UPTAKE OF NEONATAL VITAMIN K PROPHYLAXIS IN THE POSTNATAL WARDS OF KENYATTA NATIONAL HOSPITAL

BY

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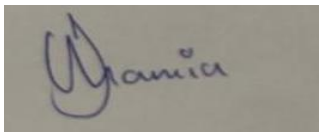
A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF MASTER OF MEDICINE IN PAEDIATRICS AND CHILD HEALTH, UNIVERSITY OF NAIROBI.

DECLARATION

I declare that this dissertation is my work and has not been published or presented for a degree in any other institution.



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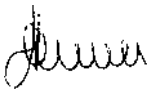
This dissertation has been presented with our full approval as supervisors.



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DEDICATION

I dedicate this work to my wife, Margaret and my daughter, Nylah. I hope the sacrifices you have endured for me to pursue this dream will be repaid to you with many opportunities for joy and success in your future.

OPERATIONAL DEFINITIONS

Neonate- A baby from birth to about 28 days of age.

Uptake – Utilization of an item.

Prophylaxis- A preventive measure.

Mortality-The state of being subject to death.

Metabolism-The chemical process that occur in a living organism to maintain life.

Malabsorption- Imperfect absorption of food material by the small intestine**.**

Disability-Physical or mental condition that limits a person movements, senses, or activities.

Absorption-The state of being engrossed in something.

Perspective-A particular attitude towards or way of regarding something.

ABBREVIATIONS

VKDB – Vitamin K deficiency bleeding

LMIC- Low- and middle-income countries

I.M – Intramuscular

Kg- Kilograms

mg- Milligrams

VK- Vitamin K

PIVKA II- Protein induced by vitamin K absence or Antagonist-II.

RCT- Randomized control trial

GFA- Ground Floor A

GFB- Ground Floor B

1A- Ward 1 A

ANC- Antenatal care

C/S- Caesarean section

SVD- Spontaneous vaginal delivery

CI- Confidence interval

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ABSTRACT

Background:

Vitamin K can prevent Vitamin K deficiency bleeding in neonates which is an infrequent (4.2 to 7.8 per 100000 live births) but a dangerous condition which can cause permanent disability and has a high mortality. Vitamin K is readily available low cost, safe and easy to use. Neonates have insufficient levels of vitamin K placing them in danger of vitamin K deficiency bleeding. Current Kenyan clinical practice guideline in line with World Health Organization promotes universal vitamin K prophylactic use in neonates.

Objectives

To determine the proportion of neonates who receive vitamin K prophylaxis at postnatal wards in Kenyatta National Hospital and to access factors affecting uptake of vitamin K prophylaxis at postnatal wards in Kenyatta National hospital.

Methodology

A hospital-based descriptive cross-sectional study. Quantitative analysis was used to determine the number of neonates who receive vitamin K prophylaxis, while qualitative analysis was used to assess factors affecting the uptake of vitamin K prophylaxis in the postnatal wards of Kenyatta National Hospital. The proportion of neonates who received Vitamin K prophylaxis was analyzed as proportion and key informant interview data was analyzed thematically.

Results

A total of 384 neonates were enrolled. The uptake of intramuscular Vitamin K in the study was very low at 6.8% with a 95% confidence interval. (26/358). There were no clinical factors i.e., parity, induction, mode of delivery and neonate gender that were statistically associated with uptake of vitamin K. Factors affecting uptake of vitamin K in postnatal ward in KNH were inconsistence stock, stock outs, lack of awareness and sensitization, lack of a follow up strategy for accountability purposes, lack of proper formulations (available formulations included 2mg and 10mg vial but the health workers preferred the 1mg vial) and low ratio (1:10) of health worker to patient.

Conclusion

Although prophylactic administration of vitamin K to neonates is relatively well integrated into policy at the global and national level the uptake in Kenyatta National Hospital is very low. Barriers to vitamin K administration were supply and access to the drug, lack of awareness and documentation, inadequate number of healthcare providers and perception that vitamin K prophylactic treatment is not a priority.

SECTION ONE: INTRODUCTION

Vitamin K acts as a cofactor for a carboxylase that catalyses carboxylation of glutamic acid residues of coagulant factors II, VII, IX, X, protein S and C (1).Vitamin K deficiency causes insufficient activity of these factors, resulting in coagulopathy (2). VKDB is an infrequent(4.2 to 7.8 per 100000 live births) but a dangerous condition which can cause permanent disability and high risk of mortality (3).It can be obviated by vitamin K administration which is cheap, accessible and safe to use.

Neonates are susceptible to VKDB (4). Transplacental passage of VK and hepatic storage of VK is limited (5). The neonate's intestinal tract is relatively sterile and gut colonization that is important for its synthesis takes days to form. Vitamin K is low in breast milk (1-4 μ g/L) (5). Neonates who are exclusively breastfed have gut colonization with lactobacilli which do not synthesize VK (6).

1.1 METABOLISIM OF VITAMIN K

Absorption of vitamin K requires unimpaired pancreatic and biliary function and fat absorptive processes. Dietary vitamin K is protein bound and is released into the small intestine because of proteolytic process of pancreatic enzymes. Bile salts then solubilize vitamin K into mixed micelles for ingestion into enterocyte whereby its incorporated into chylomicrons, this will promote assimilation into the intestinal lymphatics and portal circulation for transfer into the liver (7). Vitamin K is stored in the liver as 90% menaquinones and 10% phylloquinones (8).

1.2 TYPES OF VITAMIN K

1.Vitamin K1 or Phylloquinones is plant based and is the main form in diet used mainly for blood clotting (2,9).

2.Vitamin k2 or Menaquinone is synthesized by bacteria in the large intestines and is used in metabolism, bone mineralization, cell growth and metabolism of blood vessels wall cells (2,10).

3.The synthetic form menadione (Vitamin K3) is not used anymore due to possible toxicity(11). It has been reported to cause hemolytic anemia(2).

1.3 VITAMIN K DEFICIENCY BLEEDING

VKDB has been classified into three forms:

A. Early

Presents with bleeding within 24 hours and confined to neonates whose mothers are taking medication that prevent synthesis of VK (12).These include anti-tubercular drugs (Rifampin, isoniazid), anticoagulants and anticonvulsants (phenytoin, barbiturates, carbamazepine). Common bleeding sites include cephalohematoma, intracranial, intrathoracic, intrabdominal and umbilicus (2). This condition can be obviated by administering VK to the mother receiving such drugs at least 24 hours prior to delivery and/or withdrawing the offending drugs. Administration of VK to the neonate doesn't prevent early VKDB.

B. Classical

It occurs 1-7 days after birth (13). The areas of bleeding include the umbilical stump, gastrointestinal tract and surgical sites such as circumcision (2).Classical VKDB is common in breastfed babies than those who are formula-fed (14).Administration of vitamin K to the neonate inhibits classical VKDB (15).

C. Late

This occurs at 2-12 weeks after birth but can occur up to 6 months of age. Neonates on antibiotics and those with bowel malabsorption are in danger of this condition. Intracranial hemorrhage is common. The other areas of bleeding are gastrointestinal tract, mucus membranes, and skin (2). Parenteral neonate VK prophylaxis averts late VKDB apart from those with severe malabsorption syndromes.

1.4 INTRAMASCULAR VITAMIN K PROPHYLAXIS FOR VITAMIN K DEFICIENCY BLEEDING

A Lancet article in the 1940's demonstrated a fivefold decrease in death from bleeding in infants who received 1mg of vitamin K3(menadione) after birth. The findings brought immense importance in routine vitamin K prophylaxis. With the introduction of vitamin K1 in place of vitamin K3(associated with haemolysis), most countries begun using routine VK (16).

The Basic pediatric protocols from Ministry of Health in Kenya 4th edition 2016 indicates that.

1. VK should be administered to all neonates in healthcare facilities immediately after birth.
2. VK should be administered to less than 2-week-old babies admitted in the hospital and to the ones delivered at home.
3. For babies ≥ 1.5kg give IM 1mg of VK and babies <1.5kg give IM 0.5mg (17).

