A STUDY ASSESSING THE PERIOD PREVALENCE AND FACTORS ASSOCIATED WITH IMPAIRED SKIN INTEGRITY AMONGST PRETERM NEWBORNS ADMITTED TO THE NEWBORN UNIT AT KENYATTA NATIONAL HOSPITAL

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STUDENT'S DECLARATION

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

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LIST OF ABBREVIATIONS

ACOG:	American College of Obstetricians and Gynecologists			
ANN:	Association of Neonatal Nurses			
APCs:	An Antigen-Presenting Cell			
AWHONN:	Associations of Women's Health, Obstetric and Neonatal Nurses			
CHG -	Chlorhexidine Gluconate			
CLSM:	Confocal Laser Scanning Microscopy			
ELBW:	Extremely Low Birth Weight			
KMC:	Kangaroo Mother Care			
KDHS:	Kenya Demographic and Health Survey			
KNH:	Kenyatta National Hospital			
LBW:	Low Birth Weight			
LIC:	Low-Income Countries			
MARSI:	Medical Adhesive-Related Skin Injury			
MRSA:	Methicillin-Resistant Staphylococcus Aureus			
NBU:	Newborn Unit			
NICU:	Newborn Intensive Care Unit			
NHDU:	Neonatal High Dependency Unit			
OR:	Odds Ratios			
PRR:	Pattern Recognition Receptors			
PTNBs:	Preterm Newborn Babies			
SC:	Stratum Corneum			
SGA:	Small for Gestational Age			
SPSS:	Statistical Package for Social Sciences			
TBAs:	Traditional Birth Attendants			
TEWL:	Transepidermal Water Loss			
UON:	University of Nairobi			
VLBW:	Very Low Birth Weight			
VRE:	Vancomycin-Resistant Enterococcus			
WHO:	World Health Organization			

OPERATIONAL DEFINITIONS

Prevalence:	The proportion of persons in a population with a			
	particular disease or attribute at a specified point in time			
	or over a specified period.			
Period prevalence:	The proportion of persons with a particular disease or			
	attribute at any time during a specified interval of time.			
Neonate:	A baby under 28 days of age. (World Health			
	Organization)			
Neonatal Mortality Rate: The Neon	atal Mortality Rate is calculated by dividing the number			
	of resident newborns in a specified geographic area			
	(country, state, county, etc.) who died at less than 28			
	days of age by the number of resident live births in the			
	same geographic area (for a specified period, usually a			
	calendar year) and multiplying by 1,000.			
Term Baby:	According to the American College of Obstetricians and			
	Gynecologists committee in 2013, the label "term baby"			
	was redefined as babies born between 37 0/7 weeks to 41			
	6/7weeks of gestation. These babies are further divided			
	into early-term, full-term, late-term and post-term.			
	(ACOG committee opinion report 2013)			
Preterm Baby:	World Health Organization (WHO) defines a preterm			
	baby as a baby who is born alive before 37 weeks of			
	gestation are completed (WHO Fact Sheet 2018)'.			
Classification of Preterm Neonates				
By Gestational Age:	They are classified into three categories, that is,			
	extremely preterm (less than 28weeks), very preterm			
	(28 to 32 weeks), and moderate to late preterm (32 to 37			
	weeks).			
Skin integrity:	Skin integrity refers to skin health. A skin integrity issue			
	might mean the skin is damaged, vulnerable to injury or			
	unable to heal normally.			
Impaired Skin Integrity:	Defined as altered epidermal or dermal layers of the skin			
	as a result of injury.			

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ABSTRACT

Introduction: The skin is the human body's first line of protection against pathogens and infections of epidemiological relevance. Most preterm babies receive care the newborn unit and this predisposes them to treatment modalities that increase the risk of impaired skin integrity. Skincare for preterm babies and factors that affect skin integrity has not been well studied especially in the African context. This study aimed to establish the prevalence of impaired skin integrity and to highlight the factors associated with the impaired skin integrity in the preterm new-borns.

Objectives: The primary objective was to assess the period prevalence. The secondary objectives were to assess factors associated with impaired skin integrity in preterm babies admitted to the Newborn Unit at the Kenyatta National Hospital.

