# PREVALENCE OF VITAMIN D INSUFFICIENCY AND DEFICIENCY IN MOTHERS AND THEIR NEWBORNS AT KENYATTA NATIONAL HOSPITAL MATERNITY WARD

**BY**

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**H58/11331/2018**

**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE REQUIREMENT OF MASTER OF MEDICINE IN PEDIATRICS AND CHILD HEALTH AT THE SCHOOL OF MEDICINE, UNIVERSITY OF NAIROBI**

**NOVEMBER 2021**

**DECLARATION**

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

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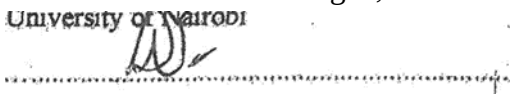

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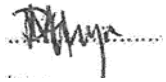

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## DEDICATION

The research is lovingly dedicated to my respective parents: Mrs. Patricia Bosibori and Mr. Charles Atandi who have been my constant source of inspiration. Without their love, prayers and support this project would not have been made possible

**ACKNOWLEDGEMENT**

I earnestly acknowledge the assistance afforded to me by my mentor and supervisors Prof. Wasunna; Dr. Laigong and Dr. Makewa whose guidance has been invaluable. I have been greatly assisted by their timely and scholarly advice, meticulous scrutiny and scientific approach all of which have greatly contributed to my ability to complete this project in time.

I thank Dr. Mungai, my lecturer, for her encouragement and willingness to assist from the time this project was conceptualized.

I am also deeply grateful to the Chairman of the Department of Paediatrics, Prof Dalton Wamalwa for his advice, guidance and encouragement.

My sincere gratitude also goes to the Kenyatta National Hospital Research and Grants office which provided the funding for this project.

I would also like to thank the Laboratory team and Research Assistants for their diligence as well my friend and my statistician Mr. Kelvin Wangira who always present when called upon.

Finally, I wish to acknowledge the support and consideration I have received from my parents, my brothers and sisters who have always been there for me.

Without the input and support from each one of you, this thesis may have gone uncompleted. Please accept my sincere gratitude.

**TABLE OF CONTENTS**

DECLARATION ..... ii
DEDICATION ..... iii
ACKNOWLEDGEMENT ..... iv
TABLE OF CONTENTS ..... v
LIST OF FIGURES ..... viii
LIST OF TABLES ..... ix
ABBREVIATIONS ..... x
OPERATIONAL DEFINITIONS ..... xi
ABSTRACT ..... xii
CHAPTER ONE: INTRODUCTION ..... 13
1.1. Background ..... 13
CHAPTER TWO: LITERATURE REVIEW ..... 15
2.1. The prevalence of Vitamin D deficiency ..... 15
2.2. Predictors of Vitamin D deficiency and insufficiency in mothers and infants ..... 15
2.3. Vitamin D deficiency in mothers ..... 18
2.4. Vitamin D deficiency in Neonates ..... 19
2.5. Maternal vitamin D status and birth weight ..... 20
2.6. Summary of Literature review ..... 21
2.7. Conceptual framework ..... 22
2.8. Problem statement ..... 23
2.9. Justification of the study ..... 23
2.10. Objectives ..... 24
2.10.1. Primary Objectives ..... 24
2.10.2. Secondary Objectives ..... 25
CHAPTER THREE: METHODOLOGY ..... 26
3.1. Study design ..... 26
3.2. Study area ..... 26
3.3. Study population ..... 26
3.4. Eligibility criteria ..... 27
3.4.1. Inclusion ..... 27
3.4.2. Exclusion criteria ..... 27
3.5. Sample size determination ..... 27
3.6. Sampling technique ..... 28

3.7. Research tool ..... 28
3.8. Recruitment of Research assistants and Training ..... 28
3.9. Recruitment and consenting of study participants ..... 29
3.10. Data collection procedure ..... 29
3.10.1. Neonate information ..... 30
3.10.2. Laboratory methods ..... 30
3.11. Validity and Reliability of the study ..... 31
3.11.1. Reliability ..... 31
3.11.2. Validity ..... 31
3.11.3. Quality control of the laboratory ..... 31
3.12. Data Collection ..... 32
3.13. Data Cleaning and Entry ..... 32
3.14. Data storage ..... 32
3.15. Data analysis and presentation ..... 33
3.16. Ethical Considerations ..... 34
3.17. Study strengths and Limitations ..... 34
CHAPTER FOUR: RESULTS ..... 35
4.1. Introduction ..... 35
4.2. Maternal socio-demographic characteristics of the study participants ..... 35
4.2.1. Maternal clinical characteristics ..... 36
4.2.2. Biographic characteristics of neonates ..... 37
4.3. The prevalence of vitamin D deficiency in mothers and neonates at Kenyatta National Hospital maternity ward ..... 38
4.3.1. Maternal Vitamin D levels ..... 38
4.3.2. Neonatal Vitamin D levels ..... 39
4.4. The predictors of vitamin D deficiency in mothers of neonates at Kenyatta National Hospital maternity ward ..... 39
4.5. Multivariate analysis ..... 41
4.6. The predictors of vitamin D deficiency in neonates at Kenyatta National Hospital maternity ward ..... 41
4.7. The relationship between vitamin D deficiency in mothers and neonates ..... 43
4.8. Association between maternal vitamin D and neonatal birthweight ..... 44
CHAPTER FIVE: DISCUSSION ..... 45
CHAPTER SIX: CONCLUSION AND RECOMMENDATION ..... 48
*6.1.* Conclusion ..... 48
6.2. Recommendations ..... 48

REFERENCES .....49
Appendix I: Consent form .....56
Appendix II: Study questionnaire .....59
Kiambatanisho I: kibali cha fomu.....61
Kiambatisho II: maswali ya kujifunza .....64
Appendix III: Workplan.....66
Appendix IV: Study Budget.....67
Study Budget.....67
Budget items Justification:.....67

LIST OF FIGURES

Figure 1: Conceptual Framework .....22
Figure 2:Prevalence of vitamin D deficiency among mothers.....38
Figure 3:Prevalence of vitamin D deficiency among neonates .....39
Figure 4: Relationship between Vitamin D Deficiency in mothers and their neonates.....43

**LIST OF TABLES**

Table 1: Summary of Literature Review .....21
Table 2:Maternal socio-demographic characteristics .....36
Table 3:Maternal clinical characteristics of the respondents .....37
Table 4:Biographic characteristic of neonates .....37
Table 5: The predictors of vitamin D deficiency in mothers at Kenyatta National Hospital ..40
Table 6:Multivariate analysis .....41
Table 7: The predictors of vitamin D deficiency in neonates at Kenyatta National Hospital maternity ward .....42
Table 8: Association between maternal Vitamin D levels and neonatal birthweight .....44

## ABBREVIATIONS

| | |
|---|---|
| **[25(OH) D]** | Calcitriol |
| **1,25 (OH) D** | Cholecalciferol |
| **25(OH)D** | 25-hydroxyvitamin D |
| **KDOQI** | The Kidney Disease Outcomes Quality Initiative |
| **KNH** | Kenyatta National Hospital |
| **UoN** | University of Nairobi |
| **VD** | Vitamin D |
| **VDD** | Vitamin D Deficiency |
| **VDR** | Vitamin D receptor |
| **VITAMIN D2** | Ergocalciferol |
| **VITAMIN D3** | Cholecalciferol |
| **WHO** | World Health Organization |

## OPERATIONAL DEFINITIONS

**Full term pregnancy-** gestation between 39 weeks, 0 days to 40 weeks, 6 days (1).

**Early term pregnancy-** gestation between 37 weeks, 0 days to 38 weeks, 6 days.

**Late term pregnancy-** gestation between 41 weeks, 0 days to 41 weeks, 6 days.

**Vitamin D ([25(OH)D]) as per Endocrine Society Clinical Practice Guideline** (2)

Vitamin D deficiency is defined as levels ≤20ng/ml.

Insufficiency is defined as levels between 21-29ng/ml.

Sufficient/ Adequate is defined as levels ≥30ng/ml.

Suboptimal vitamin D levels is defined as <30ng/ml (includes both deficiency and insufficiency).

**ABSTRACT**

**Background:** Suboptimal Vitamin D level is an increasing problem in women of childbearing age and is one of the concerns that expectant mothers are vulnerable to. Sub-optimal vitamin D levels has been associated with approximately 14% of maternal deaths and other complications such as preeclampsia, perinatal mortality, low birth weight, and respiratory distress. Therefore, there is a need to understand the prevalence of Vitamin D deficiency/insufficiency in mothers and their babies and the underlying factors.

**The objective of the study:** To determine the prevalence and predictors of vitamin D insufficiency and deficiency in neonates and their mothers at the Kenyatta National Hospital Maternity.

**Methods:** The study employed a comparative cross-sectional research design. Consecutive sampling method was used to recruit 180 study respondents and their newborns from the maternity ward of Kenyatta National Hospital. A structured questionnaire was used to collect data. Blood samples were obtained from the mother, while cord blood was obtained to investigate vitamin D insufficiency and deficiency in neonates. Binary logistic regression and Pearson correlation analysis were performed using SPSS version 25. The level of significance was assessed at 0.05.

**Results:** The results from the study showed that mothers who were involved in the study had a mean age of 29.84 (SD±5.73) years, 44.4% of them had secondary level education, 40.65% were self-employed, and 79.4% were married. The mean monthly income was $199 (SD±9.69). In investigating Vitamin D status among mothers, the prevalence of vitamin d deficiency/insufficiency among mothers was 30.5% (n =55) where 9.4% (n =17) and 21.1% (n =38) had Vitamin D Vitamin D deficiency and insufficiency, respectively. The findings from the neonates revealed that 60% were male, 81.7% had a birth weight of ≥2500g. Among neonates, the findings showed that, 12.3% of the neonates had suboptimal Vitamin D levels where 1.7% (n =3) had Vitamin D deficiency while 10.6% (n =19) had Vitamin D insufficiency. Age of the mother, p<0.0001, AOR =5.761, 95% CI (2.689, 12.34), monthly income (less than Ksh.20,000), P = 0.019, AOR =2.514, 95%CI (1.205, 5.341), parity, p<0.0001, AOR =3.244, 95% CI (0.564, 18.66) and gravidity, p= 0.008, AOR =2.395, 95% CI (0.934, 6.140) were independent predictors of suboptimal maternal Vitamin D levels. Neonatal birth weight, >1500g OR = 9.909, 95%CI (6.601, 13.170), and maternal Vitamin D levels, OR = 7.833, 95%CI (1.299, 47.237) were predictors of suboptimal vitamin D levels in neonates.

**Conclusion and recommendation:** The findings have shown that vitamin D insufficiency and deficiency is still a problem that needs to be effectively controlled. There is a need to ensure that expectant mothers check their Vitamin D levels to protect themselves and their unborn babies. There is a need to educate mothers and create awareness on Vitamin D and its sources. Further research is required to investigate the direct impact of sun exposure on Vitamin D deficiency among women in an urban setting.

# CHAPTER ONE: INTRODUCTION

## 1.1. Background

The prevalence of Vitamin D deficiency (VDD) has increased significantly in recent years (3). The Vitamin D status of the neonates is dependent on the mothers' status (4). Over the last decade, Vitamin D status in pregnant women and their neonates has gained increasing attention in obstetric and neonatal literature. Between the years 2014- 2018, published research from various global regions documented a high prevalence of VDD in pregnant women ranging from 20% - 90% (5) Furthermore, a strongly positive relationship between neonatal cord blood and maternal Vitamin D (VD) levels has been observed. (4). Different cut-off values could explain the large variation noted in the percentage prevalence of Vitamin D deficiency globally. The status and definition of Vitamin D deficiency is influenced by geographical location, seasonal variation at the time of the study, cultural and religious factors and dietary influences in countries with mandatory Vitamin D fortification (6). Maternal Vitamin D deficiency has been related to several offspring's comorbidities, including impaired bone development (7).

Different factors have been associated with vitamin D deficiency and insufficiency(8). Khalesi *et al*., in a cross-sectional study, determined that there was an association between VDD and smaller gestational age, low birth weight, gestational diabetes, and pre-eclampsia. It is known that the development of these conditions can be controlled through nutrient supplementation. Sunlight remains the primary source of Vitamin D; hence there is a strong emphasis on location and residence as a critical factor in determining Vitamin D deficiency (9). A study conducted in rural North India identified that approximately 88.6% of adolescent girls and 74% of expectant mothers were Vitamin D deficient (1).

