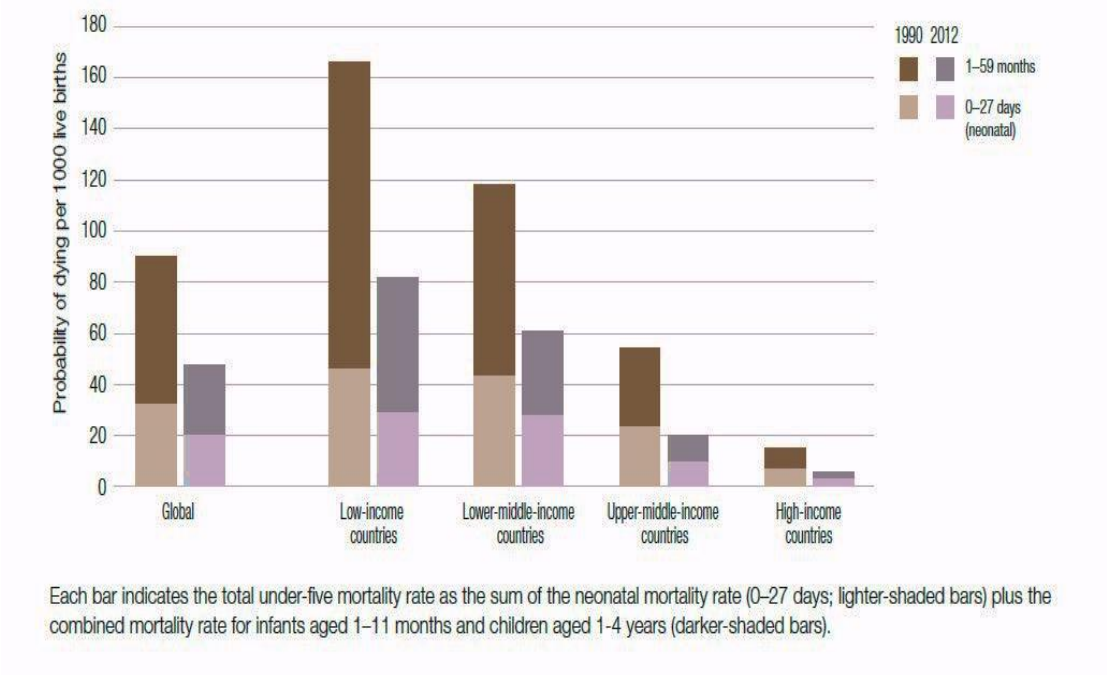
Within the initial 5 years of life, the first 28-day period has been found to be a child's most vulnerable in terms of survival.[4]

In 2012, nearly 44% of under-5 mortality occurred during the neonatal period, an increase from 39% in 1990. This trend has been noted despite the overall under-5 mortality rate reducing. Between 1990 and 2012, the under-5 mortality rate declined by 47%, from an estimated rate of 90 deaths per 1000 live births to 48 deaths per 1000 live births worldwide.[4]

High economic status countries and those of lower economic status continue to display significant differences in child mortality rates. In 2012 for example, the under-five mortality rate in low-income countries was 82 deaths per 1000 live births – more than 13 times the average rate in high-income countries. Reducing these inequalities across countries and saving the lives of more children by ending preventable child deaths are therefore key priorities.[4]

Kenya as a country is still ranked as a low-income country by the World Bank Group, and actually had comparable under-5 mortality rates in relation to the numbers quoted by the WHO for low-income countries.[5]

Figure 1 – World Health Statistics 2014



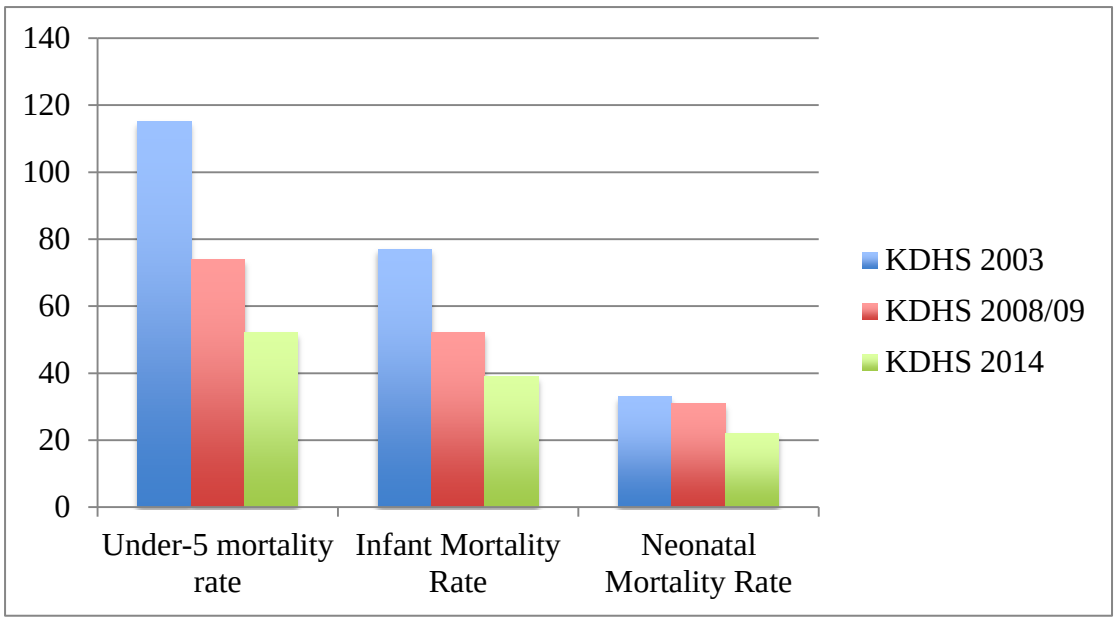
Source: WHO World Health Statistics 2014

Data from the 2008/09 Kenya Demographic and Health Survey (KDHS) shows a remarkable reduction in child mortality levels in comparison to the 2003 survey. Looking at data for the five-year period before each survey, under-five mortality declined from 115 to 74 deaths per 1,000 live births while infant mortality declined from 77 to 52 deaths per 1,000 live births.[6]

The KDHS 2008/09 report also revealed a post neonatal mortality rate of 21 deaths per 1000 live births and a neonatal mortality rate of 31deaths per 1000 live births.[6] The rates documented in the KDHS report revealed that neonatal mortality rate continues to make up a significant proportion of the under-5 mortality rate.

The more recently released KDHS 2014 report reveals a further reduction in infant and child mortality rates. The level of under-five mortality is 52 deaths per 1000 live births while the infant mortality rate is 39 deaths per 1000 live births while the neonatal mortality rate is 22 per 1000 live births.[7] This consolidates the fact that neonatal morbidity and mortality has continued to be a major deterrent towards overall reduction in child morbidity and mortality rates.

Figure 2 – KDHS 2003 - 2014



Source: KNBS

Neonatal deaths make up 42% of under-5 mortality rates and 60% of infant mortality rates.[6]

The significant contribution made towards the under-5 mortality rate by deaths within the neonatal group further shows that interventions that target this population with the aim of disease prevention and early diagnosis and management would likely translate to reduction in the under-5 burden of disease and death, provided other variables remain constant, or also continue the declining trend.