Methodology: This was an explanatory sequential mixed-method study, with quantitative and qualitative approaches. Consecutive sampling was used to achieve the sample size of the preterm babies, while purposive sampling was used to recruit the mothers/carers. A survey was conducted among the nurses. Skin assessment of the preterm babies was done weekly, up to day 14 of life. A self-administered questionnaire was used among the nurses, and focused group discussions were conducted among the mothers/carers, to assess their knowledge of preterm skin care.

Data Analysis and Presentation: Descriptive statistics were presented as means and standard deviation for continuous variables, and frequency table for categorical variables. Logistic regression was used to assess factors associated with impaired skin integrity. The qualitative data was analyzed into codes and themes according to the study objectives.

Results: The period prevalence of impaired skin integrity was found to be 23.4%, and the factor significantly associated with skin integrity was kangaroo mother care with **COR** 0.42, 95% **CI**: 0.16-0.89.

Conclusion: The prevalence of impaired skin integrity was low and kangaroo mother care conferred a protective effect.

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CHAPTER ONE: BACKGROUND

1.1 Introduction

The World Health Organization (WHO) defines a preterm newborn as a baby born at the age in weeks, of less than 37 completed weeks according to the WHO 2018 fact sheet(1). Prematurity and its complications is considered a matter of global health concern as it is directly responsible for around one-third of neonatal deaths (2). The prevalence of preterm birth is estimated to be 5-18% in the world's 184 nations (3) In a study done by Okube OT et al in 2017, it was noted that the prevalence of preterm birth at Kenyatta National Hospital was 20.5% (4).

According to UNICEF Demographics, Health &Infant mortality 2021 data, and the Kenya Demographic Health Survey of 2021, Kenya's neonatal mortality rate was 21/1000 live births (5). Improved survival of preterm babies due to the increase in accessibility of health care and proper infrastructure, has reduced the neonatal mortality rate in Kenya from 38.6/1000 live births in 1970 to 21/1000 live births in 2019 (2) (5). A relatively high neonatal mortality rate hampers the accomplishment of the Sustainable Development Goal -3, which aims to end preventable deaths of newborn babies, as well as to lower the neonatal mortality rate to at least 12 per 1000 live births (6).

Several complications occur as a result of prematurity, and each contributes to the morbidity and mortality of neonates. One of the complications associated with prematurity is an immature skin barrier function that predisposes the preterm neonate to the harsh extra-uterine environment and increases the risk of morbidity and mortality (3) (7). The skin is the body's first barrier for defense against physical injury, pathogens, and infections. In addition, it facilitates thermoregulation, water-loss control, and electrolyte balance. All these factors contribute to the ability of the neonate to adapt to the external environment (7). The outermost layer of the skin, the stratum corneum serves as the primary barrier between the body and the environment. It does not fully develop till late in the 3rd trimester (29weeks to 40weeks), therefore the skin-barrier function of preterm skin is easily compromised (8).

The majority of preterm babies receive care in their initial days to weeks of life in a neonatal unit. This predisposes them to various treatment modalities such as Newborn Intensive Care Unit (NICU) care, phototherapy, and incubator care, which may put them at a greater risk of impairment of skin integrity. Newborn care practices such as incubator care, phototherapy and radiant warmers are recommended to promote the skin health of preterm neonates during and beyond the neonatal period (9).

Skincare of preterm babies and factors that potentially affect skin integrity have not been well studied especially in the African context. Therefore, this study aimed to establish the period prevalence of impaired skin integrity, and factors affecting skin integrity of preterm babies admitted to the Newborn Unit of Kenyatta National Hospital.

CHAPTER TWO: LITERATURE REVIEW

2.1 Structure of the Skin

The skin of an infant is made up of three layers, the outermost layer, the stratum corneum, the intermediate layer, the viable epidermis, and the innermost layer, the dermis that is made up of blood vessels and nerves that supply the skin. Other cells found in the skin are the Langerhans cells, which serve the immunologic function of the skin as an antigen-presenting cell (APC), and the melanocytes which are responsible for the pigment of the human skin (8).