World Health Organization recommendation on vitamin K deficiency bleeding prophylaxis using vitamin K.

1mg of IM vitamin K should be administered to all babies within one hour of delivery. Meanwhile the mother is encouraged to breastfeed and put the baby in skin-to-skin contact.

Preterm neonates (<36 weeks and/or <2.5kg) should receive 0.5mg to a maximum of 1 mg (18).

The American Academy of Paediatrics suggested VK prophylaxis in 1961 and 1993 by using either 0.5 to 1.0 mg vitamin K parenteral or 1.0 to 2.0 mg orally. As a standard of care for healthy neonates, the I.M injection of 1mg of vitamin K at birth was suggested in 2003 by the American Academy of Paediatrics (19).This policy is therefore widely used throughout the world. Evidence from epidemiological surveillance data have demonstrated classic and late VKDB (incidence <0.2/100.000) are practically prevented under this strategy (20).

1.5 ORAL VITAMIN K ADMINISTRATION

Parents who refuse I.M vitamin K prophylaxis should be advised on oral dose of 2.0mg VK at the time of the first feeding, to be repeated at 2 to 4 and 6 to 8 weeks of age.(21)

SECTION TWO: LITERATURE REVIEW

2.1 UPTAKE OF VITAMIN K WORLDWIDE

There is limited data internationally on uptake of VK. Australia, New Zealand, and Canada are the only countries that have data published. In Otago New Zealand, IM uptake was 92.9%, oral uptake at 5.4% and refusal of VK at 1.7%. In New South Wales, Australia data showed 96.3% of IM uptake,2.6% of oral uptake and refusal of VK at 1.2%.The best uptake was from Albert, Canada with 99.3% of IM uptake and 0.4% of oral uptake with only 0.3% declining (23).There is no regional or local data on uptake of vitamin K prophylaxis.

2.2 VIEWS OF NEONATAL VITAMIN K ADMINISTRATION IN LOW-AND MIDDLE-INCOME COUNTRIES

A formative online survey of global neonatal health stakeholder was carried out by Coffee et al. They emailed the survey to 109 people mainly from low- and middle-income countries and received 23 replies that contributed to an answer rate of 21%. They got one reply each from Philippines, Denmark, Nigeria Cameroon, South Sudan, Dominican Republic, Nepal, Rwanda, Ethiopia, Zimbabwe, Papua New Guinea, Zambia, and Serbia, two replies each from Malawi, India, and the United States of America and four responses from Kenya. They found that national prevalence rate on VKDB was mostly not backed by enough data. Most (17/23) reported that VK is part of their guidelines and polices, while (12/23) reported widespread use of VK at birth. About half of those interviewed reported having qualified health workers who could identify and manage VKDB. The four responses from Kenya stated that health workers have not received training to diagnose and treat vitamin K deficiency bleeding. One out of four (1/4) indicted that they were not aware that VK is covered in the guidelines and policy, while two out of four (2/4) stated that vitamin K prophylactic administration after birth was not common. Barriers to vitamin K prophylaxis were, insufficient access, home delivery,

assumption that VK is not important, cultural practices that imply injections at birth is not agreeable to parents, lack of formulation of vitamin K suitable for neonates and not including VK in national guidelines and polices. They determined that recommendation of VK after birth is adequately incorporated into regional and national level, however its practice is underutilized. More research using in-depth country level bottleneck analysis may help identify concrete changes to the health care system (24).

2.3 INCIDENCE OF LATE VITAMIN K DEFICIENCY BLEEDING

M J Sankar et al. systematically searched MEDLINE and other online repositories. They found that late VKDB had a high incidence if VK wasn't administered after birth. The median (interquartile range) burden of late VKDB was 35(10.5 to 80) per 100000 live births overall. In LMIC was 80(72 to 80) per 100000 live births and high-income countries was 8.8(5.8 to 17.8) per 100000 live births (16).

2.4 FACTORS INFLUENCING THE UPTAKE OF NEONATE VITAMIN K

An association between leukaemia and IM vitamin K was brought up in 1992.Although these issues have not been subject to rigorous scientific review, there are still doubts about its safety. This was illustrated in a current study of vitamin K perceptions among NZ health care professionals. Universal administration of vitamin K was backed by all obstetricians and paediatricians but only approved by 55% of midwives. This indicates that professional factors may be associated with decreased vitamin K uptake(6).

2.5 PERINATAL INFLUENCES ON THE UPTAKE OF NEONATE VITAMIN K PROPHYLAXIS

Malihah Burke et al. performed a retrospective cohort study to investigate the connection between oral and IM VK with factors such as healthcare professionals, social demographic, and infant. During the time of the study, they enlisted 7,089 live births and established that IM uptake was 92.9% (6513), oral uptake was 5.4% (377) and 1.7% (119) received no VK. Vitamin K rejection was corelated with vaginal delivery, gestational age per additional week and Asian ethnicity. The probability of getting oral vitamin K was raised by having an obstetric nurse lead maternity carer. Increased lead maternity carer experience was affiliated with a reduced oral uptake of VK. The study exposed significant novel association of IM and oral VK. They concluded that ethnicity and infant factors affects uptake of vitamin K.(6)

2.6 VITAMIN K DEFICIENCY BLEEDING AND EARLY INFANT MALE CIRCUMCISION

World health organization (WHO) recommends that circumcision of males to be done between the first day of life until the 60^{th} day of life as a measure to reduce risk of human immunodeficiency acquired by heterosexuality(25). Post circumcision bleeding is common in breastfed infants. One of the rationales given by parents for avoiding circumcision in Kenya was fear of bleeding. Circumcision can be complicated with excessive haemorrhage with some cases requiring transfusion. VK can be used to prevent and treat post circumcision bleeding. VK awareness should be increased as sub-Saharan countries are prepared to intensify early infant male circumcision as part of human immunodeficiency strategies. There was a possible case of VKDB that happened during an infant circumcision clinical trial in Botswana, a country where vitamin K is routinely given after birth. Five incidents of minor bleeding occurred among 150 neonates circumcised and were well controlled by application of local pressure. A sixth neonate however kept on bleeding for more than one and half hours

regardless of local pressure application. No cause of bleeding could be found. Upon finding that this neonate was not given VK after delivery, 2mg of vitamin K1 IM was administered and bleeding seized in a half hour. VK has a fast onset and is easily affordable. VK is an important factor for ensuring standard coagulation and its deficient in neonates. Providing VK after birth is mandatory (26).

2.7 PREVENTION OF VITAMIN K DEFICIENCY BLEEDING

1700 in 100,000(1 out of 59) neonates that do not receive VK may possibly develop VKDB. If I.M VK is given the incidence of VKDB decreases to 1 in 100,000 (27). The incidence seems rare but if it happens has high morbidity and mortality. VKDB has increased due to not providing VK prophylaxis at birth. All healthy neonates require VK prophylaxis. Providing VK to neonates is important especially in resource limited areas (24).