Data from Kenyatta National Hospital reveals a similar trend. On average there has been an overall increase in the number of admission in a hospital where the current total number of beds is at 2019. The overall hospital admissions increased from an annual average of 79000 prior to institution of free maternity healthcare, to 85000 post-institution of free maternity health care.[1]

During the period January 2015 – December 2015 the hospital's labour ward admitted 16074 women. The number of neonates admitted to the neonatal ward was 4134, out of which there were 1624 deaths. The mortality rate in the neonatal unit was therefore 395/1000 (quoted per 1000 live admissions). The four paediatric general wards for the same period reported a mortality rate of 128/1000. The oncology ward recorded a mortality rate of 248/1000; the paediatric renal unit reported 289 deaths per 1000 admissions while the paediatric intensive care

unit recorded the highest rate (629/1000).[1] It is important to note, however, that these mortality rates were overall rates and not age-specific.

Childhood mortality rates have been used to represent a country's socioeconomic status and quality of life. The numbers and trends in Kenya can therefore crudely be used as an indicator of progressively improving socio-economic status and quality of life, which currently correlates with the middle-income countries.

The improvement in neonatal mortality rates has been attributed to improved delivery care with more deliveries being conducted by skilled attendants. Implementation of free-maternity care probably had a major impact on the neonatal mortality rates However, death within the first 28 days of life continues to contribute significantly towards the under-5 mortality rate, warranting further brainstorming by stakeholders with regards to measures that could lead to further reduction in neonatal morbidity and mortality.[7]

4. BACKGROUND

Neonatal morbidity and mortality contributes significantly to under-5 morbidity and mortality as previously discussed. Majority of research work that has been done, with regards to neonatal morbidity and mortality, has mainly concentrated on neonates admitted in the neonatal units.[3, 8,9]

Globally, tremendous financial and political efforts have been focused on the reduction of child mortality during the past few decades. Timely measurements of levels and trends in under-5 mortality help assess progress to achieving MDG 4, and to identify models of success.[10]
It became apparent that MDG 4 had not been achieved upon assessment in 2015. The neonatal mortality rate remained significantly high for various countries despite overall relative decline over the years. Major differences have been noted between high and low-income countries.

Table 1: Neonatal Mortality Rate 2011

Countries	Neonatal Mortality Rate (Per 1000 live births) 2011
Bangladesh	26
Brazil	10
Canada	4
Chile	5
Columbia	11
Ghana	29
India	31
Mexico	7
Nigeria	39
Pakistan	36
Sri Lanka	8
Thailand	8
United Kingdom	3
United States	4
China	9
Uganda	21
Angola	52
Ethiopia	31
Kenya	25
Tanzania	21
Cuba	3
Portugal	2

The huge difference in mortality rates between high- and low-income countries and regions is a human rights issue. The reason why the MDG4 was largely not achieved was mainly due to the

slow decline in neonatal mortality. Countries which successfully achieved MDG4 reported significant reduction in the neonatal mortality rate.[10,11]

These countries concentrated on the 4 major causes of neonatal death: asphyxia, infection, low birth weight/prematurity and congenital malformations. Success stories from countries like Chile, Portugal and Cuba are encouraging and show that it is possible to reduce newborn mortality in all countries and regions.[11]

Ten basic recommendations to achieve lower neonatal mortality rates included:[11]

1. Learn from other countries
2. Regionalization and classification of care levels
3. Easy and free access to pre- and postnatal care.
4. Encourage hospital deliveries
5. Promote breastfeeding
6. Invest in equipment and staff
7. Evidence-based treatment and guidelines
8. National and international neonatal networks
9. Free essential drugs for all pregnant women and children
10. Training programs and research

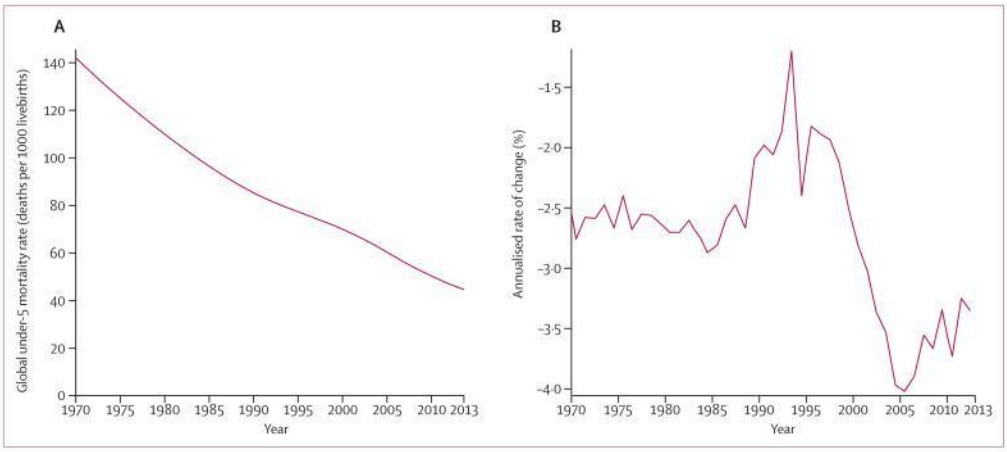
Consistent involvement of paediatricians/neonatologists would therefore help achieve most, if not all of the 10 recommendations as listed above.

Other similar research findings continue to support evidence that there is a rapid decrease in under-5 mortality rates, neonatal mortality rates included. These accelerated declines are occurring in several countries, Kenya included, and might justify enhanced policy attention and resources with the aim of augmenting these positive developments.[11]

5. LITERATURE REVIEW

Haidong W. et al came up with updated estimates of child mortality rates in early neonatal (0–6 days), late neonatal (7–28 days), post-neonatal (29–364 days), childhood (1–4 years), and under-5 (0–4 years) age groups for 188 countries from 1970 to 2013. Gaussian process regression was used with adjustments for bias and non-sampling error to synthesize the data for under-5 mortality for each country, and a separate model used to estimate mortality for more detailed age groups. They used regression models to assess the correlation between under-5 mortality and various factors including income per person, maternal education, HIV child death rates, and secular shifts. They then attempted to quantify the contribution of these different factors and birth numbers, to the overall decline of under-5 mortality rates between 1990 and 2013. Using the estimated rates of changes in under-5 mortality rates between 2000 and 2013 they were then able to extrapolate the under-5 mortality rate scenarios out to 2030.[10]

Figure 3: Under-5 Mortality Rate 1970-2013



Global under-5 mortality rate and rate of change, 1970–2013

(A) Global under-5 mortality, 1970–2013. (B) Annualised rate of change in global child mortality, 1970–2013.

Source: PMC;Lancet

They estimated that there was a 70% decline in under-5 mortality rates globally from 1970 to 2013. Out of the 188 countries, 99 showed more robust declines in child mortality between 2000 and 2013 than during the period between 1990 and 2000. This included 43 of the 48 countries assessed within Sub-Saharan Africa. However, the neonatal mortality rate proportionally increased making up 37.4% of the under-5 mortality rate in 1990 versus 41.6% of under-5 mortality rate in 2013. This was attributed to the rising numbers of births, especially in sub-Saharan Africa, which led to 1·4 million more child deaths between 1990 and 2013. On

the other hand, improved maternal education and income per person resulted in fewer deaths within the same period. Changes in secular trends resulted in 4·2 million fewer deaths. Unexplained factors accounted for only 1% change in child deaths. 30 of the developing countries have shown faster decreases since 2000 than predicted. This could be explained by overall improvement in income, education, and secular shifts.[10]

MDG4 was found to be a great challenge with a significant number of countries, especially within the developing segment, being shown to fail. Only 27 developing countries were expected to achieve MDG 4 by 2015. At the same time however, under-5 mortality rates have declined significantly since 2000 with many developing countries recording accelerated reduction in rates, especially in Sub-Saharan Africa. The Millennium Declaration and increased development assistance for health might have been a factor in faster decreases in some developing countries. Despite the progress, further accelerated reduction is required in many countries especially in Africa, Kenya included, without which under-5 mortality rates will continue to be significantly high in 2030.[10]

G. J. Escobar et al retrospectively analyzed re-hospitalization of neonates after birth hospitalization at seven Kaiser Permanente Medical Care Program (KPMCP) delivery services. The study included all live births between 1 October 1998 and 31 March 2000.[12]

The study revealed re-hospitalization rates varied by gestational age range with 3% among babies born at 34 weeks, 4.4% among babies delivered at 34–36 weeks, and 2% among babies born at or after 37 weeks. The most common diagnosis at re-hospitalization was jaundice though a majority had multiple diagnoses at admission.[12] Generalizability of this study and its findings to our set up would not be possible as the set up is that of a developed country with vast resources and advanced health care systems structured towards optimizing follow-up of neonates post-discharge.