The epidermis is made up of five layers stratum corneum, stratum lucidum, stratum granulosum, stratum spinosum and the innermost stratum basale (Figure1). Skin is a dynamic tissue that is constantly undergoing keratinocyte growth in the epidermis basal layer, and corneocyte desquamation on the surface of the outermost layer of the epidermis(10). Desquamation entails the breakdown of tight connections that keep the corneocytes together(10). Corneocytes are fixed in an intercellular lipid matrix produced from lamellar bodies and composed of fatty acids, cholesterol and ceramides in the epidermis outermost layer, the stratum corneum(11). The stratum corneum has been shown as a brick wall, with corneocytes and an intercellular lipid matrix which act as brick and mortar respectively(12), as shown in Figure 1 below.



Figure 1:Schematic representation of the epidermis layer of the human skin

*Adapted from Enhancement strategies for transdermal drug delivery systems: current trends and applications (13)

2.2 Development and Function of the Skin

The development of the skin begins during the first trimester, from the 3rd week of pregnancy during the process of gastrulation, whereby there is the formation of three distinct layers with three different cell lines, the endoderm, the mesoderm, and the ectoderm. The skin and the nervous system develop from the ectoderm. Distinct signaling determines the differentiation and layering of the skin. There is the formation of the basal layer, which becomes the basement membrane. The basement membrane separates the epidermis from the dermis (14). There is the formation of the periderm on the basement membrane that allows for growth and stratification of the epidermis up to around 24 weeks when the vernix caseosa is produced. The vernix caseosa is a protective skin layer produced from sebaceous secretions and dead corneocytes. This layer is mostly constituted of water, lipids, and proteins, and is formed as part of the barrier maturation (15). Functional maturation of the stratum corneum begins from 24 weeks of gestational age and continues through the second and third trimesters. A well-defined stratum corneum is not evident until 34 weeks of gestational age. Skin maturation occurs as a gradual and continuous process, with the degree of maturity being determined by the age of the fetus in weeks (16). Figure 2 below shows the development of the skin as described above.



Figure 2:Development of the skin at (A) 4 weeks, (B) 12 weeks and (C) in the newborn. *Adapted from Enhancement strategies for transdermal drug delivery systems: current trends and applications (17)

The skin serves as the body's first line of protection. This includes an epidermal barrier function from physical and chemical injuries, control of body temperature through sweating, and excretion of several substances from the human body (18) (Figure 3).



Figure 3:Diagram showing the structure and function of the skin.

*Adapted from Newborn and Infant skin: Physiology, Development and Care, by Marty O. Visscher et al in Clinics in Dermatology (2015) (8)

The epidermal barrier function in preterm newborns is compromised, as evidenced by increased water loss across the epidermis at 28 weeks of pregnancy and high medication absorption at a gestation of 32 weeks (16). The high surface moisture, high rate of water loss across the epidermis, the high desquamation and proliferation rates of infant skin as well as the high PH are indicators that it is still functionally evolving. As a result, the barrier function of the epidermis is weakened, exposing the skin of a newborn to physical, chemical, and microbiological assaults, as well as skin illness (19).

According to Sedin et al. the expression of developmentally controlled water channels in immature skin may also contribute to excessive water loss across the epidermis (20) (21). The skin's stratum corneum, which serves as a water-retention barrier, is made up of overlapping, dead epidermal cells that are packed with keratin. At 26 weeks, the epidermis in a foetus is still relatively thin, and the stratum corneum is scarcely visible, even though keratinization begins at about 18 weeks of pregnancy(22).

With increasing postnatal and gestational age, trans-epidermal water loss (TEWL) decreases rapidly (21). In newborns born at 24–25weeks gestation, trans epidermal water loss is about 60 g/m2/h (about 140 ml/kg/day in a 1000 g baby) in the first two days after birth at a relative humidity of 50%, then drops to roughly 45 g/m2/h by day three, then to 24g/m2/h by day 28 (23). Skin maturity is comparable to that of full-term newborns in babies born at lower gestational ages of preterm by 2–3weeks of age post-delivery. Trans- epidermal water loss drops to the same order of magnitude as full-term children by 32 weeks gestation, at 6–8 g/m2/h (approximately 12 ml/kg/day) (22).

When different characteristics of the structure of the skin, the composition, and the function are considered, it is evident that the process of skin maturation continues after birth and that the transition from life inside the womb to life outside the womb appears to last longer than the first year of life (19). Despite the fact that epidermal maturation is mostly complete before delivery from a histological standpoint, full-term newborns do not have fully developed skin at birth, with a particular note on the sebaceous and sweat glands (19).