2.8 PREVALECE AND PREDICTORS OF FUNCTIONAL VITAMIN K INSUFFICIENCY IN MOTHERS AND NEONATES.

Data Santorino et al. estimated the frequency of neonates bleeding in Uganda by performing a retrospective chart review from June-August 2010 at Mbarara regional referral hospital in southwestern Uganda where vitamin K is not always given to neonates after delivery. They enrolled 141 mother-baby pairs collected dietary, social, and demographic data. Specimens for maternal venous and neonatal cord blood were paired for the immunoassay of undercarboxylated prothrombin (PIVKA-II) a gold standard measurement for functional vitamin K deficiency in relation to its coagulation function. They observed that 33% (47/141) of mothers and 66% (93/141) of babies had vitamin K deficiency. There was no maternal or infant clinical or dietary predictors of vitamin K deficiency, promoting a plan of universal administration of neonatal VK to avert VKDB(22)

Table 1: Summary of studies in literature review

Author, Year of study, Country	Study title	Methodology	Conclusion
Coffey et al. 2018 United states of America	Current perspectives and practices of neonate vitamin K administration in low- and middle-income countries	Formative on-line survey of global stakeholders involved in neonatal health	Prophylactic administration of vitamin K to neonates is relatively well integrated into policy at the global and country levels, but its practice is underutilized.
M J Sankar et al. 2016 India	Vitamin K prophylaxis for prevention of vitamin K deficiency bleeding.	Systematic review	Given the high risk of mortality and morbidity in infants with late VKDB, it seems advisable to administer IM vitamin K prophylaxis to all neonates at birth
Malihah Burke et al. 2015 Australia	Perinatal influences on the uptake of neonate vitamin K prophylaxis	Retrospective cohort study	This study reveals several important and novel associations with mode of administration of neonate vitamin K prophylaxis.
Rebeca M. Plank et al. 2013 United states of America	Vitamin K deficiency bleeding and early infant male circumcision in Africa	Systematic review	Vitamin K is cost effective. There is need to improve availability and awareness in LMIC.
Julia C Phillipi et al. 2016 United states of America	Prevention of vitamin K deficiency bleeding	Systematic review	Prophylaxis is needed even for all healthy neonates.
Dan Santorino et al. 2010 Uganda	Prevalence and predictors of functional vitamin K insufficiency in mothers and neonates.	Retrospective chart review	Lack of identifiable predictors of neonate Vitamin K insufficiency supports strategies of universal VK prophylaxis

THEORETICAL FRAMEWORK

The theoretical framework of this study is drawn from current perspectives and practices of neonate's vitamin K administration in low- and middle-income countries by Coffee et al. and the basic pediatric protocol from ministry of health in Kenya 4th edition 2016.

Coffee et al. reported that vitamin K deficiency in LMIC may be common referring to a study done in Uganda where they found that 33% of the mothers and 66% of neonates had insufficient levels of vitamin K. They also stated that the incidence of VKDB in LMIC had a fourfold increase above developed countries due to a relative higher level of exclusive breastfeeding and nutritional deprivation. They also that barriers to vitamin K administration in LMIC included insufficient access, home delivery, assumption that VK is not important, cultural practices that imply injection at birth is not agreeable to parents and lack of formulation of vitamin K that is suitable for neonates.

On the other hand, the basic pediatric protocol from indicates that VK should be administered to all neonates in healthcare facilities immediately after birth.

These two sources provide the basis on which the study shall determine and asses the factors affecting the uptake of prophylactic vitamin K in Kenyatta National Hospital. They provide information that prophylactic administration of vitamin K is needed for all neonates to prevent VKDB which is a dangerous condition which can cause death or permanent disability.

SECTION THREE: JUSTIFICATION AND UTILITY

Neonates are vitamin K deficient. Providing VK after delivery is an essential safe and sustainable approach to avert VKDB. The Kenyan clinical guidelines in line with world health organization promote universal prophylactic administration of Vitamin K after birth. This research will promote uptake of vitamin K reducing the burden of VKDB which has a high risk of mortality and permanent disability.

Worldwide there is limited data on uptake of prophylactic vitamin K, with literature only published from high income countries. Currently there is no regional or local research on uptake of vitamin K. This research will help generate local data of vitamin K that can be used in other studies.

Although prophylactic administration of vitamin K to neonates is relatively well integrated into policy at the global and country levels, its practice appears to be underutilized. This study will sensitize and help create awareness among health workers on the importance of vitamin K.

This study will help establish the determinants of uptake of vitamin K to enhance vitamin K uptake.

3.1 RESEARCH QUESTION.

What is the uptake of vitamin K prophylaxis in neonates at postnatal wards in Kenyatta National Hospital?

3.2 **PRIMARY OBJECTIVE**

To determine the proportion of neonates who receive Vitamin K prophylaxis at postnatal wards in Kenyatta National Hospital.

3.3 **SECONDARY OBJECTIVE**

To assess factors affecting uptake of vitamin K prophylaxis at postnatal wards in Kenyatta National Hospital.

SECTION FOUR: METHODOLOGY

4.1 STUDY SETTING

The setting of the study was at the postnatal wards in Kenyatta National Hospital, the largest and oldest public main referral hospital for East and Central Africa. Kenyatta National Hospital also serves as a teaching hospital for the University of Nairobi College of Health Sciences.

There are three postnatal wards in Kenyatta National Hospital (GFA, GFB and 1A). These units are headed by a consultant. Each unit has a nursing in charge, deputy nursing charge and obstetrics and gynecology residents. There are also nurses with diverse experience and qualification in neonatal care. Each ward has a holding capacity of 32 neonates. Each ward admits approximately 15-20 neonates on consecutive days.

4.2 STUDY DESIGN

A hospital-based descriptive cross-sectional study. Quantitative analysis was used to determine the number of neonates who receive vitamin K prophylaxis in the postnatal wards of Kenyatta National Hospital while qualitative analysis was used to assess factors affecting the uptake of vitamin K prophylaxis in the postnatal wards of Kenyatta National Hospital. The qualitative data was used to explore quantitative findings.

4.3 QUANTITATIVE COMPONENT

4.3.1 STUDY POPULATION

Study population included 384 neonates admitted into the postnatal wards during the study period.

INCLUSION CRITERIA

All neonates born in Kenyatta National hospital and taken to postnatal wards during the study period.

Neonates whose guardians/parents gave consent to participate in the study.

EXCLUSION CRITERIA

All neonates born outside Kenyatta National Hospital and neonates admitted in newborn unit.

4.3.2 SAMPLE SIZE

The sample size was determined by using the Fisher's formula. Since there is no information in low middle-income countries or local data on uptake of vitamin K prophylaxis a prevalence of 50% was used to achieve maximum sample size.

Fisher's formula.

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

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = 50% (since there is no information in low middle-income countries or local data on uptake of vitamin K prophylaxis)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.50(1-0.50)}{0.05^2} = 384$$

A Sample size of 384 neonates will be required for the study.

4.3.4 SAMPLING METHOD

Currently in the postnatal wards of Kenyatta National Hospital approximately 15 neonates are admitted per day. This amounts to 105 neonates per week,420 per month and 1260 within the study period of 3 months. Systematic sampling will be used because it a low risk of data manipulation and the results will be representative of most normal population.(28)

$$\frac{\text{Total estimated study population}}{\text{Sample population}} \quad \frac{15 \times 30 \times 3}{384} = 3.5 \sim 4$$

15- Estimated number of neonates admitted per day.
30- Thirty days in a month.
3- Number of months during the study period.
384- Sample size for the study.

Therefore, the sample interval =4

Since the sample interval was 4, every 4^{th} child will be picked.

4.3.5 STUDY PERIOD

The study was conducted between January 2021 and March 2021.

4.3.4 STUDY PROCEDURE

The principal investigator or pre trained research assistant visited the postnatal ward in Kenyatta National Hospital between 10 am to 3 pm each day including weekends to recruit neonates during the study period. The research assistant was a qualified health record information officer who has a certificate of clinical research from collaborative institutional training initiative. The principal investigator trained the research assistance on data entry in the newborn record data abstraction.

Potential study participants were identified using inclusion and exclusion criteria. Parent of the participant were informed about the purpose of the study and allowed to ask questions for clarification. The questions were answered satisfactorily, and then informed consent obtained. Those who consent upon discharge the ANC booklet and nursing Kardex was analysed to determine if vitamin K was administered. If not administered data was recorded in the newborn record data obstruction and the nurse in charge and obstetrics and gynaecology residents informed.

4.3.5 DATA COLLECTION

The data was collected by the Principal Investigator and trained research assistant. The study tool was newborn record data abstraction. The newborn record data abstraction was developed in 2006 as part of the emergency treatment and triage plus admission approach. It is divided into different sections which include: (1) relevant maternal history, (2) babies' biodata and clinical history, (3) babies' examination findings and admission vital signs, (4) the basic laboratory tests ordered and (5) primary and secondary diagnosis on admission.

The newborn data abstraction tool has a treatment sheet part where data on vitamin K administration will be recorded. The source documents for the study was records (ANC booklet, Nursing Kardex).

4.3.6 DATA MANAGEMENT

Data was collected using the study instruments and entered a customized MS Access data base.