In a longitudinal study conducted in Western Kenya by Toko *et al*., a sample population of 63 mothers was selected to assess the prevalence of VDD. The findings revealed that 51% of

mothers had VD insufficiency, while 21% had VDD. The study also identified that 74% of newborns had VD insufficiency from birth, while 30% of the newborns had sub-optimal vitamin D levels as measured in cord blood (10). Based on predictors of sub-optimal vitamin D levels, a screening tool would potentially assist clinicians in deciding whom to supplement. Ideally, a clinical screening test should address a necessary public health condition for which treatment is available; have a high sensitivity and specificity; be safe, inexpensive, widely available and lead to an improvement in health outcomes(11). Therefore, the current high prevalence of Vitamin D deficiency/insufficiency within the global setting presents a strong case on the need to study the local prevalence in order to suggest appropriate policy in regards to the use of supplements (12). Understanding the current prevalence of VDD in both mothers and neonates would assist in the implementation of interventions that would work towards improvement of infant and maternal health.

Different organizations have adopted varied reference levels for Vitamin D deficiency and insufficiency creating a highly controversial context for an appropriate definition. In this context, the analysis and interpretation of 25(OH)D was made using the Endocrine Society Clinical Practice Guideline which illustrate levels≤20ng/ml as deficiency, 21-29ng/ml defines insufficiency and levels above 30ng/ml denote sufficiency (2). The Kidney Disease Outcomes Quality Initiative (KDOQI) have also adopted these reference levels in investigating Vitamin D levels in patients with Chronic Kidney Disease (CKD)(13).

## CHAPTER TWO: LITERATURE REVIEW

### 2.1. The prevalence of Vitamin D insufficiency and deficiency

Past studies on global rates of Vitamin D deficiency are useful in present attempts at studying current patterns of VDD. A study conducted by Misra et al., found that there was an increasing level of VDD across the globe, which presented the need to implement better measures targeting the etiology of VDD (14). In the United States, statistics show that approximately 45% of African Americans have high VDD (15). Al-Mahroos *et al.*, in a study conducted in Bahrain where 403 mothers and 403 newborns were assessed, determined that the overall prevalence of vitamin D deficiency and insufficiency was 88.8% and 90.3% in mothers and newborns, respectively. The study identified an association between sub-optimal vitamin D levels and delivery in the hospital, low education levels, gravida of more than four, and not using VD supplements (16). As a result of this and other similar studies, there is better knowledge of child development and its relationship with low Vitamin D status (17).

### 2.2. Predictors of Vitamin D deficiency and insufficiency in mothers and infants

Different factors predict the presence of vitamin D deficiency and insufficiency among mothers and their newborns. Mothers who have VDD are more likely to give birth to VDD infants. There was a positive linear relationship between maternal and neonate serum VD and calcium levels (18). However, increased use of VD supplements or exposure to direct sunlight results in an enhanced newborn immune system. VD has become a substantial challenge for pregnant mothers and their neonates across different settings.

According to a study conducted in Pakistan ,45% of the mothers and 55% of neonates had VDD. The study identified that low economic status, the wearing of traditional attire and reduced exposure to sunlight were associated with increased VDD (19).Song et al. found

lower level serum levels of Vitamin D in mothers and their infants who were from the upper socio-economic group and mostly preferred staying indoors, meaning there was reduced exposure to sunlight(20). Downie et al. also assessed the determinants of VDD among mothers and found that that age, socio-economic factors, parity, and education level significantly influenced VD outcomes (21). In a prevalence study conducted in Saudi Arabia on mother-infant pairs in 2020, 201 mother-infant pairs were enrolled. The findings revealed that vitamin D deficiency and insufficiency in mothers was 90.5% compared to their newborns, (86%). The study did not find an association between employment status, parity, age, skin color, and body mass index with sub-optimal vitamin D levels in mothers (22). The findings however indicated a high prevalence of vitamin D deficiency and insufficiency as being associated with dress code, gravida, and hospital type. Similarly, Ajmani et al., in a prospective study conducted in India, identified that 81% of mothers and 35.8% of babies had VDD. A different study conducted in Turkey revealed that women wearing traditional dresses outdoors have lower serum levels because of the inability to obtain VD from sunlight exposure (23). Based on the findings from Lebanon and Saudi Arabia, the rate of VDD is estimated between 26% - 84% based on different risk factors associated with VDD development, including exposure to sunlight, dress code, and level of education (24), (25).

The mode of delivery is considered a critical factor in the development and well-being of a neonate, primarily based on the mother's ability to take care of the infant (26), though from a study conducted by Naseh et al., it was identified that there was no relationship between the number of pregnancies and VDD (27). Dave et al. revealed that there was an association between VDD and Caesarian section (CS) deliveries, where only 3.5% of women who delivered through CS had VDD (4)(28). Similarly, Merewood et al., in a study including 253 mothers, results showed that the presence of VDD in mothers increased the chance of CS by four times. Therefore, it is vital to understand the level of VD, which is essential for mothers'

and neonates' wellbeing. The knowledge leads to creation of measures that ensure VD supplements are made available (29).

High VD levels have been associated with increased birth weight and reduced birth complications among neonates. A population with a sub-optimal level of VD and calcium intake in the diet is likely to have a higher incidence of risky pregnancies. Children born under such circumstances mainly have low birth weight and a weak immune system (30). Prasad et al. showed that the incidence of pre-eclampsia and hypertensive disorder with pregnancy was considerably more amongst patients whose serum level of VD was<20ng/dl. This study also identified that VD supplements reduced the risk of preeclampsia (31).

Research has also shown that inadequate intake of VD during pregnancy is also linked with sequelae such as defective intrauterine bone growth and shorter gestation. Preterm neonates are at an increased risk of metabolic bone disease, hence the need to ensure that there are sufficient Vitamin D stores for use by both the mother and the newborn. (32). Metabolic bone disease of prematurity has a prevalence of approximately 55% among infants weighing below 1000 grams and 23% among neonates weighing less than 1500 grams. Overall, the prevalence of metabolic bone disease is estimated to be between 15 - 58%(33)(30). The presence of severe VDD was also found to be associated with the development of osteopenia of prematurity (26)(34), mainly due to VD activation's immature development (35).

The requirement of Vitamin D by the body is highly influenced by different factors such as body stores during pregnancy and at birth. The human fetus is largely dependent on the mother as a source of nutrients and vitamins. It is estimated that the optimal VD content in the diet must be 400IU/day. Therefore, supplementation with Vitamin D is a significant

factor in improving neonates' health, characterized by increased birth weight and appropriate immunity in new borns. (36).

### 2.3. Vitamin D insufficiency and deficiency in mothers

Sunlight exposure remains the leading source of vitamin D; hence the need to introduce measures which ensure that pregnant mothers have a high level of exposure to sunlight.

The increasing VDD has been associated with lower levels of VD intake in women within the age-bearing age and newborn babies. VDD in newborn babies is associated with the mothers' VD levels (37). Different guidelines are used across different parts of the world. However, there is consensus that levels below 50 - 80 nmol/l are considered insufficient for effective new born health (5).

Maternal VDD has also been a significant predictor of newborn VDD, as documented in different past studies. In the United Kingdom, approximately 18% of pregnant women had VDD, while 25% in the UAE had VDD. New Zealand recorded approximately 60% VDD among pregnant mothers. A high level of VDD was present in Muslim women who normally have a particular type of dressing that covers their body, sufficiently limiting sunlight exposure (38)(7)(39). The studies have shown that newborns are at increased risk of VDD based on the high prevalence in pregnant mothers. The high prevalence of VD shows that it is essential to consider VD supplements to improve the nutrient levels among pregnant mothers to give birth to healthy children. Studies have shown that children who are born by VD-repleted mothers tend to develop VD insufficiency within eight weeks if there is no use of VD supplements (8)(4)(40). The underlying importance of maternal deficiency of VD is that the fetus develops a hypovitaminosis state that has significant adverse outcomes on innate immune function and slows down fetal and childhood bone development (41)(42). Therefore

a high level of maternal deficiency has been linked to the development of rickets in utero, which can be easily manifested at birth (43).

Understanding the physiology of VD is also important. The vitamin D content in human milk is mainly associated with lactating mothers' VD status (44). The supplementation of lactating mothers with vitamin D supplements therefore presents an important platform. The use of supplements reduces the risk of rickets since the mother has sufficient VD stores (43).

Settings where exposure to sunlight is limited and there is no emphasis on VD supplementation limits the quality of maternal health and of their newborns (45)(43). .

### 2.4. Vitamin D insufficiency and deficiency in Neonates

Recent studies have shown that there is a significant deficiency of VD across different regions in the world. According to Tayel et al., there is an increased VD deficiency in neonates from mothers who exhibited VDD (35). According to Taylor et al., mothers of rachitic newborns have shown a high prevalence of VDD. In a similar study, Stessman and Peeples highlighted high VDD in mothers of rachitic compared to mothers of non-rachitic children (34).

Owie and Afolabi determined a strong relationship between maternal VDD and newborn VDD, which provides the need to focus on building strong nutrient blocks that can help child growth (46). Gupta also identifies that VD and rickets present a very strong relationship, which helps maintain a positive context and change in improving newborn health (47).

Supplementation given to nursing mothers maintains both the mother and child's positive health and well-being. The supplementation of nursing mothers is estimated at approximately 2000 IU rather than the normal 1000 IU. The increase in the amount of supplements has a strong positive influence on the wellbeing of both the mother and the baby in terms of controlling VDD (38)(44)(45). To understand the importance of supplements to lactating

mothers, different studies have been conducted which have sought to help understand the impact of an increased number of supplements on a nursing mother. Ozdemir et al. conducted a prospective study that sought to investigate the impact of a high VD dose of up to 6400 IU/1 for six months. The findings showed that the content of VD increases significantly to 873 IU/1 without any evidence of toxicity (26). However, it is also known that VD can be increased in the milk of nursing mothers through taking VD supplements, such high doses must be effectively controlled by a healthcare provider and proved to be used safely among nursing mothers (22).

The infant risk of developing VDD is associated with limited exposure to sunlight and a suboptimal vitamin D level in breast milk. The levels of Vitamin D content in breast milk are based on the nutritional status of mothers. Promoting strong Vitamin D status among mothers is essential in improving the development of newborns and avoiding VDD-related negative outcomes (47).

### 2.5. Maternal vitamin D status and birth weight

Research has been conducted to understand the underlying relationship between maternal VD status and birth weight. According to Zamal et al., mothers with VDD give birth to low-weight newborns. The results from the study also determined that there was a relationship between mother and neonate VD levels. The neonate birth was also highly associated with maternal VD levels (48). These findings are similar to Kaur, who determined that birth weight was associated with VD levels in mothers (49).

Zamal et al. found a positive correlation between maternal vitamin D status and residence, duration of sun exposure season of the year, and calcium supplement intake (51). Studies by Prasad et al. and Sathish et al. identified that maternal education level, age, parity, and occupation were not associated with VDD levels (52).