Farhat R and Rajab M carried out a prospective study at Makassed General Hospital in Beirut from September 2009 – March 2010. The length of stay for all healthy neonates was recorded with subsequent follow up for any medical problem.[13]

478 neonates were enrolled. 307 were discharged early (<48 hours following delivery) with the overall length of stay calculated to be 39 hours. 38 (7.9%) neonates were re-hospitalized with the most common cause of this being neonatal jaundice.[13]

The conclusion made was that hospital discharge at or before 48 hours of age significantly increased risk of readmission particularly due to hyperbilirubinaemia and therefore a structured programme for neonatal follow-up following early discharge was vital in order to reduce the risk of readmission, morbidity and neonatal mortality.[13]

M. K. Mwaniki et al carried out a study on the increase in the burden of neonatal admissions to a rural district hospital in Kenya over 19years. Data on neonates was prospectively collected and compared with that of non-neonatal under-5 year olds' admissions and maternity deliveries at Kilifi District Hospital from January 1st 1990 to December 31st 2008.[14]

The research found that the proportion of neonatal admissions had significantly increased from 11% in 1990 to 20% by 2008. Majority of this increase in burden was from neonates born in hospital and especially within the first 7 days of life. Hospital deliveries were also found to have increased significantly within the same period.[14]

Over 75% of the admissions were accounted for by clinical diagnoses of neonatal sepsis, prematurity, neonatal jaundice, neonatal encephalopathy, tetanus and neonatal meningitis. Neonatal mortality made up 33% of all in-patient deaths among children under-5 in 1990 and this proportion increased to 55% by 2008.[14]

The conclusion of the study was that there was clear evidence of increasing burden in neonatal admissions at the Kilifi District Hospital, which is found in rural Kenya, in contrast to a reduction in the number of non-neonatal under-5 admissions during the 19-year period.[14]

M. English et al did a progressive 18-month observational study in Kilifi District Hospital. Their aim was to look at the causes and outcome of young infant admission.[15]

Out of 1080 infants studied within the inpatient set up, 40% were aged 0-7 days old, 24% were 8-30 days old, 17% were 31-60 days old and 18 % were aged 61-90 days old. The overall mortality rate was 18% while that of neonates aged 0-7 days was 34%. Following discharge, 5% of infants aged less than 60 days died within 2 months.[15]

Causes of morbidity and mortality in infants aged less than 2 months included severe infection and prematurity, which collectively accounted for 57% of inpatient deaths. Jaundice and tetanus resulted in another 27% of the mortality rate. The most common causes of invasive bacterial disease included Streptococcus pneumonia, Group B Streptococcus, Escherichia coli and

Klebsiella.[15] More than 20% of neonates aged 0-7 days had hypoxaemia, hypoglycaemia and inability to feed.[15]

The study therefore revealed that neonates contribute significantly to the paediatric inpatient morbidity and mortality rate.[15]

Neonates admitted in the nursery at KNH are usually those who are diagnosed with various problems following delivery, but prior to discharge of the mother from the maternity unit. They therefore tend to be younger than neonates admitted to the general wards with relatively different diagnoses in comparison to the older neonates who are admitted from home.

Neonates admitted in the paediatric general wards from home have been reported to probably have a higher mortality rate than those admitted in the NBU.[2]This is probably directly related to the delay in diagnosis and treatment of various ailments in the former population.

Other factors contributing to this higher mortality rate of neonates in the general paediatric unit in comparison to neonates admitted in the new-born unit include lack of specialized neonatal staff and scarcity of equipment including phototherapy boxes and incubators. These neonates also have to compete with other children in the general wards and babies admitted in the NBU incase of need for assisted ventilation and ICU care.[2]

Majority of the neonatal morbidity and mortality of NBU admissions are caused by immaturity, respiratory distress, neonatal sepsis and perinatal asphyxia.[3]

D.E Simiyu assessed the morbidity and mortality of neonates admitted in the general paediatric wards at KNH. He looked at 308 neonatal admission records from January to December 2000 retrospectively.[2]

He noted that first time mothers accounted for 45% of the group that had information on parity documented (272). 62% of the women had delivered in a health facility. Of these, 7% had delivered in KNH and 15% in Pumwani Hospital.
Common diagnoses at admission were suspected sepsis (71%, of which 8.4% were later proven), Jaundice (35%), Pneumonia (32%), Omphalitis (28%), Dehydration (14%), Apnoeic attacks (13%) and Hypothermia (6%). However, most neonates had multiple diagnoses during the course of admission.[2]

His results revealed a high mortality rate of 31.5% (315/1000) with 83.5% of these deaths occurring in the first week of admission and 49% occurring within the first 24 hours. The causes of mortality at this early period were apnoeic attacks, pneumonia and hypothermia. The most frequent diagnoses were suspected sepsis, dehydration, jaundice, pneumonia, diarrhoea, omphalitis and low body weight.[2]

The major limitation of the study was that being a retrospective study it was impeded by poor record keeping. The study was also limited to neonates admitted to KNH and therefore did not define the number of neonates re-hospitalized following delivery at KNH.

A study performed by E. Ng'ang'a as a requirement for her post-graduate thesis in KNH revealed a significant number of well-appearing babies in the post-natal wards have neonatal sepsis.[16]This study revealed a significant number of well-appearing neonates are probably being discharged with subclinical disease from the post-natal wards as prescribed by the current standard practices.[16]

This study was therefore performed to build on the study done above in terms of investigating the proportion of neonates' re-hospitalized following delivery at-and discharge from KNH and to determine the outcome of these admissions.

There is no published study that demonstrates the above and therefore this study aims to fill that gap. Information on the effect of clinical evaluation by paediatric residents is also lacking. This information will be vital in planning and policy making with the aim of improving neonatal management and follow-up, and therefore reducing morbidity and mortality among neonates.

6. STUDY JUSTIFICATION

Anecdotal evidence in the general wards had shown that an increasing number of neonates delivered at KNH were being re-hospitalized in the general paediatric wards. This required further objective definition and determination. There is no published study that has described the re-hospitalization rates of this group of neonates

A study by E. Ng'ang'a had previously revealed a significant number of well-appearing babies in the KNH post-natal wards have neonatal sepsis.[16] Neonates who do not exhibit overt signs and symptoms of disease are not routinely reviewed by paediatricians in KNH following delivery and could therefore be going home with undiagnosed illnesses. This could be contributing towards re-admission following discharge after delivery. Delayed diagnosis and management probably result in poor outcome following re-hospitalization.

Informal discussions with mothers of these re-hospitalized neonates in the paediatric general wards at KNH also revealed they were potentially being discharged from the post-natal wards with inadequate information with regards to proper breastfeeding practices and cord care, among others. Proper cord care has been found to significantly reduce neonatal morbidity and mortality[17].