The proportion of neonates who receive Vitamin K prophylaxis at postnatal wards in Kenyatta National hospital was analysed as proportions.

Data was entered and analysed using SPSS version 23. All statistical tests with a p-value <0.05 was considered significant.

4.3.7 DATA STORAGE

Hard copies of data was stored in a lockable safe.

4.4 QUALITATIVE COMPONENT

4.4.1 RESEARCH TEAM AND REFLEXIVITY

PERSONAL CHARACTERISTICS

The principal investigator conducted the key informant interview, he has a degree in Bachelor of Medicine and surgery currently a paediatric resident in the university of Nairobi.

RELATIONSHIP WITH PARTICIPANTS

There was no relationship established with participants prior to the commencement of the study.

4.4.2 STUDY DESIGN

THEORETICAL FRAMEWORK

The methodological orientation stated to underpin the study was ground theory. Ground theory sets out to discover or construct theory from data, systematically obtained and analysed using comparative analysis.

PARTICIPANT SELECTION

Purposive sampling was used to select participants. A sample size of 10 key informants was targeted. Participants included nurses in charge, obstetrics and gynaecological residents, obstetrics and gynaecological consultants and pharmacists.

SETTING

The interviews were face to face interview conducted in Kenyatta National Hospital. It included the principal investigator, research assistant and the key informant. Non- participants were not allowed during interviews.

STUDY PROCEDURE

The principal investigator planned on the location and time for the qualitative interview. Consent to audio and transcription was sought from the key informants which includes nurses, pharmacists, and doctors. Those who consent had an interview focusing on factors affecting the uptake of vitamin K. Factors included barriers to vitamin K prophylaxis, availability of vitamin K and importance of vitamin K.

DATA COLLECTION

The data was collected by the Principal Investigator and trained research assistant. The study tool was qualitative interview with key informants.

4.4.3 DATA ANALYSIS

Key informant interview data was recorded transcribed verbatim and imported into NVivo software for analysis. Soft copies of data was stored in a password protected folder.

4.5 ETHICAL CONSIDERATION

Ethical approval was sought from the KNH/UoN research and ethics committee. Data collection and analysis did not commence before ethics approval. Informed consent was administered to all participants. The informed consent form was administered by the principal investigator and study assistant. Persons who decline to provide informed consent were not allowed to participate in the study. Persons who choose to withdraw from the study were not disadvantaged in any way.

There were no potential risks to the patients during the study, as no invasive procedures was performed on them. Confidentiality was maintained throughout by storing all data in secure cabinet that remained locked during the study period.

4.6 QUALITY ASSURANCE OF THE DATA

The admission numbers of those participating in the study was serialized to help avoid double participation. In case of noted double entry, both newborn record data abstraction was discarded.

The research assistant is a qualified health record information officer who has a certificate of clinical research from collaborative institutional training initiative. The principal investigator trained the research assistance on data entry in the newborn record data abstraction.

The newborn record data abstraction was developed in 2006 as part of the emergency treatment and triage plus admission approach. It is divided into different sections which include: (1) relevant maternal history, (2) babies' biodata and clinical history, (3) babies' examination findings and admission vital signs, (4) the basic laboratory tests ordered and (5) primary and secondary diagnosis on admission.

Each newborn record data was checked daily to ensure that they do not contain personal identifiers to protect confidentiality of the participants. Any personal identifiers was removed. The newborn record data abstraction was safely locked in a cabinet that was only accessible to the principal investigator.

Recordings and transcripts was saved on a password protected laptop and protected external hard drive that was safely locked in a cabinet only accessible to the principal investigator and research assistance. All information that was shared during the key informant interview was treated with utmost confidentiality. Names or any other identifier was not recorded in any form. Instead, they were allocated a random number. This ensured that the principal investigator was able to know who answered the question.

The principal investigator and the research assistance did a pre-test the newborn record data abstraction tool and key informant interview guide at Kenyatta National Hospital. This was to evaluate validity and reliability of the tool.

4.7 DISSEMINATION OF RESULTS

The results compiled shall be submitted to the department of Paediatrics and Child health as hard and soft copies. These shall be presented as a poster to the faculty at the conclusion of the study. Copies of the result shall also be sent to the University of Nairobi repository for storage. The findings shall also be shared with the office of the head of department paediatrics in KNH with a view of dissemination of the new knowledge that has been generated to improve patient care.

After the audit, I will conduct CME sessions with postnatal ward staff on essential postnatal care for all babies which includes vitamin K prophylaxis. Components will be adopted from the basic paediatric protocol from ministry of health in Kenya 4th edition 2016 and World Health Organization recommendation on VKDB prophylaxis using VK.

Components on the basic paediatric protocol states that: All babies born in hospital should receive Vitamin K soon after birth. If born at home and admitted aged < 14 days give Vitamin K unless already given. 1mg Vitamin K IM if weight is ≥ 1.5kg, 0.5mg IM if weight <1.5kg.

World Health Organization recommends 1mg of IM vitamin K should be administered to all babies within one hour of delivery. Meanwhile the mother is encouraged to breastfeed and put the baby in skin-to-skin contact. Preterm neonates (<36 weeks and/or <2.5kg) should receive 0.5mg to a maximum of 1 mg.

SECTION 5: RESULTS

The study recruited 384 neonates; 26 neonates received vitamin K giving an uptake of 6.8% with a 95% confidence interval.

Socio-demographic characteristics of neonates.

The characteristics of neonates admitted at the postnatal wards in Kenyatta National Hospital are shown in Table 1. The neonates comprised 49% (189 males). The median gestational age in weeks was 39 weeks. (IQR 38 to 40 weeks) and the birth weight (Mean±SD) was 3173 ± 486. 33% of the neonates were discharged less than 24 hours, 40% discharged within 25-48 hours and 27% discharged more than 48 hours.

Table 1. Neonates Characteristics

Variables	**Frequency**	**Percentage**
Gender n (%)		
Male	189	49
Female	195	51
Gestational age in weeks Median (IQR)	39(38-40)	
Birth weight Mean±SD	3173 ± 486	
Age at discharge in hours n (%)		
≤24 hours	128	33
25-48 hours	152	40
>48 hours	104	27

Socio-demographic characteristics of mothers.

Most of the neonates in the study were delivered through spontaneous vaginal delivery that is 61% (243/384), Cesarean section accounted for 37% (141/384), assisted delivery 1% (4/384) and breech 1% (5/384). Table 2 are results of maternal characteristics.

Induction or Augmented labor accounted for 11% (40), while no induction or augmented labor accounted for 83% (320) and 6% (24) were unknown.

Majority of the mothers were HIV negative accounting for 89% (341) while HIV positive were 5% (21) and unknown 5% (22). Out of the 5% of mothers who were HIV positive 81% (17) were on ARVs while 19% (4) were not on ARVs. Percentage of seroexposed neonates on prophylaxis was 81% (17) while 19% (4) had no prophylaxis.

Table 2. Maternal Characteristics.

Variables	Frequency	Percentage
Mode of delivery n (%)		
SVD	243	61
CS	141	37
Assisted	4	1
Induction/Augmented n (%)		
Yes	40	11
No	320	83
Unknown	24	6
HIV Status n (%)		
Positive	21	5
Negative	341	89
Unknown	22	6
HIV positive (mother on ARVs) n (%)		
Yes	17	81
No	4	19
Seroexposed (child on prophylaxis) n (%)		
Yes	17	81
No	4	19

Uptake of Vitamin K

The uptake of intramuscular Vitamin K in the study was 6.8% with a 95% confidence interval. (26/358). Results are presented in Table 3.

Table 3. Uptake of Vitamin K

Uptake	Frequency(n=384)	Percentage (%)
Yes	26	6.8 (95% CI)
No	358	93.2

Table 4. Factors associated with Vitamin K uptake.