A detailed understanding of healthy newborn skin physiology is essential especially in understanding dermatological illnesses that often affect babies. Major examples include eczema (atopic dermatitis), and diaper dermatitis (24).

2.3 Clinical Manifestations of Skin Lesions in Prematurity

According to Hack M et al 2009, preterm babies in a hospital setting are prone to impaired skin integrity, with 80% of these infants suffering from a lesion during the first month of their stay (19). As a result, the body's defence system is impaired, and the altered integrity site becomes a germ entry point. This leads to sepsis in 25% of preterm and underweight babies by the third day after delivery (19). A clear distinction needs to be made on the difference between cutaneous skin lesions in neonates, and lesions that occur as a result of impaired skin integrity. A study by Gokdemir G et al in Turkey defined some of the lesions observed in some of the

neonates, such as sebaceous hyperplasia, xerosis and milia. It was noted that there is a relation in the skin lesions with gestational age, and mode of delivery (25).

During the neonatal period, skin problems such as benign transitory lesions, napkin dermatitis and associated disorders, infection-related lesions, blistering dermatoses, or mechanical injuries are frequent (26). In a neonate's skin, there are several changes ranging from temporary physiological to severely pathological lesions (26). Majority of infant illnesses are physiological, transitory, and self-limited, and do not require treatment. To evaluate which skin lesions in newborns, require early attention, one would need a solid understanding of both normal and pathological cutaneous lesions (27).

Different dermatological findings, particularly epidermal injuries in newborns have been observed in several studies. These injuries are a result of the handling of the neonate during delivery and post-delivery, and as a result of medical devices used on the baby (27) (28).

Different tools have been developed to assess the skin condition of neonates. One of such tools used is a Neonatal Skin Condition Score developed by the Association of Women's Health, Obstetric and Neonatal Nurses and the National Association of Neonatal Nurses (AWHONN/NANN). This is a 9-point scale score that focuses attention on skin dryness, erythema and skin breakdown (See Table 1) (29). This tool was validated in a study carried out by Carolyn Louska Lund et al in 2004, among 1006 neonates in NICUs and well-baby units in 27 hospitals located across the United States (29) (30). This tool was chosen to assess skin integrity as opposed to other validated tools that assess risk of injury.

	Skin condition	Score		
1	Dryness	1 = Normal, No sign of dry skin		
		2 = Dry skin, visible scaling		
		3 = Very dry skin, cracking, and fissuring		
2	Erythema	1 = No evidence of erythema		
		2 = Visible erythema, < 50% body surface		
		3 = Visible erythema, > 50% body surface		
3	Breakdown/ excoriation	1 = None evident		
		2 = Small, localized area		
		3 = Extensive		

Table 1: Neonatal Skin Condition Score

Note: Perfect score = 3, Worst score = 9

* Adapted from Lund CH, Osborne JW, Kuller J, Lane AT, Lott DA, Raines DA, Neonatal Skin Care: Clinical Outcomes of the AWHONN/NANN Evidence-Based Clinical Practice Guideline, *Journal of Obstetrics, Gynecology, and Neonatal Nursing* (2001) (29)

Standard skin care practices for premature babies reduce the overall morbidity and mortality rate. This in turn decreases their hospital stay and improves their skin health beyond the neonatal period (31) (32)

2.4 Prevalence of Impaired Skin Integrity Among Preterm Babies

In a study by August DL. et al in 2021 on the period prevalence of cutaneous injuries among neonates in 3 neonatal units in New Zealand and Australia, it was found that 206 (41.1%) neonates out of 501 developed cutaneous injuries. Out of the 206 neonates, 109 (52.9%) acquired more than one injury, mainly skin erythema and epidermal stripping. The site of the injuries were the feet (16.4 % n=64) and cheeks (12.5% n=49) (26). In another study, 169 neonates were examined for skin injuries by Habiballah. L in 2017, in a Jordanian Neonatal intensive care unit. They found that the prevalence of preterm skin injuries was 26.6%, and these were mostly adhesive-related skin injuries(33).