The American Association of Paediatrics recommends that in order to reduce readmission rates of neonates following birth admission paediatricians should be involved in the postnatal assessment and management of each neonate and mother dyad in order to perform clinical evaluation and ensure adequate breastfeeding practices in addition to the family's ability to provide adequate care for the neonate at home.[23]

Before 2015, strategies and interventions recommended by the WHO with the aim of achieving MDG4 included appropriate home care and timely treatment of complications for newborns, integrated management of childhood illness for all children under five years old, expanded programme on immunization and infant and young child feeding.

In addition, KNH receives high-risk mothers as referrals from peripheral health facilities further consolidating the need to determine the readmission rates of neonates following postnatal discharge from the hospital

7. STUDY UTILITY

The findings of the study will be disseminated to various departments and the information given to the KNH administration. This information could result in positive changes in certain policies with regards to maternal discharge practices and newborn management following delivery at the hospital.

8. OBJECTIVES

8.1 Primary Objective

To determine the effect of structured newborn clinical evaluation by paediatric registrars at Kenyatta National Hospital on re-hospitalization rates within the first month of life

8.2 Secondary Objectives

a) To determine and compare the age at admission of re-hospitalized neonates in the control and intervention groups.
b) To determine the outcome of admission as defined by vital status.

9. METHODOLOGY

9.1 Study Design

Randomized controlled study design

9.2 Study site

The location of the study was Kenyatta National Hospital's maternity unit with study participants being followed up for a specified period following enrolment.

9.3Study Population

The study group was derived from neonates born in Kenyatta National Hospital.

Inclusion Criteria:

- Well appearing (no lab confirmation), term neonates aged 0-72hours.
- Mothers had active mobile phone numbers.

Exclusion criteria:

- Preterm neonates (age <37 weeks)
- Mentally impaired mothers (secondary to illness or medication).

9.4 Study Procedures

An informed consent was obtained from participants who had met the inclusion criteria. Following recruitment, the two study groups were assigned randomly. Simple randomization was done. Random numbers were generated beforehand. These were an equal number of odd and even numbers that were then written on small pieces of paper, which were then folded. The mothers were requested to pick the folded pieces of paper and then open these up to reveal the random number assigned. All neonates whose mothers had picked odd numbers were grouped in the control arm. All neonates whose mothers had picked even numbers were grouped in the intervention arm. No blinding was done and allocation concealment was not attempted.

Intervention Group

Intervention was defined as complete examination of the neonate by a paediatric resident prior to discharge. Apart from the principal investigator, an additional 2 paediatric residents were selected and trained on how to administer the data collection tool. In order to define and guide the examination a structured tool which is routinely used within the KNH new-born unit was used, with additional information on neonatal examination being included from a standard physical examination textbook and findings summarized, with the target objectives in mind.[19]

The data collection tool was administered followed by complete physical examination. This entailed taking the babies' weight and height, head circumference, vital signs including the heart and respiratory rates per minute plus temperature determination. Each of the basic organ systems was then examined; The Central Nervous System, The Respiratory System, The Cardiovascular System, The Abdomen, The Musculoskeletal System, The Anus and Genitalia. Any neonate whose mother had previously not complained of any concerns but was found to require admission following evaluation was transferred to the newborn unit for treatment and these were captured as "early admissions".

Control Group

The first section of the data collection tool was administered on participants within the control group in order to obtain basic information including bio-data, the mode of delivery, weight at birth and mother's level of education. The neonates were then subjected to the standard management and discharge procedures currently practiced within the maternity unit with temperatures being taken by the nursing staff and non-structured breastfeeding advice being given whenever deemed necessary. Neonates admitted to the newborn unit from this group following this non-structured mode of evaluation were also captured as "early admissions"

Follow-up

This was similar for both groups. The discharge dates of the mothers and their neonates were recorded. Mothers were given the principal investigator's mobile phone number and were advised to call or send a message to the researcher in case of any illnesses and concerns, hospital visits and hospitalization. The enrolled study group was followed up via mobile phone at ages 7, 14 and 30 days. Any illnesses and hospitalizations were captured with emphasis being made on the age at admission and the outcome of admission as defined by the vital status of the neonate. Any admissions recorded before 7 days of life were captured as "early admissions" while those occurring thereafter were recorded as "late admissions". Only the first re-hospitalization was captured in the event of more than one admission within the neonatal period

Confidentiality was maintained during the entire process and no names were used during data collection or data analysis. No rewards or gifts were offered to the study population, including subscription to mobile phone networks, purchase of mobile phones and purchase of talk-time.

9.6 Sample Size Determination

Sample size per group was calculated using the formula that helps determine clinical superiority:

$$2 \times \left(\frac{Z_{1-\propto} + Z_{1-\beta}}{x}\right)^2 \times \rho \times (1 - \rho)$$

Where :

Type I error is 0.05 Thus $Z_{1-\alpha}$=1.96

Type II error is 0.2 (Power of 80%) Thus $Z_{1-\beta}$= 0.842

Using the results from the study performed by G.J Escobar et al,[12] 4.4% was the Positive response rate for the standard treatment group. G.J. Escobar's study was done in the Americas, where neonatal morbidity and mortality rates are Much lower than the rates in Kenya. Therefore the above was exaggerated 5 times, echoing the difference between the Kenyan and the American trends in neonatal morbidity and mortality

Therefore ρ

ρ= Positive response rate for standard treatment group (22% or 0.22)

χ = Difference the investigator wishes to detect (10% or 0.1 taken as significant)

Therefore:

$$N = 2 \times \left(\frac{1.96 + 0.842}{0.1}\right)^2 \times 0.22\ (1 - 0.22)$$

N = 270

Loss to follow-up was expected. The attrition rate was expected to be 10% by day 30 c

Thus the total sample size was inflated further:270÷(1-0.1) = **300 per group.**

10. ETHICS CONSIDERATION

Several ethical considerations were taken into account in the process of this research:

- The Proposal for this study was submitted to the Kenyatta National Hospital/University of Nairobi ethics and research committee for approval. The committee then gave its comments and corrections.
- The study was approved by the ethics and review committee following re-submission of the revised proposal.
- The study commenced upon approval by the ethical and research committee
- The patient's personal information e.g. names were not used in the study in order to uphold confidentiality.
- Information acquired during data collection and analysis has not been used for any other purpose besides in the clinical management of patients and academics.

Written and signed consents were obtained from each mother after a detailed explanation of the study being undertaken.

Risks

The neonates were not subjected to unnecessary tests and risks and invasive procedures were only performed upon admission within the neonatal unit.

Benefits

The study enabled early identification and empirical diagnosis of certain conditions including neonatal jaundice and sepsis. As a result, infected infants got prompt treatment averting progression to serious illness and death. The mothers also had free access to the paediatric registrars during the follow-up period and therefore obtained invaluable advice whenever necessary.

Adverse Events

No potential adverse events related to the study were identified or encountered.

11. DATA MANAGEMENT

11.1 Data Collection

A questionnaire was administered by the paediatric residents to the mothers of neonates enrolled into the study at the point of recruitment and during follow-up.

11.2 Data Entry and Analysis

The intent to treat analysis principle was employed with every randomized participant being included during data analysis whether they completed the study or not. This was especially true during the analysis of the study population's baseline characteristics. Data recorded in the data collection tools was kept confidential and stored safely by the principal investigator.