A. Clinical

		Uptake of Vitamin K			
	n	**Yes, *n (%)***	**No, *n (%)***	**OR (95% CI)**	**p-value**
Parity					
Para 1+0	123	7 (26.9)	116 (32.4)	Reference	
Above Para 1+0	261	19 (73.1)	242 (67.6)	1.3 (0.5 – 3.2)	0.564
Induction/Augmented					
Yes	40	1 (3.8)	39 (10.9)	Reference	
No	320	22 (84.6)	298 (83.2)	2.9 (0.4 – 22.0)	0.308
Unknown	24	3 (11.5)	21 (5.9)	5.6 (0.5 – 57.0)	0.148
Mode of delivery					
SVD	234	16 (61.5)	218 (60.9)	Reference	
C/S	141	10 (38.5)	131 (36.6)	1.0 (0.5 – 2.4)	0.925
Assisted	0	0 (0.0)	4 (1.1)	-	
Breech	0	0 (0.0)	5 (1.4)	-	
Neonate gender					
Male	189	11 (42.3)	178 (49.7)	Reference	
Female	195	15 (57.7)	180 (50.3)	1.3 (0.6 – 3.0)	0.467

Table 4 shows results of clinical factors associated with vitamin K. Above Para 1+0 were 1.3 times more likely to receive vitamin K compared to Para 1+0 but there was no significant association. Mothers who did not receive induction were 2.9 times more likely to receive vitamin K compared to the ones who received induction but there was no significant association. Neonates who delivered via C/S were 1.0 times more likely to receive vitamin K as compared to SVD but there was no significant association. Female neonates were 1.5 times more likely to receive vitamin K as compared to males, but no significant association was found. There were no factors which were statistically significant associated with the outcome.

Factors affecting uptake of vitamin K prophylaxis.

1.Inconsistence stock. It was reported that vitamin K is not adequately stocked in labour ward and maternity theatre. There is a delay in restocking hence some babies are discharged without receiving vitamin K.

2. Stock outs. There was a national stock out of vitamin K last year from 22nd January 2020 to 6th November 2020.

3.Lack of awareness and sensitization which makes vitamin K prophylactic treatment not a priority among health workers.

4.Lack of proper formulations of vitamin K. The available formulation in the hospital is 2mg and 10mg vial which takes time to prepare because it must be shared among babies. They opted for 1mg vial which is easy to prepare.

5.Lack for a follow up strategy for accountability purposes.

6.Low ratio of health workers to patient in labour ward. The ratio of health workers to patient is 1:10. This overburdens the health worker with the amount of work, making it difficult to ensure that all neonates receive vitamin K.

Key informant interviews

The key informant interviews were face to face interviews conducted in Kenyatta National Hospital. Consent to audio and transcription was sought from key informants. Key informants included four nurses in charge, two Pharmacists allocated to labor ward and maternity theatre, four obstetrics, and gynecology residents.

Key findings: Vitamin K prophylaxis treatment in KNH

<u>Theme 1</u>: Availability of Vitamin K

Although vitamin K is available in Kenyatta National Hospital, the stock is very inconsistent. The stock in theatre is not usually well stocked and therefore not readily available.

"***R: To be honest it is not readily available". (nurse)***

"R: Vitamin K is available in KNH however, the stock in theatre is not usually well stocked that much often so at times we don't have it". (nurse)

The pharmacists reported that they have the 2mg and 10mg vial of Vitamin K in Kenyatta National Hospital.

<u>Theme 2</u>: Barriers to use Vitamin K prophylaxis

There are several barriers to use of vitamin k prophylaxis treatment at Kenyatta National Hospital. Majorly, there are stock outs making it difficult to administer vitamin k to the recipients. The restocking takes a bit of time and the health providers reported that this causes some babies to go without the drug.

"R: Yes, there is a time when it is not available within the hospital, so the children go home without vitamin k". (nurse)

"R: We have stock out of late because I have not seen any administration of vitamin K on newborn". (nurse)

"R: Yes, because it is not readily available, we think it is out of stock". (nurse)

However, it was reported that occasionally the parents or caretakers are given prescriptions to go and buy the drug from the chemists. Another mode of mitigation is that once there is stock-out in theatre, they depend on the wards to administer vitamin k to the babies or borrow from the wards to theatre.

"***R: When we don't have, we solely depend on the wards to administer the vitamin K to babies, that has been the case, we depend on the wards". (nurse)***
"R: By giving prescriptions for parents to buy from the pharmacy/ chemist". (nurse)

Another barrier to use of vitamin K prophylaxis treatment in Kenyatta National Hospital is lack of awareness, documentation, and protocol. There is need for sensitization to the health care providers in the administration and preparation of vitamin k.

"R: There is no sensitization on vitamin K administration and there is no strict protocol whereby a child has been born and have to be administered with vitamin K". (resident)

"R: There is no strict protocol on new-born administration of vitamin K". (nurse)

"R: Sensitization to all health workers should insist that vitamin k is given". (resident)

There are few paediatric nurses deployed who are trained in neonatal care and therefore the professionals are not enough. Sometimes the labour ward is overworked by the workload and at times the midwives are not able to handle the babies born in the administration of vitamin k prophylaxis treatment.

"R: We need more paediatric nurses or those trained in neonatal care instead of depending on the midwives to give vitamin k and yet they are overwhelmed". (nurse)

"R: We only have one paediatric nurse in our unit which is a challenge". (nurse)

The professionals administering the vitamin k prophylaxis treatment reported that it takes time prepare the 2mg which is shared between two babies. It was reported that the preparation process for the 2mg is challenging, and the preference is on the 1mg. From the

pharmacy section, it was reported that the available 2mg has fewer suppliers making it difficult to restock when needed.

"R: The challenge is on the preparation because what we have is the 2mg and preparing that for two babies is hard". (nurse)

"***R: Have the 2mg which is easy to use shared by two babies, but we would like the 1mg as a single dose for one baby instead of sharing". (nurse)***

"***R: The fact that vitamin k is in 2mg and the child has to get 1mg so it would be better to have a single doze for a baby instead to dividing the 2mg for two babies". (nurse)***

"R: Prescription can be hard because the system in this hospital does not allow a nurse to prescribe but administering it yes". (nurse)

<u>Theme 3:</u> Vitamin K prophylaxis treatment priority among health workers

The vitamin K prophylaxis treatment among the health workers is not a priority. It was reported that still there are babies who go home without getting the drug. The health care workers maintained that more paediatric nurses trained in neonatal should be brought in to back up the midwives who are overwhelmed.

"***R: It should be a priority, but it is not because as I have said there is no awareness". (nurse)***

"R: Need more paediatric nurses or those trained in neonatal care instead of depending on the midwives to give vitamin k and yet they are overwhelmed". (nurse)

<u>Theme 4</u>: Adequacy of health care providers who provide Vitamin K.

The study found out that the numbers of staffs to ensure that all babies receive vitamin k prophylaxis treatment in Kenyatta National Hospital are few compared to the number of children who need the administration of the same. The capacity health workers in labour ward is low. The number of professionals trained in neonatal care is wanting. The ratio of health worker to patient is 1:10.

"***R: In theatre yes, in the labour wards no because of the ration between the patients and the nurses" (nurse)***
"***R: No, we need more staffs because the word load is a lot the ration of health provider to patient is 1 to 10***". (***nurse)***

<u>Theme 5</u>: Recommendations/ solutions to address barriers on vitamin k prophylaxis treatment

The health care providers interviewed on the vitamin K prophylaxis treatment in Kenyatta National Hospital articulated several recommendations and solutions to the barriers. One of the recommendations was making sure that the hospital which is a major referral hospital has a constant supply of vitamin k. The pharmacy department should have stocks of vitamin k readily available for supply to theatre and the paediatric wards.

"***R: The hospital should keep the flow of the drug, at least we should have the drug all the time". (pharmacist)***
"R: As pharmacists we should make sure that we have stocks in vitamin k for use any time it is need to be used by the children". (pharmacist)

"R: The department to liaise with the department of pharmacy and the supply team so that we can have a constant supply of vitamin K". (nurse)

There is need for awareness and sensitization for the health care workers as well as the pharmacists on the importance of vitamin k prophylaxis treatment through CMEs. Getting to know the importance of vitamin k will eradicate ignorance by the health workers. To have a copy of the vitamin K prophylaxis treatment in the wards to make sure that guidelines are adhered to by the health care workers.