## 2.6. Summary of Literature review

Table 1: Summary of Literature Review

| **Author, study title, setting, year** | **Research design** | **Sample size** | **Findings** |
|---|---|---|---|
| Toko et al.<br>Western Kenya (2016) | Mixed methods cross-sectional | n = 63 pairs | 51% of patients had VD insufficiency, 21% had VDD at birth, 74% of newborns had VD insufficiency, while 30% of newborns had VDD.<br>The results also showed that gestational age at delivery, maternal age, and BMI were significantly associated with VDD. |
| Khalessi et al.<br>Tehran and Iran (2015). | Cross-sectional Descriptive analytical study | 102 pairs | Around 48% of mothers had VDD with average levels of 31.46 nmol/L |
| Owie, E., & Afolabi, Lagos, Nigeria. (2018). | Cross-sectional study | 166 pairs | The prevalence of VDD in mothers was 4.8% and 29.5% in newborns.<br>Insufficiency was 28.3% in mothers and 46.1% in neonates.<br>VD supplements use in pregnancy, sunlight exposure, and the mother's dressing style were associated with VD levels. |
| Shrestha et al. Bhaktapur, Nepal. (2019). | Cross-sectional study | 79 pairs | 81% of mothers and 35.8% in their new-borns had VDD.<br>There was a linear relationship between the mother and neonate's VD levels ($p<0.001$).<br>. |

## 2.7. Conceptual framework

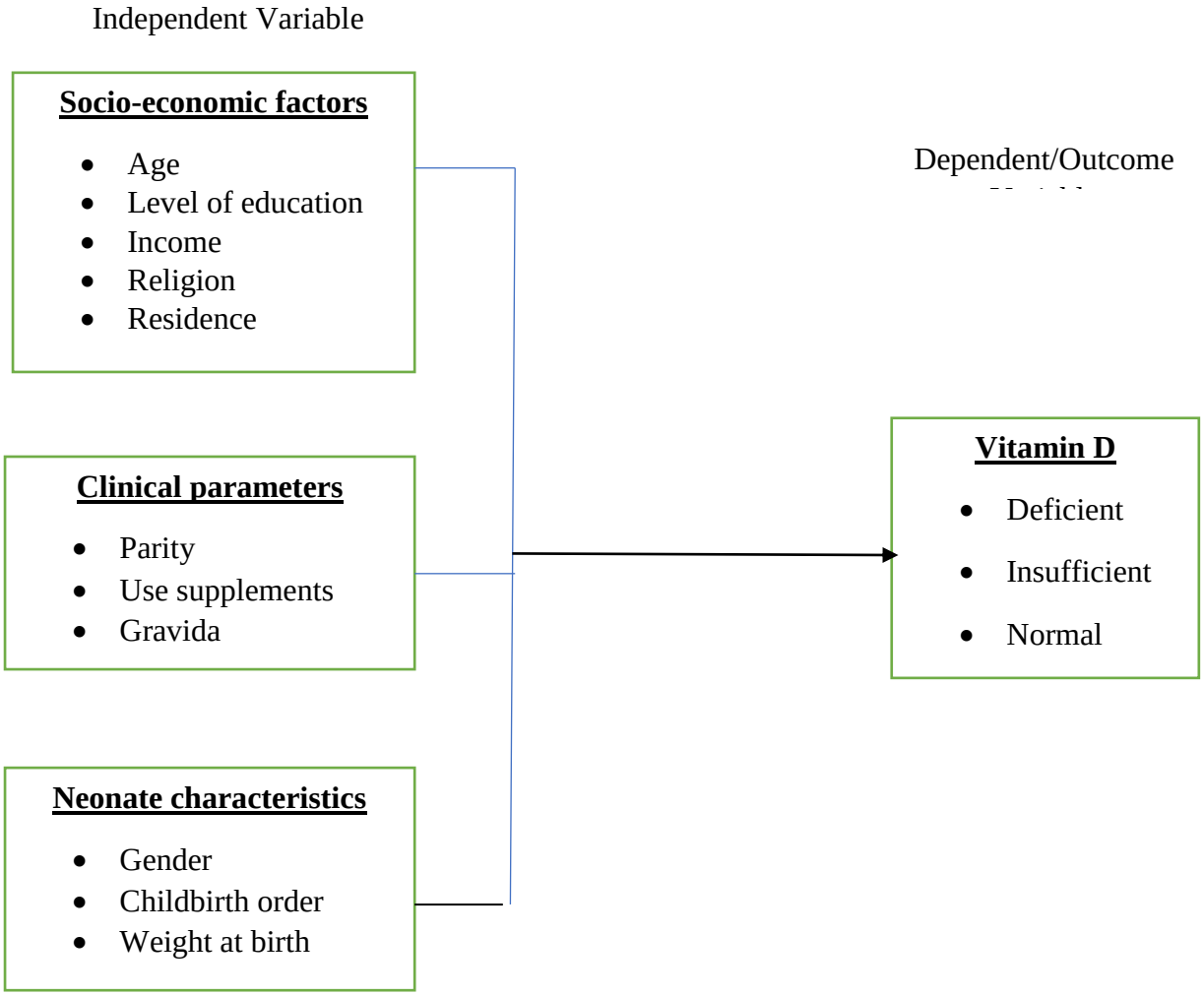



Figure 1: Conceptual Framework

## 2.8. Problem statement

Vitamin D deficiency has a detrimental effect on the growth of fetal bones which become extremely weak and prone to rickets (5). Vitamin D is also associated with osteomalacia in pregnancy hence the need to ensure it is of adequate quantity amongst expectant and lactating mothers in order to help in neonate mineral bone acquisition(50). It has also been associated with increased onset of neonatal sepsis and low birth weight. Expectant mothers with VDD tend to have weaker immune systems, which is detrimental to the well-being of the unborn child's immune system (4). Therefore, determination of the mother's and newborn status regarding VDD helps decide whether VD supplementation is necessary to prevent sepsis in newborns (41). The underlying risk factors that have been identified from past literature include lifestyle, skin color, access to sunlight, low intake of fortified food, compliance with supplements, premature birth, and insufficient vitamin intake (51).

The VDD status amongst mothers and their newborns has not been conclusively documented in Africa, although malnutrition is a major problem in Kenya and many other sub-Saharan countries. There is limited published data on VDD in Kenya, which prompts the need to understand the trend and the development of VDD and associated adverse outcomes in both mothers and newborns. KNH is the largest referral hospital in Kenya, which provides a better platform for assessing VDD prevalence in mothers and newborns.

## 2.9. Justification of the study

Despite the association between Vitamin D deficiency in pregnancy and adverse outcomes in both mothers and newborns, Vitamin D status is not routinely monitored during the antenatal visits. Overall, there has also been less focus on the prevalence of Vitamin D deficiency in Kenya, making it difficult to realize any implications of deficiency in mothers and new borns. This study was intended to approximate the current level of Vitamin D deficiency in mothers and neonates and determine associated factors.

Vitamin D status is a fundamental pillar of maternal and newborn health. Findings of VDD deficiency amongst a population creates the need to adopt strategic measures, which can reduce the threat posed by Vitamin D deficiency and insufficiency. This could include easily accessible remedies such as ensuring high exposure to the sun among expectant mothers as this activates Vitamin D in the body.

Sun exposure was not investigated in the study based on prior knowledge of inability of sun exposure questionnaire depicting the actual status of respondent actual sun exposure. Similarly, sun exposure was not also investigated based on the assumption that there were no significant differences in income and religion, which would have prompted significant variation in sun exposure levels among respondents.

The study's findings provide a better basis for understanding the implication of Vitamin D deficiency in expectant mothers and their newborns. The study also seeks to apprise all stakeholders, including the hospital and the Ministry of Health of the need to implement favorable policies aimed at improving Vitamin D levels especially in expectant mothers.

**Research question**

What is the prevalence of vitamin D insufficiency and deficiency in neonates and their mothers at Kenyatta National Hospital Maternity unit?

## 2.10. Objectives

### 2.10.1. Primary Objectives

To determine the prevalence and predictors of vitamin D insufficiency and deficiency in Neonates and their mothers at Kenyatta National Hospital maternity ward.

### 2.10.2. Secondary Objectives

1. To determine the prevalence of vitamin D insufficiency and deficiency in mothers and their neonates at Kenyatta National Hospital maternity ward.
2. To determine the predictors of vitamin D insufficiency and deficiency in mothers of the neonates at Kenyatta National Hospital maternity ward.
3. To determine the relationship between vitamin D insufficiency and deficiency in mothers and that of their neonates at Kenyatta National Hospital maternity ward.

# CHAPTER THREE: METHODOLOGY

## 3.1. Study design

The study adopted a cross-sectional research design. Inferences were made based on a specific understanding of independent and dependent variables. The researcher's focus was on engaging the respondents at a single point in time.

## 3.2. Study area

The study was performed at the Kenyatta National Hospital maternity ward. Kenyatta National Hospital is the largest Teaching and Referral public health institution for the College of Health Sciences, University of Nairobi. The hospital sits in a vast land covering about 5 hectares and has about 50 in-patient wards with hospital bed-capacity of 2000 (52). Maternity ward is divided into two sections, which include a general wing and a private wing. In 2019, there were 12944 deliveries in General wards and 862 in private wing. The number of admissions was 13722 in both General and private wards. The average number of deliveries daily were 35 in the general wing and three in the Private section.

## 3.3. Study population

The study population included mothers and their neonates in Kenyatta National Hospital Maternity Ward. Expectant mothers in the maternity ward mainly follow three main routes. One of the routes is the mother and child clinic where mothers who are due are directed to maternity ward, mothers who come from home or as referrals from other hospitals and are brought for specialized delivery and mothers on elective caesarian section delivery. Once the mothers are admitted following any of the discussed routes, they are eligible to be recruited into the study. First, expectant mothers who meet the inclusion criteria were identified in labor or before labor when delivery is due. Once the baby is born, blood samples were

collected: both maternal blood and Cord blood was collected, which enabled the assessment of both maternal and neonatal Vitamin D levels.

### 3.4. Eligibility criteria

#### 3.4.1. Inclusion

Inclusion criteria consist of:

- all new admissions to the maternity ward.
- mothers who are at full term in the maternity ward.
- mothers scheduled for elective caesarean section delivery.
- those who consent to the study.

#### 3.4.2. Exclusion criteria

- The study excluded preterm neonates or deliveries and postdates. Preterm neonates and post dates are special groups who have special characteristics hence likely to have influence on Vitamin D level determination.
- Mothers on anticonvulsants were excluded from the study. Anticonvulsants lower vitamin D levels which had detrimental influence on the efficacy of this study.
- Mothers who were unstable mentally were excluded mainly because they were unable to understand the purpose of the study and make poor judgement regarding participation.
- Mothers who declined to consent were excluded.

### 3.5. Sample size determination

According to Shrestha et al. (2019), the prevalence of VDD in mothers and neonates was 35.8% (65). Therefore, the sample was calculated using Fischer's formulae.

$n = z^2 pq/e^2$

Where n is the sample population

$Z^2$ is the abscissa of the normal curve (1.96)

p is the estimated prevalence in the population (0.358)

q is (1-p) the proportion of an attribute that is absent in the population (0.642)

e is the margin of error included in the study (5%)

Therefore, the sample size was

$n = Z^2Pq/e^2$

$n = (1.96^2)\ (0.358*0.642)/0.0025)$

$= 0.45047/0.05^2$

= 180

The sample size included a minimum of 180 mothers and 180 newborns.

### 3.6. Sampling technique

The study employed consecutive sampling where all new admissions into the maternity ward and consent were recruited. Consecutive sampling is efficient, considering that the researcher identified respondents as they come until the sample size was attained. The recruitment included 180 mothers in the maternity wards who understood the study (53).

### 3.7. Research tool

A questionnaire was used to attain better research outcomes. The questionnaire included questions related to the study outcomes.

### 3.8. Recruitment of Research assistants and Training

The researcher recruited four research assistants. The research assistants comprised of qualified clinical officers who have experience in dealing with expectant mothers in an organized and interactive way to ensure effective communication of the study's purpose to the target respondents.

### 3.9. Recruitment and consenting of study participants

The recruitment process began after approval from UoN-KNH ERC and KNH Administration. The research assistants assisted in recruitment of study participants. The women who satisfied the inclusion criteria formed the sampling frame from the maternity ward. The recruitment was done consecutively daily until the sample size was attained. Written informed consent was obtained from each of the participants. With further help from the research assistants, the researcher explained the purpose of the study to potential participants with emphasis on confidentiality of their information and the use of the study findings for academic purposes only. Only those mothers who consented were included in the study. Those who did not consent were excluded from the study. Upon recruitment in the study, a unique registration number were given to each of the participants to help in identification during the data collection process. This was done to ensure a high level of confidentiality and privacy of the respondent information.

### 3.10. Data collection procedure

With the assistance of the research assistants, the researcher administered the structured questionnaire to the expectant mothers upon their understanding of the purpose of the study and satisfaction with the privacy plan outlined by the researcher. The respondents were required to provide demographic information, including age, level of education, residency, and income. Clinical data was captured. The information that was captured included but was not limited to Vitamin D supplementation, gravida, and parity. Blood samples were taken for the measurement of vitamin D levels [25(OH)D]. The research assistants recruited at least 5 mothers in the study daily. The whole data collection process took approximately 4 weeks.