According to Cristiane et al who conducted a one-month study in a Neonatal unit of a public hospital in Brazil in 2014, the weight of the preterm neonate had a very important impact on the prevalence of skin lesions. The low weight of the premature babies was directly associated with a higher prevalence of skin lesions(34). The lesions reported in the study were erythema, hematomas, pustules, and blisters. The upper limbs were reported to be the most affected with the lesions at 52% (34). Despite these findings, very few studies have been done on the prevalence of skin lesions among preterm neonates. We shall be looking at some of the factors associated with skin lesions in the next few paragraphs.

2.5 Factors Associated with impaired skin integrity in Prematurity.

Several factors contribute to the development of skin lesions in preterm newborn babies. Since the newborns' skin maturity differs with gestational age, preterm babies manifest various lesions due to chemical, mechanical and physical stimuli that they are exposed to (35). The fragility of the newborn skin is inversely proportional to the gestational age. Therefore, very young preterm babies can get injuries from practices as minor as touch thus directly contributing to the morbidity and mortality of the infant (35). Below are some of the factors reported to have an effect on the skin integrity of preterm neonate.

2.5.1 Hydration Status

The prematurity of the preterm newborn's skin and the high surface area to body weight ratio contribute greatly to the trans epidermal water loss. The initial days after delivery are when trans epidermal water loss is largest (20) (21) (22). Water loss through the skin may surpass urine volume in babies under 28weeks gestation who are nursed under radiant warmers. Without proper steps to reduce the trans epidermal water loss, the loss may exceed urine volume and result in dehydration of the preterm neonate (21). It is challenging to keep a newborn with a high trans epidermal water loss warm since each milliliter of water evaporated from the skin results in a loss of 560 calories of heat and thus these losses must be accounted for to avoid dehydration (36).

2.5.2 Radiant Warmers

Radiant warmers are commonly used to efficiently manage body temperature and provide consistent warmth over exposed body parts in ill preterm and term babies (37). Multiple researchers have indicated that radiant warmers have a great impact on insensible water loss in neonates(38). Radiant warmers can also cause the skin to dry out quickly (36). In this regard, Roychoudhury and Yusuf argued that humidity should be provided for all infants less than 32

weeks gestation, this acts as a means of improving thermal stability, skin integrity by reducing evaporation heat and water loss, and in regulating fluid and electrolyte balance (38).

2.5.3 Phototherapy

Phototherapy is the preferred mode of treatment of neonatal jaundice (hyperbilirubinemia) through exposure of the newborn to artificial blue light. It is considered a high-impact non-invasive method which works by use of light to break the bilirubin thus enabling its metabolism and excretion (39).

For phototherapy to work, a large body surface area must be exposed to light at a certain distance. This has a direct effect on the skin integrity of the skin by causing thermal burns and indirectly by causing increased trans epidermal water loss. Although phototherapy toxicity is uncommon, several cutaneous outbreaks have been observed (39).

Phototherapy may cause purpuric and bullous eruptions in newborns with cholestatic jaundice. Congenital porphyria can be identified by discord and severe blistering under phototherapy (40) (41).

2.5.4 Invasive Procedures and Medical Devices

Various invasive procedures and insertion of medical devices are done on premature neonates in Neonatal Intensive Care Unit (23). Preterm neonates with different surgical conditions undergo surgical procedures that leave them with wounds and areas of breaching in the skin of the newborns. These can easily serve as a conduit for spread of infections that could be life threatening such as sepsis. Sites of entry of some of the medical devices can easily become areas for bacterial biofilms to grow increasing the chances of causing sepsis. Various methods of securing these devices can easily cause damage to the skin while some of the devices cause increased trans epidermal water loss (42).

Continuous positive airway pressure (CPAP) as a non-invasive method of ventilation is one of the most common procedures in the NICU and one of the most common causes of newborn skin lesions (19) (23). According to a systematic review done by Imbulana DI, et al babies with less than 30 weeks of gestational age are more susceptible to pressure lesions caused by the mask/nasal prongs used during use of the CPAP machine (43). Moreover, studies done have shown that the leading cause of device related skin lesions is associated with device fixation, heat sources, use of drugs intravenously, and use of chemical products to clean the devices and the skin around them (23) (44) (45).