"R: Maybe among the health care workers not all know the importance of vitamin K prophylaxis; CMEs would help even to the pharmacy staffs". (nurse)

"R: Maybe among the health care workers not all know the importance of vitamin K prophylaxis; CMEs would help even to the pharmacy staffs de readily available to the recipients". (nurse)

The vitamin K prophylaxis treatment should be prepared in 1mg which would be easy to administer to the neonates as opposed to the current 2mg which has to be divided to two babies.

"R: Preparation which is easy as in 1mg instead of 2mg". (nurse)

More health care providers should be deployed to manage the workload in labour ward. Professional paediatric nurses trained in neonatal care should be increased in the paediatric ward as well as in labour ward to help the midwives who are overwhelmed by the workload in labour ward to administer vitamin k to the neonates. The resident paediatric doctors should be reinstated back. There should be a follow-up strategy to follow-up on babies who have received vitamin k and proper documentation made for tracing purposes.

"R: There is need for more midwives and paediatric nurses." (nurse)

"Because the hospital trains neonatal nurses, we should have these nurses administering vitamin k, every shift day and night". (nurse)

"R: We used to have resident paediatricians, but they were withdrawn so we need to have them back in this unit". (nurse)

SECTION SIX: DISCUSSION

The key finding in the study is that vitamin K uptake in Kenyatta National Hospital was low at 6.8% as compared to other studies carried out in Australia and Canada which had an I.M uptake of 93.6% and 99.3%. A retrospective cohort study by Malinah Burke et al. carried out in New Zealand in Queen Mary Maternity centre which is a tertiary level maternity and neonate care found that the I.M uptake was 92.9%.

A study carried out in Uganda in 2010 at Mbarara regional referral hospital showed that 33% of mothers and 66% of neonates had vitamin K deficiency. Neonates are at risk of developing vitamin K deficiency bleeding which can cause permanent disability or death, ensuring that all ne receive prophylactic vitamin K is crucial(22).

Vitamin K prophylaxis can prevent VKDB(23). A formative online survey of global stakeholders involved in neonates health carried out in 2018 showed that respondents from Kenya that vitamin K administration after birth was not common(24).

The World Health Organization and Ministry of health in Kenya recommends that neonates receive intramuscular injection of vitamin K at birth(17). Evidence from multiple surveillance studies show that the introduction of vitamin K prophylaxis reduces the incidence of VKDB. Current recommendation supports universal prophylaxis due to lack of predictors of vitamin K deficiency. Ensuring that neonates receive vitamin K is particularly critical in places where access to healthcare and blood products and transfusion is limited(22).

Male circumcision has been shown to reduce the risk of heterosexually – acquired human immunodeficiency virus. (HIV) infection in men. Male circumcision in early infancy defined as 1-60 days of life by the World Health Organization is recommended as part of HIV prevention strategies because of its relative ease and safety. Given the potential scale up of early infant male circumcision in resource limited settings more attention must be paid to the prevention and treatment of potential post circumcision bleeding associated with vitamin K deficiency. Post circumcision bleeding is of particular concern in the developing world where most infants are breastfed and thus at increased risk of VKDB. In a report from Kenya one of the reasons given by parents for not wanting to circumcise an infant was fear of bleeding and in a trial of circumcision in Zambia most of the adverse event were excessive bleeding with one case requiring transfusion. Therefore, the use of vitamin K to prevent or treat post circumcision bleeding deserves urgent attention as countries in sub- Saharan Africa are poised to scale up early infant male circumcision as part of HIV prevention intervention(25).

This study showed that there were no clinical factors which were statistically significant associated with the uptake of vitamin K. A study done in New Zealand found that greater gestational age and birth weight were associated with oral vitamin K and with no prophylaxis. Neonates delivered by operative or assisted vaginal delivery were more likely to receive I.M vitamin K(29).

Factors that affect uptake of vitamin K prophylaxis were stock outs, inconsistent stocks in theatre and labour ward, lack of proper formulations of vitamin K, lack of awareness and documentation, inadequate number of healthcare providers and vitamin K prophylactic treatment considered not a priority among health workers. A study done by Patricia S et al. showed that the most frequent cited barriers to more widespread vitamin K prophylaxis in LMIC were (in rank order) high rates of home birth (which precluded injections that mist be given by skilled health workers), lack of access and availability of vitamin K, perception that vitamin K prophylactic treatment is not a priority among health workers, lack of vitamin K formulations appropriate for infants, cultural practices suggesting that injections at birth is not acceptable to parents and vitamin K not included in national guidelines and polices(24). Supply and access to vitamin K is a major barrier in Kenya. Few months before the study was conducted there was a national stock out of vitamin K which lasted for about 2 months. During this period majority of public hospitals lacked vitamin K preparations. This study did not capture the possible effect of vitamin K prophylactic administration after a stock out. Throughout the study there was sufficient stock of vitamin K in pharmacy. Stock inconsistence are due to improper quantification in pharmacy and theatre and labour ward not ordering the drug in a timely manner.

Formulations of vitamin K that exist in Kenyatta National Hospital are the 2mg and 10mg vial which must be shared among neonates Healthcare providers find it difficult to prepare as compared to the 1mg vial which is for a single neonate due to the amount of workload. Healthcare providers in labour ward reported to be overwhelmed with the number of patients they attend to, thus resulting to giving less care to the neonate and prioritizing on the mother's well-being.

STUDY STRENGTH

The study highlighted weakness in the prophylactic administration of vitamin K, if these issues are addressed it will improve the uptake of prophylactic vitamin K in Kenyatta National Hospital.

LIMITATION

This study was carried out in one centre, a multicentre study should be carried out involving a larger number of participants.

CONCLUSION

Vitamin K is effective, low cost and easy to use. Vitamin K can prevent VKDB which is a dangerous condition that can cause permanent disability and high mortality. Neonates are at risk of VKDB. The world health organization and ministry of health in Kenya promotes universal administration of vitamin K after birth. Ensuring that neonates receive vitamin K is crucial. Vitamin K uptake in Kenyatta National Hospital was very low. Barriers that emerged were supply and access to the drug, lack of awareness and documentation, inadequate number of healthcare workers providers and perception that vitamin K prophylactic treatment is not a priority.

RECCOMENDATIONS

1. Constant supply of vitamin K. Proper quantification in pharmacy to avoid stock outs. Ensuring that vitamin K is ordered in a timely manner in theatre and labour ward to avoid stock inconsistence.
2. Creation of awareness and sensitization through CMEs and inserting guidelines on vitamin K administration in theatre and labour ward.
3. Acquire proper vitamin K formulation by stocking the 1mg vial instead of the 2mg vial which will be easy to administer to the neonates.
4. Deploy more healthcare workers in labour ward to manage the workload. To ensure that there is a paediatric nurse in every shift.
5. Create a follow up strategy on babies who have received vitamin K and proper documentation.

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APPENDIX I: CONSENT FORM

English version

This is a form designed to seek the informed consent of individuals recruited to participate in the study. Individuals aged 18 years and above will expressly provide their consent to participate in the study.

Title of the Study

The title of the study is: 'Uptake of neonatal vitamin K prophylaxis in the postnatal wards of Kenyatta National Hospital'.

Principal Investigator

Institution: School of Medicine, Department of Paediatrics, University of Nairobi

Supervisors

1. Dr. Aluvaala
2. Prof. Jowi

Invitation to Participate in the Study

My name is Dr. Josphat Mbuvi Chamia, a Postgraduate student at the School of Medicine, University of Nairobi. I am conducting a research study titled '*Uptake of neonatal vitamin K prophylaxis in the postnatal wards of Kenyatta National Hospital.'* I am inviting you to participate in this research study. However, before you decide to participate, it is important that you understand why the research is being conducted and what it entails. Kindly read the following information carefully and ask the researcher any questions or clarifications where you need more information. Participation is purely voluntary, and you can consent either immediately after getting this information or after a period of consultation.