### 3.10.1. Neonate information

The information that was assessed in the study was obtained during delivery. The neonate information captured included gender, weight at birth and childbirth order. The cord blood was also taken to the laboratory for testing the presence of Vitamin D deficiency.

### 3.10.2. Laboratory methods

#### 3.10.2.1. Sample collection and storage

On wearing clean gloves, the research assistants drew a clean venipuncture using a spirit swab. Six mls of venous blood was drawn using a disposable syringe. Blood collected was put in one plain vacutainer tube for Vitamin D analysis.

After delivery, 6 mls of cord blood was collected to investigate Vitamin D deficiency. Each tube consisting of a sample drawn from mother and newborn was coded with a serial number indicating mother sample and neonate sample. The mother's sample were serialized following the questionnaire, such as "M01" while the subsequent newborn serialization was "N01".

#### 3.10.2.2. Sample transportation.

The collected specimen was accurately sealed and placed in a rack in a cool box. The samples were taken to the KNH laboratory 16 within 1-2 hours of sample collection.

#### 3.10.2.3. Storage of samples

The samples were refrigerated at a temperature of -70°C pending the measuring of 25-hydroxy VD.

#### 3.10.2.4. Laboratory

ELISA method was used to measure 25-hydroxy VD. Deficiency criteria of 25-hydroxy VD was defined in a similar manner in both mothers and neonates. The samples were centrifuged and the serum obtained and stored in the vials and then analyzed by the Cobas 6000 Roche machine. The Cobas 6000 machine uses the bridging principle of antigen antibody reaction

that is then measured electronically. Vitamin D's measurement were assessed and defined as deficiency being <20ng/mL, insufficient as 20-30 ng/mL while >30 being considered as VD sufficient.

### 3.11. Validity and Reliability of the study

#### 3.11.1. Reliability

Reliability is a measure of the consistency of an assessment tool (54). A measure is considered being reliable when it produces the same results for different participants. Reliability provides a focus on the consistency of a given measure. A professional pediatrician and a statistician evaluated the research tool

#### 3.11.2. Validity

Validity is the extent to which a given measurement can provide accurate results that correspond to the real world (55). A tool is assessed to determine whether it produced the results intended based on the methodology adopted. Heale and Twycross identified that the degree of accuracy in evaluation varies significantly and thus provides a strong focus on essential concepts that help determine whether a given treatment method that has been suggested can achieve the desired outcomes (56). This was achieved through the pre-test of the tool. External validity was achieved using randomly selected participants.

#### 3.11.3. Quality control of the laboratory

Quality control measures and standard operating procedures were always adhered to during the research. Specimens collected during this period were collected while maintaining proper collection methods and storage using appropriate and sterile containers. The samples collected were clearly labeled immediately after collection. Specimens were then stored at recommended temperatures. Internal and external quality is undertaken at the laboratory.

Internal quality control was done once daily. For external quality, Huqas reagents are used, and external quality runs 3 times in a year.

As part of quality assurance, the Principal Investigator took 1 in every 10 samples to an external referral lab (Pathologist Lancet Kenya) for comparison. Levels within one standard deviation were deemed satisfactory.

### 3.12. Data Collection

The data collection was conducted from the patient records based on the inclusion criteria. Data collection was involved selecting patient files based on the inclusion criteria, which is essential in defining an improved understanding of specific measures that help obtain accurate results. The data was collected systematically to ensure that the findings are accurate. With the help of the research assistants, the principal investigator obtained all patient's files within the study period and divided by sample size to obtain the desired sampling interval, which ensured that the results are accurate and less biased from a statistical point of view.

### 3.13. Data Cleaning and Entry

The data collected using questionnaires and forms was checked daily for completeness by the researcher. Collected data was entered in Epi-Data 3.1 database and then analyzed using SPSS computer package, version 25 (57).

### 3.14. Data storage

The consent forms, questionnaires, and forms did not contain personal identifiers. Once they were filled, they were locked up in a safe cupboard. The laptop that was used in the analysis of the data had a password that limited access to authorized personnel only. The consent forms and questionnaires will be safely stored for five years, after which they will be destroyed.

### 3.15. Data analysis and presentation

Before analysis, quantitative data was coded, cleaned, and edited to ensure that it was accurate. Data was analyzed through SPSS version 25.0.

**Descriptive analysis**

Descriptive statistics was used to describe the socio-demographic characteristics of the sample population. Among the variables used for this included but was not limited to gender, age, level of education, occupation, and marital status. To present the outcome of this analysis tables and graphs were used which formed part of the report writing. The tables generated were given mean, modes, frequencies, and percentages based on the data measurement level.

**Objective 1: The prevalence of vitamin D insufficiency and VDD**

Prevalence of vitamin D insufficiency and VDD in mothers and neonates at KNH maternity ward was calculated based on the formula

% Prevalence = * 100

Where a = Number of mothers/ neonates with vitamin D insufficiency/VDD

b = Number of mothers/neonates without vitamin D insufficiency/VDD

**Objective 2: Relationship between vitamin D insufficiency and VDD in mothers and their neonates**

A correlation analysis was conducted to help understand the strength, direction, and significance of the relationship between Maternal Vitamin D levels and Neonate Vitamin D levels.

**Objective 2: Determinants of vitamin D insufficiency and VDD in mothers and neonates**

A binary logistic regression analysis was conducted to determine independent factors that predict VDD among mothers and neonates attending Kenyatta National Hospital maternity ward.

The analysis was done using SPSSv25. The hypothesis was tested at 95% confidence level.

### 3.16. Ethical Considerations

The nature of the study limits the underlying ethical issues which need to be exhaustively developed. Approval to carry out the study was sought from KNH-UoN ERC and PCMH Ethics. Permission was also sought from the hospital management which allowed access to the patient files. All stakeholders were informed about the study. Confidentiality, anonymity, and privacy was fully guaranteed throughout the study. Because of Covid 19, the researcher put guidelines that helped protect both the participants and the research assistants. The four research assistants underwent Covid-19 testing before the onset of the data collection process. The researcher also ensured that surgical masks were available for both the research assistants and participants to control infection. The researcher provided hand sanitizer for use before the collection of data. The research assistants endeavored to maintain a social distance of 1.5 meters when engaging the participants.

### 3.17. Study strengths and Limitations

The study's strengths include a focus on cord blood, which allows for a direct measure of VD that the fetus received in utero.

The focus on both mother and newborn provides a broader perspective of VDD in reproductive health and making a meaningful comparison.

The study's limitations included the inability to measure sun exposure to the mother directly. Another limitation was that we did not have the corresponding PTH, calcium, and phosphorus values, which could have helped us understand the physiology of Vitamin D and its effect on various parameters in a better way. Dietary intake and sun exposure during the antenatal period was also not recorded.

# CHAPTER FOUR: RESULTS

## 4.1. Introduction

The study was conducted to determine the prevalence, predictors and relationship between maternal and neonatal vitamin D deficiency. The study included a sample of 180 mother-neonate pairs. All the questionnaires were filled and returned for analysis representing a 100% response rate.

## 4.2. Maternal socio-demographic characteristics of the study participants

The findings showed that, mean age was 29.84 (SD±5.73), almost half of the respondents, 44.4% (n =80) had secondary level education, 40.65 (n =73) were self-employed, 79.4% (n = 143) were married. In assessing residence of the respondents, 86.1% (n =155) resided in urban areas. Almost all of the respondents, 95.6% (n =172) were Christians. The mean monthly income was $199 (SD±9.69) as shown in Table 2 below.

Table 2:Maternal socio-demographic characteristics

| | | Frequency (n) | Percentage (%) |
|---|---|---|---|
| Age | Mean (SD) | 29.84(5.73) | |
| | Median (IQR) | 30(25 - 34) | |
| | ≤30 Years | 117 | 65 |
| | >30 Years | 63 | 35 |
| Level of education | Never attended | 1 | 0.6 |
| | Primary | 33 | 18.3 |
| | Secondary | 80 | 44.4 |
| | Tertiary | 66 | 36.7 |
| Occupation | Salaried | 35 | 19.4 |
| | Self employed | 73 | 40.6 |
| | Unemployed | 72 | 40 |
| Marital status | Single | 35 | 19.4 |
| | Married | 143 | 79.4 |
| | Divorced or separated | 2 | 1.1 |
| Residence | Rural | 25 | 13.9 |
| | Urban | 155 | 86.1 |
| Religion | Christian | 172 | 95.6 |
| | Muslim | 8 | 4.4 |
| Monthly income | Mean ($) | $199 (9.69) | |
| | Median ($) | $200(100 - 295) | |
| | ≤$200 | 66 | 36.7 |
| | >$200 | 114 | 63.3 |

### 4.2.1. Maternal clinical characteristics

Maternal clinical characteristics were also assessed, and the findings as shown in Table 3 revealed that the median parity among respondents was 2 (IQR: 1 – 3). The median gravida was 3 (IQR: 2 – 4). Majority of the respondents; 97.2% (n = 175) did not report use of Vitamin D supplements such as osteocare (n =3) and zedcal (n =2).

Table 3:Maternal clinical characteristics of the respondents

| | | Frequency (n) | Percentage (%) |
|---|---|---|---|
| Parity | Median (IQR) | 2 (1 -3) | |
| | ≤2 | 155 | 86.1 |
| | > 2 | 37 | 13.9 |
| Gravida | Median (IQR) | 3 (2 – 4) | |
| | ≤3 | 117 | 65.0 |
| | > 3 | 63 | 35.0 |
| Use of Vitamin supplements | Yes | 5 | 2.8 |
| | No | 175 | 97.2 |

### 4.2.2. Biographic characteristics of neonates

The results as showed in Table 4 found that, 60% (n =108) of the neonates were male, 81.7% (n =147) had birth weight of more than 2500g while 29.4% (n =53) were second born, 28.8% (n =52) were firstborns.

Table 4:Biographic characteristic of neonates

| **Characteristics** | **Frequency** | **Percentage** |
|---|---|---|
| **Gender** | | |
| Male | 108 | 60 |
| Female | 72 | 38.9 |
| **Weight at birth** | | |
| Less than 1500g | 8 | 4.4 |
| 1500 - 2500 | 25 | 13.9 |
| above 2500g | 147 | 81.7 |
| **Birth order** | | |
| Firstborn | 52 | 28.8 |
| Second born | 53 | 29.4 |
| Third born | 37 | 20.6 |
| Fourth born | 19 | 10.6 |
| 5th and above | 19 | 6.1 |

### 4.3. The prevalence of vitamin D deficiency in mothers and neonates at Kenyatta National Hospital maternity ward

The study also sought to investigate the prevalence of vitamin D deficiency in mothers and neonates. The Cobas 6000 machine, which uses the bridging principle, did the analysis: antigen antibody reaction that is then measured electronically. Vitamin D deficiency was evaluated based on the Endocrine Society Clinical Practice Guideline which illustrate ≤20ng/ml for deficiency, 21-29ng/ml for insufficiency and above 30ng/ml as sufficiency (2).

#### 4.3.1. Maternal Vitamin D levels

The prevalence of vitamin D deficiency was 9.4% (n =17) and insufficiency was 21.1% (n =38) among mothers as shown in Figure 2.

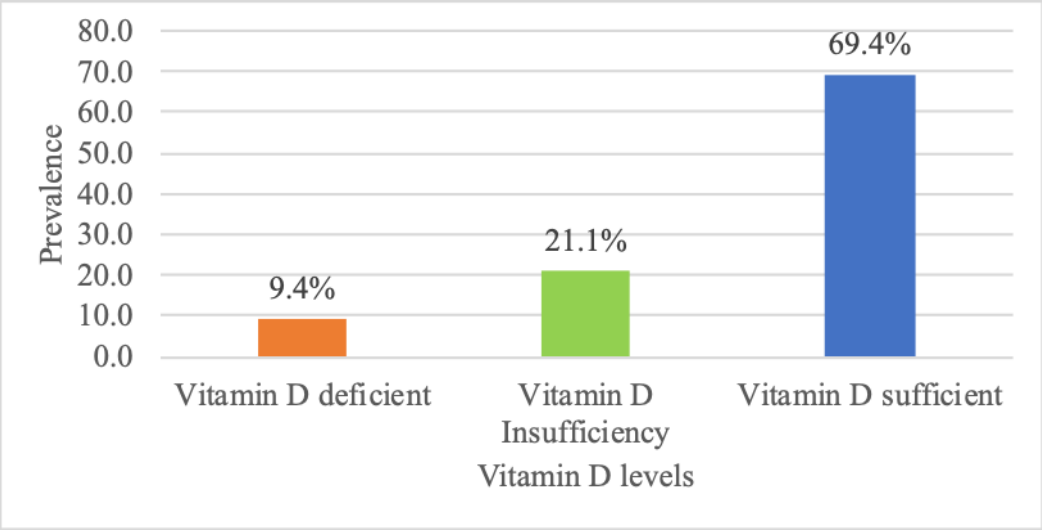



Figure 2:Prevalence of vitamin D deficiency among mothers

### 4.3.2. Neonatal Vitamin D levels

The study also sought to investigate neonatal vitamin D levels as shown in Figure 3. The findings showed 1.7% (n =3) had Vitamin D deficiency while 10.6% (n =19) had Vitamin D insufficiency.