A link log was used to code all personal details of the mother- baby pairs. Data was then retrieved from all questionnaires and newborn assessment forms and stored in a database. Data was then entered into computer using data entry screens incorporating range and consistency checks. Further cleaning was carried out after entry using frequency distributions and cross-tabulations until no more errors could be detected. Any errors which the investigator was unable to resolve was declared missing. An updated statistical software – Statistical Products and Service Solutions (SPSS version 23) was used to enter and analyze the data. The baseline characteristics were then identified and univariate analysis employed, followed by inferential statistics in order to compare the two groups (intervention and control groups). The continuous data was summarized using mean, median and standard deviation. Chi-square was used to infer comparativeness of the two study groups. Logistic regression was further used to define certain baseline characteristics.

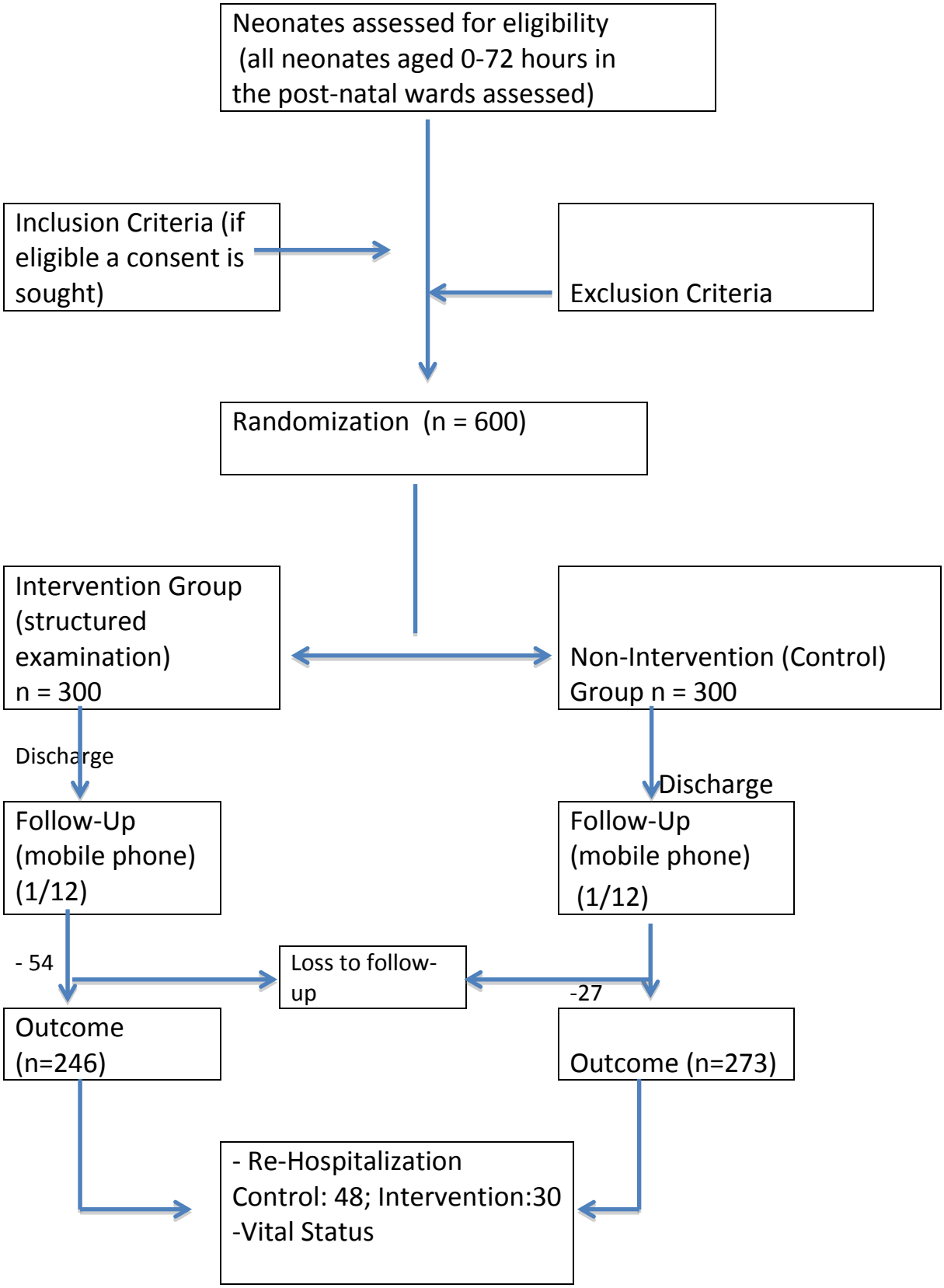
These results have been tabulated. Bivariate analysis was used to investigate any association between the response variable and the two study groups, thereby analyzing the effect of intervention on the outcome. Odd's Ratio was used in this analysis.

Categorical data was summarized in terms of proportion. The proportion of hospitalized babies was computed with comparisons being made between early and late admissions. The loss to follow-up was also computed and taken into account during analysis of the effect of intervention on re-hospitalization rates. The vital status was also described.

12. RESULTS

12.1 Study Profile

Figure 4: Study Profile



12.2 Baseline Characteristics

The baseline characteristics of the newborns and their mothers are shown below in table 2. Majority of the mothers reported a previous pregnancy, 74% for the control group and 56.7% for the intervention group. This was regardless of the outcome of the previous pregnancies. Majority of the neonates were delivered via spontaneous vertex delivery; 70% of neonates in the control group and 72% of neonates in the intervention group. 81% of mothers in the control group reported were married while in the intervention group this proportion was 80.7%. The median age of recruited mothers in both the study arms was 24 years while majority of them reportedly completed secondary school education (93% and 96% of the control and intervention groups respectively). The control group comprised of 52.7% male neonates and 47.3% female neonates while there was an equal proportion of male versus female neonates within the intervention group (50% each).

Table 2: Baseline Characteristics

Study Group	**Control group n=300**		**Intervention Group n=300**		**p value**
Variable	**Frequency**	**Percent**	**Frequency**	**Percent**	
Parity					
1st Pregnancy	78	26%	130	43.3%	<0.001
≥ 1 Pregnancy	222	74%	170	56.7%	
Mode of Delivery					
SVD	210	70%	216	72%	0.176
C/S	90	30%	84	28%	
Marital Status					
Single	57	19%	58	19.3%	0.870
Married	243	81%	242	80.7%	
Mother's Age (median 24 years)					
≤20 years	57	19%	57	19%	0.725
>20 years	243	81%	243	81%	
Level of Education					
Primary	21	7%	12	4%	0.114
≥Secondary	279	93%	288	96%	
Gender of Neonate					
Male	158	52.7%	150	50%	0.597
Female	142	47.3%	150	50%	

There was a statistically significant difference between the two groups in terms of parity ($p<0.001$). Since neonates born of first time mothers are more likely to be re-hospitalized,[22,23]

this statistical difference was expected to dampen the subsequent results of the study. Multivariate analysis was further done using multinomial logistic regression. This revealed that neonates born to first time mothers within the intervention group were more likely to be re-hospitalized within the first 3 days of life (p=0.003).