Please read the information provided carefully and feel free to ask questions or seek clarification from the researcher or any other doctor of your choice if you need clarification or if you need additional information about this study. Upon providing your consent, you will be recruited into the study. If you consent to participate in the study, you will be recruited into the study consecutively. Within the course of the study, personal information and other relevant

information will be sort and collected for research purposes only. The information will be handled with utmost confidentiality. The information will only be accessed by the researcher and any other person authorized to do so by the KNH/UON ethics and research committee. All personal identifiable information (PIN) will be coded to protect your identity. All notes, interview transcriptions, and any other information will be kept in a locked file cabinet, and any electronically collected PIN will be stored in a password protected personal computer and external storage devices.

Study Procedure

Upon recruitment, participation in the study will be through interviews, as well as other information that will be important in the completion of this study. As mentioned earlier, participation is voluntary and you may choose to withdraw from the study at any stage, and such a decision and action will not affect how you access treatment and other healthcare services in this hospital or institution.

Benefit(s)

There will be no direct benefit to you for your participation in this study. However, as a participant in this study, you will make immense contributions towards the development of the knowledge and understanding of the condition that will benefit healthcare practitioners locally, regionally, and globally, particularly in understanding the condition. Such an understanding will foster the achievement of evidence-based care patient' management objectives. There will be no remuneration or financial benefits to you for participating in this study.

Risk(s)

There are no additional risks to you because of your involvement or participation in this study. All the general protocols, professional ethics and conduct will be always observed and adhered to during the study to minimize and if possible, to eliminate any risks that may result from your involvement in this study.

This study proposal has been reviewed and approved by the KNH/UON ERC which is a body that ensures the protection of persons like yourself that take part in research studies.

This approval has been granted after the submission of the study proposal to the committee by the Chairman of the Department of xx, School of Medicine of the University of Nairobi with the approval of my university supervisors.

In the very event that you require any additional information or for any other purpose regarding this study, relevant contact details are listed below:

Dr. Josphat Mbuvi Chamia
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KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke

APPENDIX 2: CONSENT CERTIFICATE

I……., out of my own free will, give consent of myself /my proxy…… to take part in this research study carried out by Dr. Josphat Mbuvi Chamia, the nature of which has explained to me. I also understand and acknowledge that my participation in the study is purely voluntary. I understand that I am free to withdraw this study consent, and subsequently, from the study, at any time. I also understand that withdrawing my consent, and subsequently, from the study, will not affect the quality of care given to myself/my proxy at the Kenyatta National Hospital.

Signature of participant/Guardian/Next of kin……

Date……

Left thumbprint if participant illiterate (witness to countersign)

I certify that the above consent has been freely given in my presence.

Witness Name……. Witness Signature…….

Date…….

STATEMENT BY THE RESEARCHER

I, Dr. Josphat Mbuvi Chamia, confirm that the information relating to this study as contained in the information sheet has been accurately read to the participant. I confirm that I have ensured that the participant understand the content. The participant understands that:

1. Declining to provide his or her consent or otherwise participate in this study will not affect the quality of care offered at this institution.
2. All information provided by the participant will be treated with strict confidentiality.
3. The findings, and subsequently, the conclusions and inferences drawn thereof, may be used to influence local, regional, and global clinical practice of patients undergoing the procedure, urethral stricture.

I further confirm that the participant has been allowed to consult and seek clarification of all aspects of this study and that he/she has freely and willingly given consent to participate in the study. The participant has also been provided with a copy of the informed consent form.

Name of researcher ……

Signature…….

Date…….

CONSENT TO AUDIO AND TRANSCRIPTION

This study involves the audio of your interview with the researcher. Neither your name nor any other identifying information will be associated with the audio recording or the transcript. Only the research team will be able to listen(view) to the recordings.

The tapes will be transcribed by the researcher and erased once the transcriptions are checked for accuracy. Transcripts of your interview may be reproduced in whole or in part for use in presentation or written products that result from this study. Neither your name nor any other identifying information (such as your voice) will be used in presentations or in written products resulting from the study.

By signing this form, I am allowing the researcher to audio tape me as part of this research.

Participant's Signature ……. **Date** …….

APPENDIX 3: KEY INFORMANT INTERVIEW STRUCTURE

Face to face interview

Date Interview number

INTRODUCTION

My name is Dr Josphat M Chamia. I am pursuing my master's degree in paediatric and child health in the university of Nairobi. I am conducting a study on factors affecting the uptake of vitamin K prophylaxis at postnatal wards in Kenyatta National Hospital. With me are my two research assistants Mr……. and Mrs…… who will be assisting me in the study. We have selected you as a key informant because of your special relationship to the area of the research topic. This is a voluntary participation without any interest attached. In case you are not comfortable with any part of the interview you are not compelled to respond. As evidence of your free and voluntary participation I would like to request you to sign below.

Initial……. Signature……. Date…….

We are going to ask you a few questions. We expect this session to be as interactive as possible. Be as truthful as you can. In the process of the discussion tape record of the proceeding may take place. In all issues respect, confidentiality, dignity, and responsible behaviour will be observed. All issues discussed will be only for the purpose of this research and will never be mentioned in any other forum. In case you don't understand any of the questions kindly seek clarifications. Let us now discuss each of the following questions.

KEY QUESTIONS

Social demographic information

a). Age of participant

b). Gender of the participant

c). Duration of stay at the unit (how long have you worked at the unit/department?

d). Position at the unit/ Speciality

Main questions

Q1. Availability of vitamin K?

- Appropriate vitamin K preparations
- Do you have stock outs?
- In instances of stock-outs, how do you mitigate?

Q2. What are the barriers to use of vitamin K prophylaxis?

Q3. Is Vitamin K prophylactic treatment a priority among health workers?

- If yes or no, give reasons.
- What has been your experience as a health care worker?

Q4. What is the coverage of vitamin K in the hospital?

- Do all babies receive Vitamin K?
- Compare the ones delivered during the day vs night.
- Compare the caesarean section vs vaginal delivery?

Q5. Do you think you have adequate number of staff to ensure that all babies receive vitamin K?

If yes or no, give reasons.

Q6. What recommendations or solutions would you suggest addressing the barriers on vitamin K prophylactic treatment?

CLOSING QUESTION

Do you have any recommendations or solutions in addressing barriers on vitamin K prophylactic treatment?

SUMMARY

This will involve a quick summary of the major components heard throughout the interview. Finally thanking them for the interview.

APPENDIX 4: NEWBORN RECORD DATA ABSTRACTION

NEWBORN RECORD DATA ABSTRACTION
1. ADMISSION NOTES

Date		Quest. Type	
Hospital ID		Quest. No	
Ward ID		HW code.	
Did the admitting clinician use a Newborn Admission Record form during admission?			Y ☐ N ☐
Was there a individual file/folder for the baby			Y ☐ N ☐

Baby's perinatal details

Baby Name		Date of Admission	/ / 20	IP No.		E					
DOB	dd mm yy	Age	days	hrs	Sex	F ☐	M ☐	Birth Wt	. kg		
Gest'n	wks	Temp (°C)		Apgar	1m	5m	10m	Wt now	. kg		
BBA?	Y ☐	N ☐	*..if Yes born where*	Home☐	Other health facility ☐						
Delivery	SVD☐	Assisted☐	Breech☐	CS☐	E						
ROM	<18h	>18h	E								

Mother's details

IP No.													
ANC Visits	Y	N	LMP	dd mm yy	EDD	dd mm yy	TT rec'd	Y	N	E			
Gravidity		Parity		Bl'd Gp		Rh gp	+	-	E				
Labour	hrs	Induction / Augmented	Y	N	E	Fever	Y	N	E	Anti-biotics	Y	N	
HIV	+	-	E	*if HIV +ve, ARVs given*	Mother Y☐ N☐ E ☐		Baby Y☐ N☐ E ☐						

Resuscitation record

1.Documentation of Resuscitation	Y	N	E	
2. If yes what was done	Action			
Warmth	Dried and covered	Y	N	E
Airway	Suctioned	Y	N	E
	Opened	Y	N	E
Breathing	BVM	Y	N	E
Circulation	ECC	Y	N	E
Drugs given	1.			
	2.			