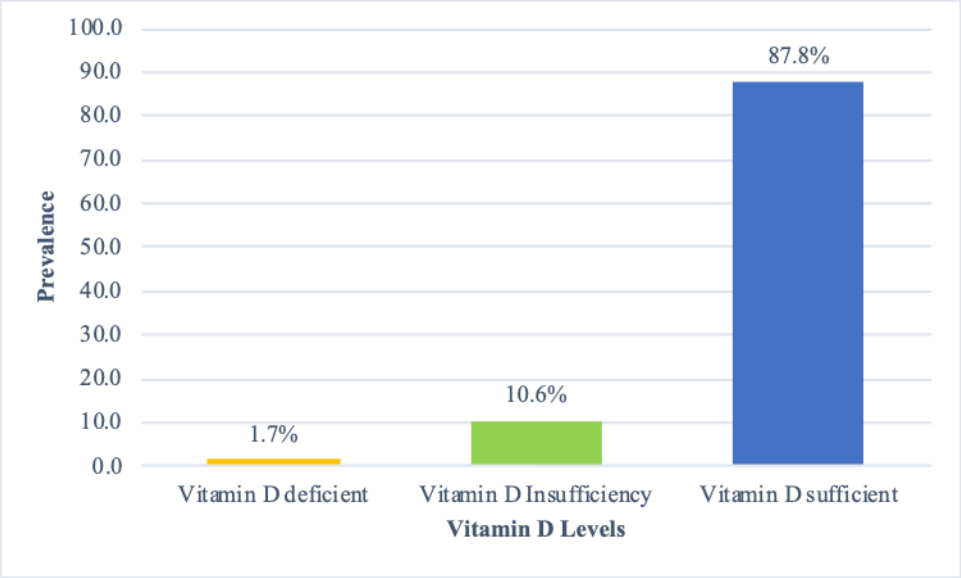



Figure 3: Prevalence of vitamin D Insufficiency and deficiency among neonates

## 4.4. The predictors of vitamin D insufficiency and deficiency in mothers of neonates at Kenyatta National Hospital maternity ward

A binary logistic regression analysis was conducted to identify predictors of vitamin D deficiency in mothers of the neonates at Kenyatta National Hospital as shown in Table 5. The findings revealed that, age (greater than 30 years), Monthly income (Less than $200), parity (less than 2) and gravida (Less than 3) were significant predictors of suboptimal maternal Vitamin D levels. The results revealed that, mothers who were aged 30 years or below were 0.19 times less likely to have suboptimal Vitamin D levels, OR = 0.187, 95%CI (0.094, 0.370) compared to those aged above 30 years. Mothers who reported to earn less than $200 were 4.2 times more likely to have suboptimal Vitamin D levels, OR =4.182, 95% CI (2.139, 8.174) compared to those who earn more than $200. Mothers with a parity of less than 2 were 6 times more likely to have suboptimal vitamin D levels, OR =5.975, 95%CI (1.357, 26.316)

compared to mothers with parity of more than 3. Additionally, mothers with gravida of less than 3 were 3 times more likely to have suboptimal Vitamin D levels, OR =2.757, 95%CI (1.301, 5.841) compared to those with gravida of more than 3. Mothers who gave birth to children weighting less than 2500g at birth were 4 times likely to have suboptimal vitamin D levels, OR = 3.924, 95%CI (1.637 – 9.410) compared to those weighing above 2500g.

Table 5: The predictors of vitamin D deficiency in mothers at Kenyatta National Hospital

| | | **Vitamin D Levels** | | **P-value** | **OR** | **95% C.I.for OR** | |
|---|---|---|---|---|---|---|---|
| | | **Suboptimal** | **Adequate** | | | **Lower** | **Upper** |
| Age | Less or equal 30 years | 21(17.9) | 96 (82.1%) | | Ref | | |
| | More than 30 years | 34(54) | 29(46%) | **P<0.001** | 0.187 | 0.094 | 0.37 |
| Education | Never attended | 0 | 1 (100) | 0.454 | Ref | | |
| | Primary | 7(21.2) | 26(78.8%) | 1 | 0 | 0 | |
| | Secondary | 29(36.3) | 51(63.8) | 0.421 | 0.666 | 0.247 | 1.793 |
| | Tertiary | 47(71.2) | 19(28.8) | 0.34 | 1.407 | 0.698 | 2.836 |
| Occupation | Salaried | 14(40) | 21(60) | 0.403 | Ref | | |
| | Self employed | 21(28.8) | 52(71.2) | 0.205 | 1.733 | 0.741 | 4.057 |
| | Unemployed | 20(27.8) | 52(72.2) | 0.895 | 1.05 | 0.51 | 2.164 |
| Marital status | Single | 12(34.3) | 23(65.7) | 0.89 | Ref | | |
| | Married | 43(30.1) | 100(69.9) | 0.999 | 2.351 | 0 | 0 |
| | Separated | 0 | 2(100) | 0.999 | 10.12 | 0 | 0 |
| Monthly income | Less than 20000 | 35(53) | 31(47) | **P<0.001** | 4.182 | 2.139 | 8.174 |
| | Greater than 20000 | 22(19.3) | 92(80.7) | | Ref | | |
| Residence | Rural | 8(32) | 17(68) | | Ref | | |
| | Urban | 47(30.3) | 108(69.7) | 0.463 | 0.866 | 1.081 | 0.436 |
| Parity | ≤2 | 53(34.2) | 102(65.8) | **0.018** | 5.975 | 1.357 | 26.316 |
| | >2 | 2(8) | 23(92) | | Ref | | |
| Gravidity | ≤3 | 43(36.8) | 74(63.2) | **0.008** | 2.757 | 1.301 | 5.841 |
| | >3 | 12(19) | 51(81) | | Ref | | |
| Vit D supplements | Yes | 1(20) | 4(80) | 0.608 | 0.56 | 0.061 | 5.13 |
| | No | 54(30.9) | 121(69.1) | | Ref | | |
| Birth weight | Above 2500g | 2(25.0) | 6(75.0) | | Ref | | |
| | Below 2500g | 14(56.0) | 11(44) | **0.031** | 3.924 | 1.637 | 9.41 |

*Dependent variable: Maternal Vitamin D*

### 4.5. Multivariate analysis

A multivariate analysis was conducted controlling for not significant variables in the bivariate model Table 6. The findings revealed that, Age of the mother, p<0.0001, AOR =5.761, 95% CI (2.689, 12.34), Monthly income (less than Ksh.20,000), P = 0.019, AOR =2.514, 95%CI (1.205, 5.341), parity, p<0.0001, AOR =3.244, 95% CI (0.564, 18.66) and gravidity, p= 0.008, AOR =2.395, 95% CI (0.934, 6.140) were independent predictors of suboptimal maternal Vitamin D levels.

Table 6:Multivariate analysis

| | | P-value | AOR | 95%CI (AOR) | |
|---|---|---|---|---|---|
| | | | | Lower | Upper |
| Age | Age of the mother | 0.000 | 5.761 | 2.689 | 12.341 |
| Monthly income | < Ksh.20,000 | 0.019 | 2.514 | 1.205 | 5.341 |
| | ≥Ksh., 20,000 | | Ref | | |
| Parity | ≤2 | P<0.0001 | 3.244 | 0.564 | 18.658 |
| | >2 | | Ref | | |
| Gravidity | ≤3 | 0.008 | 2.395 | 0.934 | 6.140 |
| | >3 | | Ref | | |

### 4.6. The predictors of vitamin D insufficiency and deficiency in neonates at Kenyatta National Hospital maternity ward

The study also sought to determine predictors of vitamin D deficiency in neonates. A binary logistic regression was performed as shown in Table 7. The results revealed that birth weight and maternal vitamin D status were independent predictors of suboptimal Vitamin D levels in neonates. Neonates who born weighing less than 1500g were 10 times likely to have suboptimal vitamin D levels, OR = 9.909, 95%CI (6.601, 13.170) compared to those born

weighing above 2500g. Similarly, neonates born weighing 1500g to 2500g were 8 times more likely to have suboptimal vitamin D levels, OR = 7.833, 95%CI (1.299, 47.237) compared to those born weighing above 2500g. Neonates born of mothers who had suboptimal vitamin D levels were 2 times likely to have suboptimal vitamin D levels, OR = 2.158, 95%CI (1.060 – 4.416).

Table 7: The predictors of vitamin D insufficiency and deficiency in neonates at Kenyatta National Hospital maternity ward

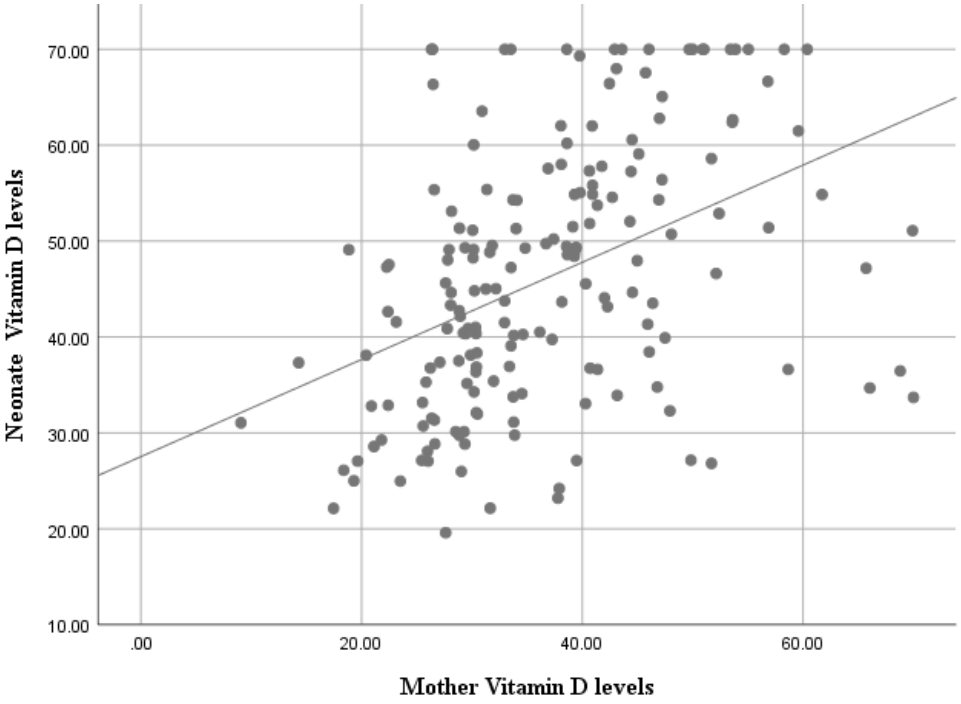
| | | Neonatal Vitamin D levels | | | | 95% C.I.for OR | |
|---|---|---|---|---|---|---|---|
| | | Suboptimal | Adequate | Sig. | OR | Lower | Upper |
| Mother's age | Less or equal to 30 years | 12(10.3%) | 105(89.7%) | 0.276 | 0.606 | 0.246 | 1.493 |
| | Greater than 30 years | 10(15.9) | 53(84.1%) | | 0.189 | | |
| Birth order | 1st born | 8(14.5) | 47(85.5) | | Ref | | |
| | 2nd born | 11(19.3) | 46(80.7) | 0.293 | 2.383 | 0.472 | 12.024 |
| | 3rd born | 1(3) | 32(97) | 0.133 | 3.348 | 0.691 | 16.224 |
| | 4th born or higher | 2(6.7) | 28(93.3) | 0.509 | 0.438 | 0.038 | 5.087 |
| Gender of the child | Male | 13(12.0) | 95(88) | 0.902 | 1.061 | 0.415 | 2.707 |
| | Female | 8(11.4) | 62(88.6) | | Ref | | |
| Birth weight | Above 2500g | 2(25.0) | 6(75.0) | | Ref | | |
| | 1500 to 2500g | 14(56.0) | 11(44) | **0.025** | 7.833 | 1.299 | 47.237 |
| | Less than 1500g | 6(4.1) | 141(95.9) | **p<0.0001** | 9.909 | 6.601 | 13.170 |
| Maternal Vitamin D | Sufficient | 7(5.6) | 118(94.4) | | | | |
| | Deficient | 15(27.3) | 40(72.7) | **0.001** | 2.158 | 1.060 | 4.416 |

Dependent variable: Neonatal Vitamin D

### 4.7. The relationship between vitamin D insufficiency and deficiency in mothers and neonates

Pearson correlation analysis was conducted to determine whether there was a significant relationship between maternal and neonatal vitamin D. The findings show that there was a significant positive relationship between maternal and neonatal vitamin D levels ($r = 0.427$, $p < 0.001$).