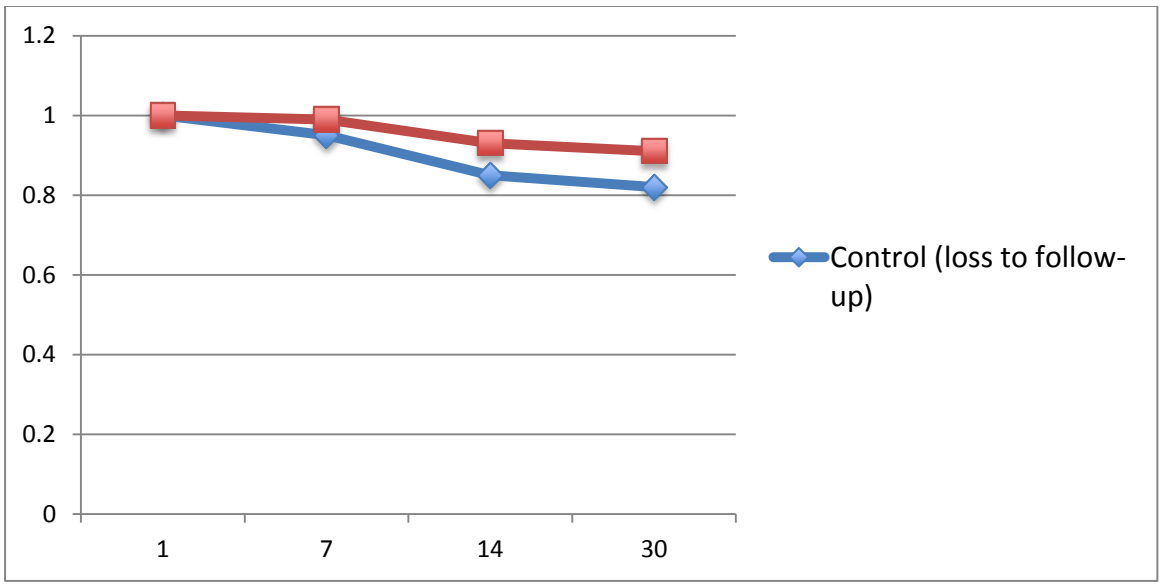
12.3 Follow-up

The neonates were followed up via mobile phone at 7 days, 14 days and 30 days. At the end of the data collection period the proportion of mothers who provided data was higher for the intervention group (91%) as opposed to the control group (82%). Majority of the loss to follow-up occurred within the first 14 days of data collection, cumulatively accounting for 15% and 6.6% within the control and intervention groups respectively. The total proportions lost to follow-up were 18% and 9% of the control and intervention groups respectively. (Table 3)

Table 3: Loss to Follow-up

Loss to Follow-up	Control Group n=300		Intervention Group n=300	
	Number	Percent	Number	Percent
By 7 Days	16	5.3%	4	1.3%
By 14 Days	29	9.7%	16	5.3%
By 30 Days	9	3%	7	2.3%
Total	54	18%	27	9%
Complete Reporting	246	82%	273	91%

Figure 5: Loss to follow-up



Differential loss to follow-up was noted. 'Worst case scenario' was assumed and upon analysis the differences in follow-up did not affect the outcome.

12.4 Re-hospitalization Rates

Table 4 illustrates the respective re-hospitalization rates for the control and intervention groups. The newborns who were lost during the follow-up process were not included in this analysis and therefore n=246 for the control group and n=273 for the intervention group.

Within the first 30 days of life 19.5% of the control group and 11% of the intervention group had required re-hospitalization apart from the birth hospitalization. During reporting, regardless of the number of re-admissions reported for each neonate, only one was taken into account. The calculated Odd's Ratio was 0.5093 where p-value = 0.0073 with a 95% confidence interval (0.3110-0.8340). (Table 4)

Overall, majority of the re-hospitalizations occurred before 7 days of life with 64.5% of the re-admissions in the control group versus 80% of the re-admissions within the intervention group being recorded at or before 7 days of age. (Table 5)

Table 4: Re-hospitalization Rates

Study Group	**Control Group n=246**		**Intervention Group n=273**		**ODDS RATIO**
Admission Required	**Frequency**	**Percent**	**Frequency**	**Percent**	
NO	198	80.5%	243	89%	OR = 0.5093 95% CI (0.3110-0.8340 p value - 0.0073
YES	48	19.5%	30	11%	

Table 5: Age at Re-hospitalization

Age at Re-hospitalization	**Control Group n=48**		**Intervention Group n=30**		**P value**
	Frequency	**Percent**	**Frequency**	**Percent**	
Early Admissions (≤7days)	31	64.6%	24	80%	0.081
>7-30 days (late admissions)	17	35.4%	6	20%	
Total	**48**		**30**		

12.5 Outcome

The outcome of each episode of re-hospitalization was defined by the vital status of the neonates as shown on table 6. 89.6% of the re-hospitalized group from the control arm were discharged alive while 10.4% of the same group died. Of the intervention group 93.3% of neonates admitted were discharged alive while 6.7% died. (Table 6)

Table 6: Outcome of Re-hospitalization

	Control group n=48		Intervention Group n=30		P value
Outcome	Frequency	Percent	Frequency	Percent	
Alive	43	89.6%	28	93.3%	0.282
Dead	5	10.4%	2	6.7%	

The calculated Odd's Ratio was 0.6143, 95% confidence interval: 0.1114 to 3.3880, P = 0.5759

13. DISCUSSION

This study set out to look at the re-hospitalization rates of newborns within the first month of life following birth hospitalization at Kenyatta National hospital when managed and discharged using the current standards of practice within the maternity unit and comparing this to the re-hospitalization rates of newborns subjected to structured clinical evaluation by the paediatric registrars while documenting the day of re-admission and outcome of these incidences of re-hospitalization.

Within the group that completed the follow-up process, the control group reported 48 cases of re-hospitalization (19.5%) while the intervention group reported 30 cases of re-hospitalization (11%). Using Odd's Ratio, it was determined that the simple intervention (structured clinical evaluation of newborns within the first 3 days of life following delivery at Kenyatta National Hospital) resulted in a 50% reduction of re-hospitalizaiton rates. (OR=0.5093; 95% CI 0.3110-0.8340; p=0.0073). R. Kihara's study showed that a simple intervention (phone based counseling) resulted in improved breastfeeding practices, and child morbidity and mortality.[21] E. Ng'ang'a revealed that a significant number of well appearing neonates had neonatal sepsis within the KNH post-natal wards. Majority of these neonates therefore presumably show overt signs and symptoms of disease after discharge.[16]

Majority of these incidences of re-hospitalization occurred by 7 days with 64.6% and 80% of the admissions within the control and intervention groups respectively being recorded by 7 days. There was no statistical difference in terms of age at re-hospitalization between the two groups (p=0.081) though the trend was towards significance. A study done in a large Utah healthcare system showed majority of neonatal readmissions occurred within the first 2 weeks of life.[22]

Of the neonates who were re-hospitalized, those who died in hospital were 5 from the control group and 2 from the intervention group. The mortality rate within the control group therefore calculated to be 20/1000 live births while in the intervention group the mortality rate was 7/1000 live births. The overall calculated death rate using the neonates who completed follow-up as the denominator was 13/1000 live births. The difference in mortality rate between the two groups was not statistically significant. (p=0.282). The calculated Odd's Ratio was 0.6143, 95% confidence interval: 0.1114 to 3.3880, P = 0.5759, further revealing no statistical difference between the two groups in terms of mortality rates.

The group that had been lost to follow-up was not factored in during this calculation.

Of the neonates followed up via mobile phone, there was a recorded drop-out rate of 5.3% by 7 days and a cumulative drop-out rate of 15% by 14 days within the control group. The overall loss-to-follow up rate within this group by 30 days was 18%. The cumulative drop-out rate within the intervention group by 30 days of follow-up was 9% with majority being lost to follow-up by 14 days (6.6%). The lower attrition rates within the intervention group may have been the result of the rapport built during the examination of the neonates by the paediatric residents and therefore improved level of confidence in the entire process. Even so, assuming a worst-case scenario picture (those lost to follow-up taken as having been re-hospitalized) the intervention still had a similar effect on re-hospitalization rates.