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History

Length of illness			days
Fever	Y	N	E
Difficulty breathing	Y	N	E
Apnoeas	Y	N	E
Diarrhoea	Y	N	E
Convulsions	Y	N	E
Partial / focal fits	Y	N	E
High pitched cry	Y	N	E
Difficulty feeding	Y	N	E
Severe vomiting	Y	N	E

Admission Examination

Temp	°C	Resp Rate	/min	O_2 Saturation	%	Pulse	/min	Weak	Norm	E

		Normal	Abnormal			
General Exam	Appearance	Well	Sick			E
	Nutrition	Normal	SGA	Large (>4kg)		E
	Jaundice	None	+	+++	NC	E
	Pallor	None	+	+++	NC	E
	Skin	Normal	Bruising	Rash	Severe Pustules	E
	Gestational age(wks)					E
Airway / Breathing	Cry	Normal	Hoarse	Weak / absent		E
	Airway	Normal	Stridor	Noisy breathing		E
	Grunting	None	Sustained			E
	Cyanosis	None	Central		NC	E
	Indrawing	None / mild	Severe	Sternal retraction		E
	Chest movement	Symmetrical	Asymmetrical			E
	Breath Sounds	Normal	Crackles			E
Circulation	Femoral pulses	Present	Absent			E
	Skin warms at	Hand	Forearm	Elbow	Shoulder	E
	Capillary refill	< 2 secs	2-3 secs	> 3 secs		E
	Heart sounds	Normal	Murmur			E
Disability						
	Abnormal movements	None	Jittery	Fitting	NC	E
	Tone	Normal	Floppy	Stiff	NC	E
	Suck reflex / feeding	Normal	Absent / unable		NC	E
	Fontanelle	Normal	Bulging			E
Abdo	Abdomen	Normal	Distended	Scaphoid	Large liver	E
	Umbilicus	Normal	Flare / red skin	Pus	Bleeding	E
Congenital Anomaly		Y	N			E

Admission Diagnoses					
Birth asphyxia	☐	*Meconium aspiration*	☐	*Other diagnosis 1 (name below)*	☐
Premature / LBW	☐	*Twin delivery*	☐		
Newborn RDS	☐	*Jaundice*	☐		
Neonatal sepsis	☐	*Meningitis*	☐		
Congenital abnormality	☐				

Investigations ordered – Record only the first of each type				
	Ordered?	Result written in clinical records		Result
HIV test	Y / N	No information on result	Result Present	Pos / Neg
Lumbar Puncture (microscopy)	Y / N	No information on result	Result Present	

Medical Review	Time in hours
Time to first review after admission	6 ☐ 6-12 ☐ 12- 24 ☐ >24 ☐ E ☐

2. DAILY CASE NOTES

Ward rounds	
Was the baby seen daily by a doctor in the last seven days prior to discharge/death?	Y ☐ N ☐
Major rounds in the last seven days prior to discharge/death?	0 ☐ 1 ☐ 2 ☐ >2 ☐

3. TREATMENT SHEET

Is there a treatment sheet in the file? Y ☐ N ☐

If Y proceed below

3.1 Treatment – *Record only the initial treatment prescribed (at admission)*

Was drug prescribed?		Drug prescription				
		Route	Dose	Units	Freq	Days
Antibiotics						
Ampicillin	Yes / No	iv / im		mg		
Gentamicin	Yes / No	iv / im		mg		
Ceftriaxone	Yes / No	iv / im		mg		
Penicillin	Yes / No	iv / im		mg / iu		
Supportive Care						
Vitamin K	Yes / No	im		mg	stat	
Paracetamol	Yes / No	im / po		mg / mls		
Phenobarbital (Loading)	Yes / No	iv / im / po		mg / tabs		
Phenobarbital (Maintenance)	Yes / No	iv / im / po		mg / tabs		
Diazepam	Yes / No	iv / im / po		mg	stat / prn	

3.2 Oxygen – *Record data only about the immediate admission events*

Oxygen ordered?	**Y ☐** **N ☐**		
Describe how prescribed	No detail ☐		
	Flow rate	l/min	Ncatheter / NProng / Mask / Other

3.3 Supportive care for the sick neonate- supplementary feeding and fluid management

A. Were supplementary feeds or fluids prescribed for the baby (If Baby was Breast feeding well, answer no)?	**Yes / No**	If No, then skip section A, if yes continue.

Feed prescribed	Feeds prescription for first 4 hours			
	Feeds started	Mode of feeding	Feed Vol	Freq / 24hrs
EBM / NNF / Mix / None / Other	☐ Within 1h ☐ 1-2h ☐ Not known	☐ NG tube ☐ Cup and spoon ☐ E	mls / E	/ E

B. Was the Baby given fluids using iv route?	**Yes / No**	If No, then skip section B, if yes continue.

Fluid prescribed	Fluid prescription for the first 24 hrs		
	Rate prescribed	Rate (ml / kg /h)	Total Vol (24h)
HSD+5% Dext / 10% Dext / N Sal /Other	Y ☐ N ☐		mls

3.4 Prescriber

Name of prescriber is legible	**Y ☐ N ☐**
Signature of prescriber is present	**Y ☐ N ☐**

4. MONITORING

4.1 Weight				
Is the baby's weight charted?				Y ☐ N ☐
Frequency of charting	daily	every 2 days	every 3 days	once a week
4.2 Vital signs chart				
Is there a vital signs chart?				Y ☐ N☐
What parameters are recorded?	Temperature ☐	Respiratory rate ☐	Pulse rate ☐	Oxygen saturation ☐
Frequency of charting in 1st 48hrs	1 ☐ 2 ☐ 3☐ 4 ☐ >4☐ 0☐	1☐ 2 ☐ 3☐ 4 ☐ >4☐ 0☐	1☐ 2 ☐ 3 ☐ 4 ☐ >4☐ 0☐	1☐ 2 ☐ 3 ☐ 4 ☐ >4☐ 0☐
4.3 Fluid monitoring chart				
Is there a fluid monitoring chart?				Y ☐ N ☐
Frequency of charting in 1st 48hrs	1 ☐ 2 ☐ 3☐ 4 ☐ >4☐ 0☐	1 ☐ 2 ☐ 3☐ 4 ☐ >4☐ 0☐	1 ☐ 2 ☐ 3☐ 4 ☐ >4☐ 0☐	1 ☐ 2 ☐ 3☐ 4 ☐ >4☐ 0☐

5. DISCHARGE INFORMATION

Is there a discharge/Death summary? Y ☐ N ☐									
Discharge Date	/ /201			Outcome	Alive / Dead / Refer'd / Absc'd				
Discharge Diagnoses: Select ONE *primary diagnosis (tick 1) and secondary diagnoses (tick 2)*									
Birth asphyxia	1 ☐	2 ☐	*Meconium aspiration*	1 ☐	2 ☐	*Other diagnosis 1 (name below)*	1 ☐	2☐	
Premature / LBW	1 ☐	2 ☐	*Twin delivery*	1 ☐	2 ☐				
Newborn RDS	1 ☐	2 ☐	*Jaundice*	1 ☐	2 ☐	*Other diagnosis 1 (name below)*	1 ☐	2☐	
Neonatal sepsis	1 ☐	2 ☐	*Meningitis*	1 ☐	2 ☐				
Congenital abnormality	1 ☐	2 ☐				Not recorded ☐			

Discharge Treatment – Record only the treatment prescribed to be taken away						
Was drug prescribed? Y ☐ N ☐	**Drug prescription**					
	Route	Dose	Units	Freq	Days	
1 Multivitamins Y ☐ N ☐	po					
2 Folate Y ☐ N ☐	po					
3	po					
4						
5						
Vaccines admn during hospitalisation	BCG	Y ☐ N ☐ E ☐	OPV	Y ☐ N ☐ E☐		
Last weight recorded		Date recorded				
Follow Up	Not arranged	Hospital	Disp / H. Centre			