Figure 4: Relationship between Vitamin D insufficiency and Deficiency in mothers and their neonates



### 4.8. Association between maternal vitamin D levels and neonatal birthweight

The study also sought to investigate whether maternal Vitamin D levels predict low birthweight in neonates. The results found that maternal vitamin D levels predict neonatal birthweight ($p<0.05$). An increase in maternal vitamin levels was associated with 1.04 times increase in neonatal birth weight, OR = 1.040, 95%CI (1.040, 1.141).

Table 8: Association between maternal Vitamin D levels and neonatal birthweight

| | | | | 95% C.I.for OR | |
|---|---|---|---|---|---|
| | | P-value | OR | Lower | Upper |
| Step 1[a] | Maternal Vitamin D levels | P<0.0001 | 1.090 | 1.040 | 1.141 |

a. Variable(s) entered on step 1: maternal Vit D levels.

## CHAPTER FIVE: DISCUSSION

The study's focus was on the prevalence of vitamin D deficiency in mothers and in neonates. Sixty five percent of mothers who were enrolled were aged 30 years or below. Forty four percent of the mothers had secondary level education, and more than two-thirds of the mothers were married. These findings are comparable to Al-Mahroos et al. (2013) whose study conducted in Bahrain found that the average age of mothers who participated in the study was 29 years. (16).

The prevalence of sub-optimal maternal vitamin D levels was found to be 30.5% while the neonatal prevalence was 12.3%. This is much lower compared to a study conducted in Western Kenya which found that 51% of mothers had vitamin D insufficiency while 21% had vitamin D deficiency(10). This could be explained by study design. In our present study we used a cross sectional study design while the study in Western Kenya utilized the longitudinal study design approach.

In another study conducted in United States , Vitamin D deficiency and insufficiency was found to be 38.9% in mothers and 29.8% in neonates (58). Similarly, the prevalence was also lower than Al-Mahroos et al. (2013) which found that the prevalence of VDD was 88% among mothers and 90% among neonates based on a sample of 403 pairs that were investigated (16). Likewise, Shreetha et al., in a prospective study conducted in Nepal, identified that 81% of the mothers and 35.8% of the babies had VDD. The difference could be attributed to the climate in Kenya, a tropical country located at the equator with lengthy periods of sun exposure. In contrast, these other countries have long winter seasons thus people stay indoors or use heavy clothing leading to a high VDD prevalence.

The study further showed a positive linear relationship between maternal and neonatal serum VD and calcium (59).

The independent predictors of maternal suboptimal vitamin D levels include age, monthly income, socio-economic status, education level, parity and gravida. The findings revealed that mothers aged more than 30 years were less likely to have suboptimal vitamin D levels. This could be because of more knowledge and ease of seeking quality healthcare services as compared to young mothers. In our study, education level was not significant predictor of maternal suboptimal vitamin D levels (21). Similar findings were obtained in studies conducted by Prasad et al. and Sathish et al. which identified that maternal education level and occupation were not associated with VDD levels (52).

The results from our study also showed that mothers who gave birth to children weighing less than 2500g were likely to have sub-optimal vitamin D levels. These findings are comparable to Khalessi who found that Maternal Vitamin D deficiency may increase the risk of low birth weight neonates and modifying maternal nutrition behavior to increase their vitamin D intake could be beneficial on pregnancy outcomes (6). Similarly, Chen et al in a meta analytic review including studies conducted in Asia found that the incidence of low birth weight infants was significantly associated with maternal suboptimal vitamin D levels (60).

The study also assessed predictors of sub-optimal vitamin D levels in neonates. The findings revealed that low birth weight below 2500g and sub-optimal maternal vitamin D levels were determinants of sub-optimal vitamin D levels in neonates. Thus, children born weighing less than 2500g were likely to have sub-optimal vitamin D levels. These findings are comparable to Sauder et al in a study conducted in United States which found that, mothers with sub-optimal vitamin D levels gave birth to low weight new-borns.

The findings also revealed that there was a statistically significant relationship between maternal and neonatal vitamin D deficiency. Mothers who had suboptimal vitamin D levels were likely to give birth to neonates with suboptimal vitamin D levels. Owie and Afolabi

determined a strong relationship between maternal and new-born vitamin D levels, which necessitates the need to build strong nutrient blocks that will promote child growth and development. (46).

# CHAPTER SIX: CONCLUSION AND RECOMMENDATION

## *6.1.* Conclusion

The study results showed the prevalence of vitamin D deficiency and insufficiency to be 9.4% and 21.1% respectively.

Among neonates who were investigated in the study, the prevalence of vitamin D deficiency and insufficiency was 1.7% and 10.6% respectively.

Age, monthly income, parity, gravida and low birth weight were significant independent predictors of maternal Vitamin D deficiency. In addition, the results showed that low birth weight and Vitamin D deficiency in mothers were independent predictors of Vitamin D deficiency in neonates.

## 6.2. Recommendations

1. The introduction of policies that promote routine checkup of vitamin D levels among expectant mothers.
2. Future studies to investigate the effect of sun exposure on Vitamin D deficiency.

**REFERENCES**


1. McKenna MJ, Murray B. Vitamin D deficiency. In: Endocrinology and Diabetes: A Problem-Oriented Approach. 2014 Oct 26:293.

2. Holick MF, Binkley NC, Bischoff-Ferrari HA, Gordon CM, Hanley DA, Heaney RP, et al. Evaluation, treatment, and prevention of vitamin D deficiency: An endocrine society clinical practice guideline. Journal of Clinical Endocrinology and Metabolism. 2011 Jul 1;96(7):1911-30.

3. Vatandost S, Jahani M, Afshari A, Amiri MR, Heidarimoghadam R, Mohammadi Y. Prevalence of vitamin D deficiency in Iran: A systematic review and meta-analysis. Nutr Health [Internet]. 2018;24(4):269–78. Available from: http://dx.doi.org/10.1016/S2214-109X(19)30457-7

4. Boyle V. Vitamin D and pregnancy. Obstetrics, Gynaecology and Reproductive Medicine. 2014 Oct 1;24(10):315-6.

5. Elsori DH, Hammoud MS. Vitamin D deficiency in mothers, neonates and children. J Steroid Biochem Mol Biol. 2018 Jan 1;175:195-9.

6. Khalessi N, Kalani M, Araghi M, Farahani Z. The Relationship between Maternal Vitamin D Deficiency and Low Birth Weight Neonates. J Fam Reprod Heal. 2015 Sep;9(3):113.

7. Sablok A, Batra A, Thariani K, Batra A, Bharti R, Aggarwal AR, et al. Supplementation of Vitamin D in pregnancy and its correlation with feto-maternal outcome. Clin Endocrinol (Oxf). 2015 Oct;83(4):536-41.

8. Josefson JL, Feinglass J, Rademaker AW, Metzger BE, Zeiss DM, Price HE, et al. Maternal obesity and vitamin D sufficiency are associated with cord blood vitamin D insufficiency. J Clin Endocrinol Metab. 2013 Jan 1;98(1):114-9.

9. Prentice A, Schoenmakers I, Jones KS, Jarjou LMA, Goldberg GR. Vitamin D deficiency and its health consequences in Africa. Clin Rev Bone Miner Metab. 2009;7(1):94–106.

10. Toko EN, Sumba OP, Daud II, Ogolla S, Majiwa M, Krisher JT, et al. Maternal vitamin D status and adverse birth outcomes in children from Rural Western Kenya. Nutrients. 2016;8(12):1–11.

11. Van Schoor NM, Lips P. Worldwide vitamin D status. Best Practice and Research: Clinical Endocrinology and Metabolism. 2011 Jan 1:15-40.

12. Płudowski P, Karczmarewicz E, Bayer M, Carter G, Chlebna-Sokół D, Czech-Kowalska J, et al. Practical guidelines for the supplementation of vitamin D and the treatment of defcits in Central Europe - Recommended vitamin D intakes in the general population and groups at risk of vitamin D deficiency. Endokrynol Pol. 2013 64(4):319-27.

13. Kramer H, Berns JS, Choi MJ, Martin K, Rocco M V. 25-Hydroxyvitamin D testing and supplementation in CKD: An NKF-KDOQI controversies report. Am J Kidney Dis. 2014;64(4):499–509.

14. Misra M, Pacaud D, Petryk A, Collett-Solberg PF, Kappy M. Vitamin D deficiency in children and its management: review of current knowledge and recommendations. Pediatrics. 2008 Aug 1;122(2):398-417.

15. Haggerty LL. Maternal supplementation for prevention and treatment of vitamin d deficiency in exclusively breastfed infants. Breastfeeding Medicine. 2011 Jun;158(695):1-6.

16. Al-Mahroos FT, Al-Sahlawi HS, Al-Amer E, Mahmood NA, Sandhu AK, Sharida H, et al. Prevalence and risk factors for vitamin D deficiency among mothers in labor and their newborns. Bahrain Med Bull. 2013 Apr 1;52(3):1115-25.

17. Luxwolda MF, Kuipers RS, Kema IP, Van Der Veer E, Dijck-Brouwer DAJ, Muskiet FAJ. Vitamin D status indicators in indigenous populations in East Africa. Eur J Nutr. 2013 Oct 1;74(4):321-5.

18. Ajmani SN, Paul M, Chauhan P, Ajmani AK, Yadav N. Prevalence of Vitamin D Deficiency in Burka-clad Pregnant Women in a 450-Bedded Maternity Hospital of Delhi. J Obstet Gynecol India. 2016;6(2):729–75.

19. Ritu G, Gupta A. Vitamin D deficiency in India: Prevalence, causalities and interventions. Nutrients. 2014;6(2):729–75.

20. Song SJ, Si S, Liu J, Chen X, Zhou L, Jia G, et al. Vitamin D status in Chinese pregnant women and their newborns in Beijing and their relationships to birth size. Public Health Nutr. 2013 Jul 19;357(3):266-81.

21. Downie D, Antipatis C, Delday MI, Maltin CA, Sneddon AA. Moderate maternal vitamin A deficiency alters myogenic regulatory protein expression and perinatal organ growth in the rat. Am J Physiol - Regul Integr Comp Physiol. 2005 Mar 1;29(2):871-4.

22. Das S, Narayan S, Rai S. Is 400 IU per day of Vitamin-D given to healthy well-nourished mothers antenatally enough to prevent neonatal Vitamin-D deficiency? Med J Armed Forces India. 2018 Jan 11;340.

23. Özdemir AA, Gündemir YE, Küçük M, Sarıcı DY, Elgörmüş Y, Çağ Y, et al. Vitamin D deficiency in pregnant women and their infants. JCRPE J Clin Res Pediatr Endocrinol. 2018;30(69):31.

24. Article R. Vitamin D deficiency in Saudi Arabians : A reality or simply hype : J Fam Community Med. 2018 Oct 1;74(4):321-5.