The baseline characteristics of the control and intervention groups were found to be comparable in terms of mode of delivery ($p=0.176$), marital status ($p=0.870$), maternal age ($p=0.725$), maternal level of education ($p=0.114$) and gender of the neonate ($p=0.597$). There was a statistically significant difference between the two groups in terms of parity ($p<0.001$). Since neonates born of first time mothers are more likely to be re-hospitalized,[22,23] this statistical difference was expected to dampen the subsequent results of the study. Multivariate analysis was further done using multinomial logistic regression. This revealed that neonates born to first time mothers within the intervention group were more likely to be re-hospitalized within the first 3 days of life ($p=0.003$). A study carried out by a post-graduate student from Kenyatta University revealed majority of the patients seen at KNH have attained secondary education and below. It can be inferred that people with secondary education and below prefer to seek health services from KNH probably as a result of the affordability of services offered at the hospital. It is likely that individuals who have acquired at least some tertiary education opt to seek health services from private institutions, probably because they can afford it or have access to health insurance. [20]

The assumption made in this study was that mothers admitted in the maternity unit are of similar economic background. A Study by Faith Mahinda showed after the income bracket of Ksh. 41,000, utilization of KNH as the hospital of choice decreases. Those in the income bracket of below 41,000 are the highest users of KNH. [20]

13.1 Study Limitations

The following challenges were noted:

- There was loss-to-follow up recorded within both groups, with 18% of the control group lost by the final day of follow-up and 9% of the intervention group lost by the same day.
- Mode of randomization did not completely deal with some confounders most importantly the parity.

13.2 Strengths of the study

The study was able to objectively reveal advantages of neonatal clinical evaluation prior to discharge of the mother-baby pair.

During follow-up, the mothers were able to obtain free advice from the principal investigator.

14. CONCLUSION

The following conclusions were made following data analysis:

- Structured neonatal evaluation by paediatric registrars prior to discharge from the maternity unit following delivery resulted in a 50% reduction of re-hospitalization rates by the end of the study period.
- The age at readmission was comparable for both the control and intervention groups with majority of the admitted neonates being re-hospitalized within the first week of life.

15. RECOMMENDATIONS

These included the following:

- Routine and structured neonatal examination by the paediatrics team is necessary and advised for neonates following delivery, and prior to discharge of their mothers.
- The causes of re-hospitalization also require definition and therefore a study focusing on this would be of importance.

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APPENDIX A

INFORMED CONSENT

Informed Consent form for neonates and their mothers, who will be invited to participate in this study from the post-natal wards at Kenyatta National Hospital

[Principle investigator]- Dr. Veronica Obunga
[Programme]- Post-Graduate Student, University of Nairobi, Paediatrics and Child Health Department

Research Topic: Hospitalization rates of babies born at KNH within the first month of life

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

My name is Dr. Veronica Obunga, currently post-graduate a student at the University of Nairobi. I am carrying out a study and would like to invite you to participate in the study, after I have given you information regarding the same. Before making any decisions, you can consult anyone you feel comfortable with about the research. In case you do not understand something kindly do not hesitate to stop me and I will take time to explain. You can also ask questions later

Purpose of the research

Illness and death within the first month of life is a major problem worldwide, Kenya included. Currently 22 out of every 1000 babies born will die within 28 days of life. I am interested in looking for ways to reduce this burden. One of the simple ways could be by examination of babies after they are born, daily, until discharge. I am therefore carrying out a research to find out if this is better than the usual care we give to newborn babies in the maternity wards.

Type of Research Intervention

This research will involve examination of your baby and thereafter following you and your baby up via mobile phone. The follow-up will be carried out for a month.

Participant selection

I am inviting any mother who delivered a baby less than 3 days ago and has a mobile phone to participate in this research

Voluntary Participation

Your participation is entirely voluntary and whether you choose to participate or not, you will still continue to receive treatment at this facility. If you choose to participate you may change your mind later and stop participating.

Procedures and Protocol

We do not know whether changing the procedures while you and your baby are still in the hospital and thereafter following you up will have a significant effect especially in reducing chances of re-hospitalization once you have been discharged. We therefore will need to compare the two procedures: the new one and the usual standard procedures. For us to make comparisons we will need to put the people who agree to take part into two groups. This will be done randomly and every participant will have an equal chance of being assigned to one of the groups.

One group will go through the usual procedures while the other group will go through the procedures under investigation. You will not know which group you have been assigned to so that we can reduce chances of influencing the results of the research. Once we have collected all the information we need, we will compare which of the two procedures has the best results.

The standard procedures of management within the post-natal wards will be instituted on the first group of participants. The other group will undergo examination by a doctor from the

children's unit. Upon discharge, we will continue following you up for a month. This will be done to determine whether your baby has experienced any symptoms, whether he/she has been admitted and what the outcome of that admission is. In the event of any illness, you can communicate with us (a number will be provided) in between our follow-up calls.

Risks

Participation in this study will not put you and your baby at any unusual risk. You and your baby will not be given any medicine other than those prescribed by your doctor. We therefore do not anticipate any drug side effects apart from those caused by any medicine your doctor might prescribe.

Benefits and Reimbursements

If you participate in this research, you will have the benefit of being able to communicate with a doctor even when at home during the first month. You will therefore be able to raise any queries and concerns any time during the one-month period and be advised accordingly. There will however be no monetary compensation and we will not be responsible for your mobile phone charges.

Confidentiality

The information that we collect from this research will be kept confidential and only the researchers will be able to see the information we collect. The results from the research will be provided to the university and Kenyatta National Hospital while maintaining confidentiality. At the end of the study, we will delete all the participants' mobile phone numbers.

Right to Refuse or Withdraw

You do not have to participate if you do not wish to do so, refusal will not affect you and your baby's treatment at this facility. If you agree to participate, you can stop participating at any time without losing any of your rights as a patient here.

Who to Contact

Veronica Obunga: 0721919802

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/month/year

Statement by person taking consent:
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1.
2.
3.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICF has been provided to the participant.

Print name of person taking the consent: _____

Signature of person taking the consent:_____

Date: _____
Day/month/year

Dr. Veronica Obunga 0721919802

Signature _____

Date _____

Supervisors

Prof. F. N. Were

Prof. D. Wamalwa

Dr. Nyambura Kariuki

ETHICS AND RESEARCH COMMITTEE.

KNH/UON-ERC

P.O. Box 20723, Nairobi

APPENDIX B

KIBALI CHA KUSHIRIKI KATIKA UTAFITI

Fomu kwa ajili ya watoto wachanga na mama zao, ambao wataalikwa kushiriki katika utafiti huu baada ya kujifungua katika Hospitali ya Taifa ya Kenyatta]

[Kanuni mpelelezi] - Dr Veronica Obunga

[Shule] - Mwanafunzi, Chuo Kikuu cha Nairobi, Idara ya Afya ya watoto

Utafiti: Viwango vya kulazwa hospitalini watoto wachanga waliozaliwa katika Hospitali ya Taifa ya Kenyatta ndani ya mwezi mmoja

Utapewa nakala hii.

SEHEMU I: Taarifa

Jina langu ni Dk Veronica Obunga,mwanafunzi katika Chuo Kikuu cha Nairobi.Ninafanya utafiti na ningependelea kuwakaribisha kushiriki katika huu utafiti, baada ya kuwapea habari kuuhusu.Kabla ya kufanya maamuzi yoyote, unaweza kushauriana namtu yeyote. Ukikosa kuelewa usisite kuuliza maswali.

Madhumuni ya utafiti

Ugonjwa na kifo ndani ya mwezi wa kwanza baada ya watoto kuzaliwa ni shidakubwa duniani kote.Hivi sasa 22 kati ya kila watoto 1,000 waliozaliwa watakufa ndani ya siku 28 za maisha.Nia yangu ni kutafuta njia ya kupunguza hii shida.Moja ya njia rahisi inaweza kuwa uchunguzi wa watoto baada ya kuzaliwa, hadi utekelezaji.Utafiti huu unafanywa ili kujua kama hii ni bora kuliko huduma ya kawaida sisi hutoa kwa watoto wachanga katika wodi ya uzazi.