2.5.5 Use of Topical Products (Skin Cleansers and emollients)

Various topical products are used in the day-to-day procedures on the neonates in the NICU. Some are useful in protection and prevention of skin lesions, while others contribute to some chemical effects that are detrimental to the skin integrity. Products such as lubricants, special emollients and hydrocolloids are effective in reducing physical and mechanical trauma (32). Antiseptic solutions, antibacterial and antifungal ointment application can easily alter the normal microbial flora of the preterm baby's skin thus weakening the skin immune mechanism. Some of these products could also cause skin irritation and chemical burns compromising the skin structure (46). According to Munson KA, et al, indiscriminate application of topical medication in preterm neonates may increase the risk of nosocomial infections and such are not recommended for use for prophylactic reasons but can be used as treatment (46).

Safe and effective antiseptic use in neonatal intensive care units is mandatory. High efficacy and a low number of side effects from chlorhexidine have permitted avoidance of the use of mercurial and iodine derivatives, but methanol use can be unsafe in extremely preterm newborns (47). Bringue et al. *r*eported two cases of chemical burn after skin cleansing, due to alcoholic chlorhexidine (0.5%) use for umbilical catheter insertion in extreme preterm babies (47).

2.5.6 Use of Adhesives

During their hospital stay, use of adhesives and tape in the premature babies is inevitable because they are mainly used to secure medical and monitoring devices. Medical adhesive-related skin injury (MARSI) has been found to be a common occurrence for both term and preterm babies in NICU (48). Removal of the tape and adhesive easily causes abrasions, erythema, and ulceration. This has been shown to lead to a loss of up to 70 to 90 % of the stratum corneum (49).

In premature babies, due to immaturity of cell development and immunity, any injury can take days for the epithelium to regenerate thus. However small, this is a significant injury, and is a portal for microbial entry that can cause infections. As much as reduction of area of skin in contact with tape would be recommended, there are very few controlled studies on methods to remove dressing on skin and minimize injury and thus care should be taken when handling the adhesives with neonates. The most common type of adhesive associated injury in neonates has been shown to be epidermal or skin stripping. Adhesive associated lesions can range from mild to fatal (48).

According to the study by Christiane C. Timbo et al from Brazil, the upper limbs were found to be the most common site of adhesive associated injury with 20 cases (40%) –lesions <2cm, 17 cases (33%) –lesions between 1-2cm and 14 cases (27%) –lesions >2cm (34). This was attributed to the fact that the upper limbs and extremities were the places of choice for invasive procedures such as drawing blood and intravenous cannulation. Therefore, adhesive products are essential to secure medical devices but are a significant factor contributing to skin breakdown (34).

2.5.7 Kangaroo Mother Care

According to the Canadian Pediatric Society, Fetus and Newborn Committee, kangaroo mother care has been shown to be an effective method in the management of low birth weight and premature newborns, and decreases morbidity and mortality in low and high-income countries (50). Lawn et al found that Kangaroo Mother Care was associated with a decrease of approximately 50% of the neonatal mortality rate (51).

Kangaroo Mother Care contributes directly and indirectly to improved skin condition of the preterm neonate by transfer of skin normal flora from mothers' to babies' skin, thus improving the newborns immunity(50). According to Adisasmita et al, a preterm neonate treated with Kangaroo Mother Care shows more stable body temperature, increased body weight, reduced incidence of severe infection, hypothermia, nosocomial infections and prolonged hospital stay all of which directly contribute towards skin integrity (52).

2.5.8 Incubator Care

According to a study done by Agrens J. et al in 2005, the ambient humidity of an incubator is vital in promoting the maturity of the epidermal barrier function of the preterm skin and in temperature regulation which is a known function of the skin. It was found that the maturity of the preterm skin was better, and the trans epidermal water loss was less in the lower relative humidity of an incubator (53).

2.5.9 Knowledge and Practice of Skin Care on Preterm Babies

During their stay in the hospital, preterm babies are subjected to a variety of medical and nursing interventions (54). Although nurses may not have control over many of the conditions that put preterm newborns at risk for skin breakdown, they may have a beneficial impact on outcomes by assessing, preventing, treating, and continuous evaluation of the skin integrity of the infants (55).

Skin injuries require special care, quick decision making, effective intervention and precise attitude by the caregivers or nurses. While some studies have demonstrated that higher levels of education are a strong predictor of better patient outcomes, others show that nursing education lacks fundamental understanding and nursing care for the preterm newborns' skin (54) (56).