25. Kearney JM, Khadrawi I, Harastani R, Stack M. Vitamin D Supplementation Practices in Pregnancy and During Infancy and Other Behaviors Related To Vitamin D Status among a Sample of Muslim Women in Ireland and Saudi Arabia. J Nutr. 2015 Aug 1;122(2):398-417.

26. Bhimji KM, Naburi H, Aboud S, Manji K. Vitamin D Status and Associated Factors in Neonates in a Resource Constrained Setting. Int J Pediatr. 2018 Oct 1;74(4):321-5.

27. Naseh A, Ashrafzadeh S, Rassi S. Prevalence of vitamin D deficiency in pregnant mothers in Tehran and investigating its association with serum glucose and insulin. J Matern Neonatal Med. 2018 Jun;18(2):153-65.

28. Dave A, Verma M, Jain N, Dave A. A study of vitamin D levels and associated deficiency in pregnancy and its effect on maternal and fetal outcome. Int J Reprod Contraception, Obstet Gynecol. 2016 Feb 1;135(2):279-82.

29. Merewood A, Brooks D, Bauchner H, MacAuley L, Mehta SD. Maternal birthplace and breastfeeding initiation among term and preterm infants: A statewide assessment for Massachusetts. Pediatrics. 2006 Mar 1;241(1):79-82.

30. Ross AC, Manson JE, Abrams SA, Aloia JF, Brannon PM, Clinton SK, et al. The 2011 Dietary Reference Intakes for Calcium and Vitamin D: What Dietetics Practitioners Need to Know∗∗This article is a summary of the Institute of Medicine report entitled Dietary Reference Intakes for Calcium and Vitamin D (available at http://www.io. J Am Diet Assoc. 2011 May 1;74(4):321-5.

31. Prasad D, Smita KS, Nisha S. Vitamin D in Pregnancy and its Correlation with Feto Maternal Outcome. Age (Omaha). 2018;30(69):31.

32. McCarthy RA, McKenna MJ, Oyefeso O, Uduma O, Murray BF, Brady JJ, et al. Vitamin D nutritional status in preterm infants and response to supplementation. Br J Nutr. 2013;5(1):1–5.

33. Singh G, Singh G, Brar H, Malik S. Vitamin D levels in preterm and term neonates at birth. Int J Contemp Pediatr. 2017 Aug 5;147(19):1-9.

34. Stessman LE, Peeples ES. Vitamin D and Its Role in Neonatal Hypoxic-Ischemic Brain Injury. Neonatology. 2018 Nov 10;375(19):1817-20.

35. Tayel SI, Soliman SE, Elsayed HM. Vitamin D deficiency and vitamin D receptor variants in mothers and their neonates are risk factors for neonatal sepsis. Steroids. 2018;

36. Hossain N, Khanani R, Hussain-Kanani F, Shah T, Arif S, Pal L. High prevalence of vitamin D deficiency in Pakistani mothers and their newborns. Int J Gynecol Obstet. 2011 Feb 1;74(4):381-1.

37. Al-Wassia H, Abo-Ouf N. Prevalence of vitamin D deficiency in mother–infant pairs in a tertiary hospital in the west coast of Saudi Arabia. J Clin Neonatol. 2016;5(4):243.

38. Dawodu A, Wagner CL. Prevention of vitamin D deficiency in mothers and infants worldwide - A paradigm shift. Paediatrics and International Child Health. 2012.

39. N. T. Vitamin D deficiency across Asia. Osteoporosis International. 2010 Nov 10;35(19):7-9.

40. Ayadi ID, Nouaili EBH, Talbi E, Ghdemssi A, Rached C, Bahlous A, et al. Prevalence of vitamin D deficiency in mothers and their newborns in a Tunisian population. Int J Gynecol Obstet. 2016 Dec 3;361(16):56-9.

41. Abbasian M, Chaman R, Amiri M, Ajami ME, Jafari-Koshki T, Rohani H, et al. Vitamin D Deficiency in Pregnant Women and Their Neonates. Glob J Health Sci. 2016 Jan 1;74(4):321-5.

42. Hornsby E, Pfeffer PE, Laranjo N, Cruikshank W, Tuzova M, Litonjua AA, et al. Vitamin D supplementation during pregnancy: Effect on the neonatal immune system in a randomized controlled trial. J Allergy Clin Immunol. 2018;5(1):1–2.

43. Dhandai R, Jajoo M, Singh A, Mandal A, Jain R. Association of vitamin D deficiency with an increased risk of late-onset neonatal sepsis. Paediatr Int Child Health. 2018

Apr 3;31(8):5-9.

44. Wu Z. Vitamin D supplementation in neonates. BMJ Qual Improv Reports. 2014 Feb 1;135(2):2-8

45. Kiely M, O'Donovan SM, Kenny LC, Hourihane JOB, Irvine AD, Murray DM. Vitamin D metabolite concentrations in umbilical cord blood serum and associations with clinical characteristics in a large prospective mother-infant cohort in Ireland. J Steroid Biochem Mol Biol. 2017 Feb 1;135(2):279-82.

46. Owie E, Afolabi BB. Vitamin D deficiency in pregnant women and newborns in Lagos, Nigeria. J Obstet Gynaecol (Lahore). 2018 May 1;89:491-5.

47. Gupta T, Wahi S, Gupta N, Arora S, Gupta S, Bhatia P. Correlation of Vitamin D Levels in Term Normotensive and Pre-eclamptic Patients in Labor. J Obstet Gynecol India. 2016; 19(1):315-9.

48. Zamal A, Manazir AS, Firdaus U, Noor N, Ss S. Neonatal and Pediatric Medicine Relationship between Maternal Vitamin D Levels and Risk of Low Birth Weight in Term Newborns : A Case Control Study. 2019;5(1):1–5.

49. Kaur H. Prevalence of Vitamin D Deficiency in Pregnant women. J Med Sci Clin Res. 2019;7(4):10–5.

50. Karras SN, Shah I, Petroczi A, Goulis DG, Bili H, Papadopoulou F, et al. An observational study reveals that neonatal vitamin D is primarily determined by maternal contributions: Implications of a new assay on the roles of vitamin D forms. Nutr J. 2013 Oct 1;74(4):321-5.

51. El Rifai NM, Abdel Moety GAF, Gaafar HM, Hamed DA. Vitamin D deficiency in Egyptian mothers and their neonates and possible related factors. J Matern Neonatal

Med. 2014 Oct 1;74(4):321-5.

52. Kenyatta National Hospital. Strategic Plan 2013-2018. 2018; ;5(1):1–5.

53. Etikan I. Sampling and Sampling Methods. Biometrics Biostat Int J. 2017 Feb1;51(4):3-4.

54. Thyer BA, Franklin CS, Cody PA, Ballan M. Reliability and Validity in Qualitative Research. In: The Handbook of Social Work Research Methods. 2019;4(1):1–3.

55. Kurian G. Reliability and Validity Assessment. In: The Encyclopedia of Political Science. 2014 Feb 1;56(9):81-3.

56. Heale R, Twycross A. Validity and reliability in quantitative studies. Evid Based Nurs. 2015 Jan 4;32(1):121-2.

57. Hinton P. SPSS Explained. SPSS Explained. 2014: 5(4):243.

58. Marshall I, Mehta R, Ayers C, Dhumal S, Petrova A. Prevalence and risk factors for vitamin D insufficiency and deficiency at birth and associated outcome. BMC Pediatr. 2016 Jan 1;51(4):3-4.

59. Shrestha D, Budhathoki S, Pokhrel S, Sah AK, Shrestha RK, Raya GB, et al. Prevalence of vitamin D deficiency in pregnant women and their babies in Bhaktapur, Nepal. BMC Nutr. 2019; 5(1):1–5.

60. Chen Y, Zhu B, Wu X, Li S, Tao F. Association between maternal Vitamin D deficiency and small for gestational age: Evidence from a meta-analysis of prospective cohort studies. BMJ Open. 2017 Sep 2;32(1):321-2.

## APPENDICES

### Appendix I: Consent form

**Introduction**

My name is Dr. Josephat Atandi, I am a post graduate student and a pediatrics register at Kenyatta National Hospital undertaking a master's degree in Paediatrics and child health, in the school of Medicine, Department of Pediatrics and Child Health, University of Nairobi.

This study is being conducted with the permission of Kenyatta National Hospital- University of Nairobi and Ethics and research committee (KNH-UON ERC Protocol no……).

**Study background**

The prevalence of Vitamin D deficiency (VDD) has been increasing significantly in recent years. The Vitamin D status of the neonates is dependent on the mother status. Recently, Vitamin D status in pregnant women and their neonates has gained increasing attention in the obstetric and neonatal literature. Published research from various regions in the world have documented a high prevalence of VDD in pregnant women ranging from 20% - 90%.

**The study objective**

To determine the prevalence and predictors of vitamin D deficiency in Neonates and their mothers at Kenyatta National Hospital Maternity unit.

**Study procedures**

Upon consent to participate in the study, you will be given a unique registration number which will help in identification during the data collection process. This will be done to ensure that there is high level of confidentiality and privacy of the respondent information. With the help of a research assistant, your demographics as well as those of the newborn will be used to fill the data collection form. Six mls of venous blood will be drawn using a disposable syringe. Blood collected will be put in one plain vacutainers tube for Vitamin D analysis. After delivery, 6 mls of cord blood will be collected to investigate the presence of Vitamin D deficiency. These results will be taken to the lab to investigate presence of Vitamin D deficiency.

**Voluntariness of participation**

Participant into the study is purely on voluntary basis. You will not be coerced into participating into the study against your will. The research assistant will guide you in understanding your right to participate or not participate.

**Confidentiality**

All responses will be treated as strictly confidential, and no participant's results will individually but only in aggregate form.

Participation in this study is voluntary, and there will be no monetary compensation.

The participants also reserve all the rights to withdraw themselves and their data from the study at any time.

**Benefits**

- Free evaluation of vitamin D.
- A copy of the results will be provided to the primary physician and yourself.
- The results will assist in improving management and follow up of the neonates and mothers.
- If the findings indicate Vitamin D deficiency, you will be advised to get Vitamin D supplements.

**Risks, stress and discomfort**

- Slight Pain at the puncture site following specimen collection.
- Swelling may appear at the site of the venipuncture.
- Note: should any of the above occur, feel free to contact Dr. Josephat Atandi

**The right to withdraw**

Remember, your participation is entirely voluntarily. Should you consider changing your mind midway, you have the right to do so, and you shall not suffer any consequence whatsoever.

**Sharing of results**

The results of this study may be presented during scientific and academic forums and may be published in scientific medical journals and academic papers.

**Participants consent**

I confirm that the organizer has explained fully the nature of the study and the extent of activities which I will be asked to undertake and that I have received an information sheet. I confirm that I have had adequate opportunity to questions about this study. I understand that my participation is voluntary 'and that I may withdraw at any time during the study, without having to give a reason. I agree to take part in this study by filling in the questionnaire.

Participant:

Name…….sign…….…… Date……..…

Researcher/Research Assistant:

Name……. …… sign……. ……Date……...

In case of any issues or challenges related to this study, please contact me on **0728135102** or Dr. Paul Laigong on **0735 769615** or KNH/UON ERC Secretariat on Tel.2726300 ext 44102, uonknherc@uonbi.ac.ke.

Thank you for sparing your precious time dedicated to participating in this study exercise.

**Appendix II: Study questionnaire**

Questionnaire Code……Date of Data Collection…….

**Directions for completing the questionnaire**

i. Please do not write your name in any of the pages of the questionnaire.

ii. Please carefully read the instructions at the beginning of each section of the questionnaire before answering the questions in that section.

iii. Please answer all the questions in each section if possible.

**Section A: Socio-Demographic characteristics of the parents/ caregivers**

1. What is your age …….?
2. What is your highest level of education?

Never attended [ ]

Primary [ ]

Secondary [ ]

Tertiary/ University [ ]

3. What is your occupation?

Salaried employee [ ]

Self-employed [ ]

Unemployed [ ]

Others specify…….

4. What is your marital status?

Single [ ]

Married [ ]

Divorced/separated [ ]

Widow [ ]

5. What is your average monthly income? (in Kshs) …….
6. Your Residence

   Rural [ ] Urban [ ]

7. What is your religion

   Christian [ ] Muslim [ ] Hindu [ ]

   Others …….