Aina ya Utafiti

Utafiti huu utahusisha uchunguzi wa mtoto wako na baada ya hapo tutawafuatilia kwa mwezi kupitia simu ya mkononi.

Mshiriki uteuzi

Tunakaribisha mama yeyote ambaye amejifungua chini ya siku tatu iliyopita ambaye ana simu ya mkononi kushiriki katika utafiti huu

Ushirikishwaji wa hiari

Ushiriki wako ni hiari kabisa. Ukikubali au la, bado utaendelea kupokea matibabu katika hospitali hii.Ukichagua kushiriki unaweza kubadili akili yako baadaye na kuacha kushiriki.

Taratibu na Itifaki

Tunataka kutafuta tofauti kati ya matibabu aina mbili. Kila mshiriki ataekwa katika pande moja

ya utafiti na matibabu tofauti kutumiwa kakita kila kikundi.

Kundi moja watapewa matibabu kawaida wakati kundi lingine watapitia matibabu tofauti ambayo inachunguzwa.Hutaweza kujua kundi lakokwa ajili ya kupunguza uwezekano wa kushawishi matokeo ya utafiti.Baada ya kukusanya taarifa zote tunahitaji, tutalinganisha kundi hizo mbili na kuangalia matibabu gani ni bora kuliko nyingine.

Mkiwa nyumbani, tutaendelea kuwasiliana kupitia simu ya mkononi kwa muda wa mwezi mmojaili kuwajulia hali na kuwapa ushauri wowote.

Hatari

Kushiriki katika utafiti huu haitakuweka wewe na mtoto wako katika hatari yoyote mbali na ile ya kawaida.

Faida

Kushiriki katika utafiti huu itakupa faida ya kuwa na uwezo wa kuwasiliana na daktari hata mkiwa nyumbani.Hata hivyo hakuta kuwa na fidia ya fedha na hutalipiwa kutumia simu ya mkononi

Usiri

Habari kutokana na utafiti huu itakuwa siri ya watafiti.Matokeo kutoka utafiti zitatolewa kwa chuo kikuu cha Nairobi na Hospitali ya Taifa ya Kenyatta.

Haki ya kukataa

Kukataa kushiriki hakuta kuathiri wewe na mtoto wako.Ukikubali kushiriki, unaweza kuacha kushiriki wakati wowote bila chuki.

SEHEMU YA II: Kibali

Nimesoma maelezo haya/nimesomewa maelezo haya na nikapewa nafasi ya kuuliza maswali na yakajibiwa.Nimekubali kushiriki katika utafiti huu.

Jina la Mshiriki: _____
Sahihi ya Mshiriki: _____
Tarehe: _____
(Siku / mwezi / mwaka)

Taarifa iliyotolewa na mtafiti:
Nimempa mshiriki maelezo kuhakikisha kwamba mshiriki anaelewa kuwa yafuatayo yatafanyika:
1.
2.
3.
Nathibbitisha ya kwamba mshiriki alipewa nafasi ya kuuliza maswali kuhusu utafiti huu, na maswali yote yakajibiwa.Nathibitisha kuwa amekubali kuwa mshiriki katifa utafiti huu kwa uhuru na kwa hiari.

Mshiriki atapewa nakala hii.

Jina la mtafiti: _____
Sahihi: _____
Tarehe: _____
(Siku / mwezi / mwaka)

Dk Veronica Obunga 0721919802
Sahihi: _____
Tarehe: _____
Wasimamizi

Prof. F. N. Were
Prof. D. Wamalwa
Dk. Nyambura Kariuki

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KNH / UON-ERC
PO Box 20723, Nairobi

APPENDIX C

QUESTIONNAIRE SAMPLE

HOSPITALIZATION RATES OF BABIES BORN AT THE KENYATTA NATIONAL HOSPITAL WITHIN THE FIRST MONTH OF LIFE QUESTIONNAIRE

INTRODUCTION

A post-graduate student in the UON Paediatrics and Child Health department is carrying out this study. The main aim of the study is to determine the proportion of babies being admitted after being delivered at KNH. The information provided will be handled with confidentiality and you will not be identified by name.

Are you still willing to participate in the study? 1. Yes 2. No (Thank respondent and move to/look for the next respondent to interview**)**

Attach respondent's consent form with hospital and phone numbers

For Official Use Only

Interviewer Name :_____	Date of interview: _____
Questionnaire number :	Respondent's Phone Number:

SECTION A: DEMOGRAPHIC INFORMATION

Questions	Coding category (circle or tick)	Skip to Q
1) Age of respondent	**In complete years_____**	
2) Highest level of education attained	1. Primary 2. Secondary 3.College 4. University	
3) Marital Status	1 Single - Never married 2 Married 3 Separated/Divorced 4 Widowed	
4) Parity (this baby included)		
5) LNMP; EDD; GBD (at delivery)	Ask for LNMP then calculate the rest	
6) DOB (Baby's)	Age (completed days)	
7) Mode of delivery	1. SVD (duration of labour? PROM?) 2. Elective C/S (Include indication) 3. Emergency C/S (Include indication)	
8) Birth Weight (gms) and Length(cms)		
9) Gender	**M/F**	
10) Breastfeeding commenced within		
11) Current concerns? Including symptoms and signs		**Examine Baby fully as in Section B**

SECTION B: EXAMINATION OF NEONATE(Intervention Group)

Questions	Coding category (circle or tick)	Other
12) APGAR SCORE (as recorded)		
13) Head circumference		
14) General examination	1.Temperature 2. Pallor 3. Jaundice 4. Cyanosis 5. Dehydration	
2. Head	1. Scalp 2. Fontanelles 3. Ears 4. Eyes 5. Nose 6. Mouth 7. Palate	
3. Limbs, Fingers and Toes		
4. Respiratory System	1. Respiratory Rate 2. FAN, Indrawing 3. Breath sounds	
5. Cardiovascular System	1. Heart Rate 2. Pulses (including delays) 3. Apex 4. Heart Sounds 5. Murmurs	
6. Abdomen	1. Cord 2. Organomegaly	
7. CNS	1. Tone 2. Reflexes	
8. Anus and Genitalia		
9. Admission required?	1. Yes (impression and date) 2. No	

SECTION C: FOLLOW-UP

Questions	Coding category (circle or tick)	Other
10. Date of Discharge	1. From maternity ward 2. From NBU (Diagnosis, Duration, Outcome)	
11. Follow-up	1. Illnesses (symptoms? Diagnosis?) 2. Hospitalization? (Name of hospital) 3. Age at hospitalization 4. Duration of hospitalization 5. Outcome (Dead or Alive)	WHO 2014 Verbal Autopsy tool to be adopted

APPENDIX D

TIMETABLE

Activity	Action by	Period															
		Jan 15	Feb 15	Mar 15	Apr 15	May 15	Jun 15	Jul 15	Aug 15	Sep 15	Oct 15	Nov 15	Dec 15	Jan 16	Feb 16	Mar 16	Apr 16	May 16
Writing Research Proposal	Student																	
Revising and Finalizing Proposal	Student & Supervisor																	
Ethical Approval	KNH-ERC																	
Data Collection	Student R. Assistant																	
Data Checks and Cleaning	Student																	
Data Analysis and Interpretation	Student Biostatistician																	
Writing up	Student Supervisor																	
Dissertation submission	Student																	