**Section B: Clinical parameters**

8. Parity []
9. Gravida []
10. Have you used Vitamin D supplements?
    Yes [] No [ ]

**Section C: Laboratory results**

| **11. Serum Vitamin D (calcitriol) (ng/ml)** | **12. Vitamin D [25(OH)D]ng/ml** |
|---|---|
| | |

**Section B: Biographic Data of the neonate (*Choose One Response Only*)**

13. Gender of the child.

Male [ ] Female [ ]

14. Weight at birth (In grams) …….
15. What is the Birth order of the child?

    First [ ]

    Second [ ]

    Third [ ]

    Others specify…….

16. Do you have other children? Yes [ ] No [ ]
17. If yes, how many……
18. Is there another child that had similar problem? Yes [ ] No [ ]

| **19. Cord blood Vitamin D (calcitriol) (ng/ml)** | **20. Vitamin D [25(OH)D]ng/ml** |
|---|---|
| | |

**Kiambatanisho I: kibali cha fomu**

**Utangulizi**

Jina langu ni Dkt. Josephat Atandi, mimi ni mwanafunzi wa baada ya kuhitimu na kujiandikisha pediatrics katika hospitali ya Taifa ya Kenyatta na kufanya shahada ya uzamili katika pediatrics na afya ya watoto, katika shule ya tiba, Idara ya pediatrics na afya ya watoto, Chuo Kikuu cha Nairobi.

Utafiti huu unafanywa kwa idhini ya hospitali ya Taifa ya Kenyatta-Chuo Kikuu cha Nairobi na kamati ya utafiti (KNH-UON Itifaki ya ERC No ... ...).

**Masomo ya msingi**

Kuenea kwa upungufu wa vitamini D (VDD) imekuwa ikiongezeka kwa kiasi kikubwa katika miaka ya hivi karibuni. Hali ya vitamini D ya watoto hutegemea hali ya mama. Hivi karibuni, hali ya vitamini D katika wanawake wajawazito na watoto yao imepata umakini mkubwa katika fasihi ya ukunga na watoto wachanga. Kuchapishwa tafiti kutoka mikoa mbalimbali duniani na kumbukumbu ya kuenea kwa wanawake wajawazito kuanzia 20% - 90%.

**Lengo la utafiti**

Ili kubaini maambukizi na Uabiri kwa upungufu wa vitamini D katika watoto na mama zao katika kitengo cha uzazi wa hospitali ya Kenyatta.

**Hatua za kujifunza**

Baada ya idhini ya kushiriki katika utafiti, watapewa nambari ya kipekee ya usajili ambayo itasaidia katika utambuzi wakati wa mchakato wa ukusanyaji deta. Hii itafanyika ili kuhakikisha kwamba kuna kiwango cha juu cha usiri na faragha ya taarifa ya mhojiwa. Kwa msaada wa Msaidizi wa utafiti, demografia yako pamoja na wale wa mtoto mzawa itatumika kujaza fomu ya ukusanyaji wa data. MLS sita ya damu ya vena itakuwa inayotolewa kwa kutumia sindano ziada. Damu zilizokusanywa itakuwa kuweka katika moja ya wazi ya viputainers tube kwa ajili ya uchambuzi wa vitamini D. Baada ya kuzaa, 6 MLS ya damu ya kambakitovu itakuwa zilizokusanywa ili kuchunguza uwepo wa vitamini D upungufu. Matokeo haya itakuwa kuchukuliwa kwa maabara ya kuchunguza uwepo wa vitamini D upungufu.

**Wito wa ushiriki**

Mshiriki katika utafiti ni rena kwa msingi wa kujitolea. Huwezi kuwa na wakati kushiriki katika kujifunza juu ya mapenzi yako. Msaidizi wa utafiti atawaongoza katika kuelewa haki yako ya kushiriki au sio kushiriki.

**Usiri**

Majibu yote yatakuwa ya siri sana, na hakuna matokeo ya mshiriki peke yake isipokuwa tu kwa aina ya jumla.

Ushiriki katika utafiti huu ni wa kujitolea, na hakutakuwa na fidia ya fedha.

Washiriki pia huhifadhi haki zote za kujitoa wenyewe na data zao kutoka katika masomo wakati wowote.

**Faida**

- Bure tathmini ya vitamini D.
- Nakala ya matokeo itakuwa zinazotolewa kwa daktari msingi na wewe mwenyewe.
- Matokeo itasaidia katika kuboresha usimamizi na kufuatilia watoto na mama.
- Kama matokeo yanaonyesha vitamini D upungufu, utakuwa wanashauriwa kupata vitamini D virutubisho.

**Hatari, dhiki na usumbufu**

- Kidogo maumivu katika tovuti panongaji kufuatia ukusanyaji kigongo cha specimen.
- Uvimbe inaweza kuonekana katika tovuti ya venipuncture.
- Kumbuka: lazima yoyote ya kutokea hapo juu, kujisikia huru kuwasiliana na Dkt. Josephat Atandi

**Haki ya kuondoa**

Kumbuka, ushiriki wako ni wa hiari kabisa. Unapaswa kufikiria kubadilisha mawazo yako Midway, una haki ya kufanya hivyo na hamtakubali matokeo yoyote.

**Kushiriki matokeo**

Matokeo ya utafiti huu yanaweza kuwasilishwa wakati wa vikao vya kisayansi na kitaaluma na inaweza kuchapishwa katika shajara za matibabu ya kisayansi na karatasi za kitaaluma.

**Ridhaa ya washiriki**

Mimi kuthibitisha kwamba Mratibu ina alielezea kikamilifu asili ya utafiti na kiwango cha shughuli ambayo mimi itakuwa aliuliza kufanya na kwamba mimi kupokea karatasi ya habari. Mimi kuthibitisha kwamba nimekuwa na fursa ya kutosha kwa maswali juu ya utafiti huu. Ninaelewa kwamba ushiriki wangu ni wa kujitolea na kwamba ninaweza kutoa wakati wowote wakati wa masomo, bila ya kutoa sababu. Ninakubaliana na kushiriki katika utafiti huu kwa kujaza Dodoso.

Imesainiwa na mshiriki..... Tarehe.....

Katika hali ya masuala yoyote au changamoto zinazohusiana na utafiti huu, tafadhali wasiliana nami mnamo **0728 135 102** au Dkt. Paul laigong **0735 769615** au KNH/uon sekretarieti ERC juu ya Tel. 2726300 atini 44102, uonknherc@uonbi.ac.ke.

Asante kwa kiume wakawawacha hai muda wako wa thamani kujitolea kushiriki katika zoezi hili la utafiti.

**Kiambatisho II: maswali ya kujifunza**

Msimbo wa maswali..... Tarehe ya ukusanyaji data.....

**Maelekezo ya kukamilisha Dodoso**

iv. Tafadhali usiandike jina lako katika kurasa zozote za Dodoso.

v. Tafadhali soma kwa makini maelekezo mwanzoni mwa kila sehemu ya Dodoso kabla ya kujibu maswali katika sehemu hiyo.

vi. Tafadhali jibu maswali yote katika kila sehemu ikiwa inawezekana.

**Sehemu ya: tabia za kijamii kwa watu wa wazazi/walezi**

21. Una umri gani.....?
22. Je, kiwango chako cha elimu ya juu ni kipi?

Usiwahi kuhudhuria []

Msingi []

Sekondari []

Elimu ya juu/Chuo Kikuu []

23. Je, kazi yako ni ipi?

Mfanyakazi wa salaried []

Kujiajiri []

Ajira []

Wengine Taja.....

24. Je, hali yako ya ndoa ni ipi?

Single []

Ndoa []

Iliyoachwa/kugawanywa []

Mjane []

25. Mapato yako wastani wa kila mwezi ni nini?
    Chini ya 10, shilingi 000

    10001-20000 shilingi

    shilingi 20001-30000

    Shilingi za juu-30,000

26. Makazi
    Miji ya vijijini []

27. Dini
Mkristo [] Mwislamu []

Wengine.....

**Sehemu ya B: vigezo vya kliniki**

28. Usawa []
29. Ujauzito
30. Tumia virutubisho
    Ndiyo Hapana []

**Sehemu ya C: matokeo ya maabara**

| **31. Serum vitamini D (calcidiol) (ng/ml)** | **32. Vitamini D [25 (OH) D] ng/ml** |
|---|---|
| | |

**<u>Sehemu ya B: data ya Biographia ya mtoto (*Chaqua Jibu moja tu*)</u>**

33. Jinsia ya mtoto.

Mwanaume [] mwanamke

34. Uzito wa kuzaliwa (katika gramu)

Chini ya 1500 [] 1500 – 2500 [] 2600-3500 [] juu ya 3500 []

35. Je, mpango wa uzazi wa mtoto ni upi?
    Kwanza []

    Pili []

    Tatu []

    Wengine Taja.....

36. Una watoto wengine? Ndiyo Hapana []
37. Kama ndiyo, ni wangapi .....
38. Je, kuna mtoto mwingine ambaye alikuwa na tatizo sawa? Ndiyo Hapana []

| **39. CORD damu vitamini D (calcidiol) (ng/ml)** | **40. Vitamini D [25 (OH) D] ng/ml** |
|---|---|
| | |

**Appendix III: Workplan**

| | Dec-2019 -Feb 2020 | Feb 2020 July 2020 | Oct/ Nov 2020 | Dec/Jan 2020 | Jan 2020 Feb 2021 | March 2021 | April 2021 |
|---|---|---|---|---|---|---|---|
| Development of Proposal | | | | | | | |
| Proposal submission to ethics | | | | | | | |
| Data collection | | | | | | | |
| Data analysis | | | | | | | |
| Thesis Writing | | | | | | | |
| Poster Presentation | | | | | | | |
| Thesis Submission | | | | | | | |

**Appendix IV: Study Budget**

The following is the expected budget for the study:

Study Title: PREVALENCE OF VITAMIN D DEFICIENCY IN MOTHERS AND NEWBORNS

AT KENYATTA NATIONAL HOSPITAL MATERNAL AND CHILD UNIT. (P205/03/2020).

**Study Budget**

| **Components** | **Unit of Measure** | **Duration/ Number** | **Unit Cost (Kshs)** | **Total Cost (Kshs)** |
|---|---|---|---|---|
| **Personnel** | | | | |
| Research Assistant | | 3 | 15000 | 45000 |
| Statistician | | 1 | 30000 | 30000 |
| Participants | | 64 | 100 | 6400 |
| Transcribing Fee | | | | |
| **Printing** | | | | |
| Consent Form | copies | 1 | 100 | 100 |
| Assent Form | | | | |
| Questionnaires | copies | 1 | 100 | 100 |
| Interview Guide | | | | |
| Final Report | | 3 | 500 | 1500 |
| **Photocopying** | | | | |
| Consent Form | copies | 150 | 50 | 7500 |
| Assent Form | | | | |
| Questionnaires | copies | 150 | 50 | 7500 |
| Interview Guide | | | | |
| Final Report | | 6 | 250 | 1500 |
| Final Report Binding | | 3 | 100 | 300 |
| **Diagnostic Services** | | | | |
| Vitamin D kits/reagent | kits | 4 | 63000 | 252000 |
| consumables | | 7 | - | 15750 |
| LAB ASSSISTANT | | 1 | 30000 | 30000 |
| | | | | |
| **Other costs** | | | | |
| ERC Fees | 1 | 1 | 2000 | 2000 |
| Records Access Fee | | 1 | 500 | 500 |
| Poster Printing | | | | |
| | | | | |
| **Total** | | | | **398,650** |

**Budget items Justification:**

1. The budget is necessary as outlined: including facilitation of the research assistants; participants will need Masks for them for protection during this covid19 as a measure to protect them from cross-infection

2. The other budget lines will include cost of reagents; test tubes and storage costs and lab assistant facilitation; and, facilitation for research statistician.
3. Vitamin D kits: 63000 per kit * kits: Kshs. 252,000

4. Consumables:15750

I. Gloves: 3boxes: @ 200 per piece: = Kshs. 600
II. Spirits swabs: 2boxs @300 per box = Kshs. 600
III. Scalp veins 3box 300pcs @ Kshs 8 = Kshs. 2400
IV. Plains tubes with gel 400pc @1200 = Kshs: 4800
V. Serum tubes 400pcs @8 per pc = kshs.3200