Aside from the structure and physiology of the young skin, preterm newborns in the NICU are at an increased risk of damage due to their continual need of the use of life-saving intrusive equipment and procedures (35) (57). In the NICU, nursing care for neonates' skin comprises of bathing, topical application of emollient oils and other products; use of cutaneous solutions for antisepsis and dressings; maintenance of temperature, avoidance of unnecessary exposure to the environment, and use of incubators (with humidity control). Invasive procedures requiring skin rupture, such as venous or arterial punctures, and the application or removal of adhesives are common. This necessitates a review of the materials used and a reduction in damage caused (42).

Changes in placement, as well as the positioning of infants, are tactics for lowering the danger of pressure damage and heat loss, as well as providing better comfort to the baby, resulting in lower rates of deformities and contractures (31).

As a result, nursing aims to keep babies nested by mimicking the maternal uterine environment while also promoting healthy growth and development. Nursing protocols for preterm newborns' skincare exist, allowing for the systematization of treatment with an emphasis on injury prevention and health promotion. They advise the nursing team on how to care for the immature integument as well as products and topical agents that are appropriate for use on the immature integument (58).

Management of any skin injury among newborn babies requires continuous assessment and should be individualized and carried out by trained personnel. Thus, successful management of these lesions requires optimum competence and knowledge among the professionals involved in order for them to detect, evaluate and manage appropriately (59) (60) (61).

It is thus important to find out the existing knowledge, attitude and practices among nurses who are the main caregivers while the babies are in the hospital. Evidence-based medicine and clinical guidelines can provide the nurses with tools for scientific basis and this study aimed to give light on the need for such a tool (58).

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CHAPTER THREE: STUDY JUSTIFICATION, RESEARCH QUESTIONS AND RESEARCH OBJECTIVES

3.1 Problem Statement

There is a paucity of studies that have been conducted in the region to assess the prevalence of impaired skin integrity among preterm neonates and the variables that contribute to it. Therefore, the current study aimed to assess the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted to the newborn unit at Kenyatta National Hospital.

3.2 Study Justification

In Kenya, there are no set guidelines for the care of the skin of premature babies as compared to developed countries. Moreover, there aren't many or any local studies on this issue and this study will add a local context to the evidence base. This study aimed to investigate the prevalence of skin lesions among preterm babies and the factors affecting skin integrity among preterm neonates. With this information, recommendations were made for standardized care and practice guidelines.

3.3 Research Question

What is the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted to the Newborn Unit at Kenyatta National Hospital?

3.4 Study Objectives

3.4.1 Primary Objective

To assess the period prevalence of impaired skin integrity among preterm neonates admitted in Newborn Unit at Kenyatta National Hospital

3.4.2 Secondary Objectives

- ii. To assess the factors associated with impaired skin integrity in preterm neonates admitted to Newborn Unit at Kenyatta National Hospital
- To assess the knowledge and perception of mothers/carers and nurses on care of skin of preterm babies admitted in Newborn Unit at Kenyatta National Hospital.

CHAPTER FOUR: METHODOLOGY

4.1 Study Design

This study adopted an explanatory sequential mixed-methods study design. The quantitative arm adopted a cross-sectional study method while the qualitative arm adopted a phenomenological study method. The quantitative data was collected through direct assessment of the preterm neonates using a skin assessment tool, and a survey among the nurses using self-administered structured questionnaires. The qualitative data involved conduction of focused group discussions among the mothers/carers. The quantitative data from the preterm neonates and the nurses survey was first collected, and then based on the findings, the qualitative data was then collected from mothers/carers.



Figure 4: Flow diagram showing the Study Design

This study design was appropriate for this study because the qualitative findings would validate the quantitative findings and further explain the outcomes. The qualitative findings would provide insight into the interpretation of the quantitative findings.

4.2 Study Setting

The study was conducted at the Newborn Unit of Kenyatta National Hospital over a period of three months, Dec 2022 to Feb 2023. This is the largest tertiary referral facility in the East and Central Africa region. It is also the largest teaching and referral hospital in the country, serving students from the University of Nairobi. It is located in Nairobi, which is the capital city of Kenya with a patient population of about 5 million. The hospital handles approximately 10,000 deliveries each year.

The Newborn Unit (NBU) is subsequently busy as it caters for an average of 200 babies a month and approximately 18-20% of the admissions to the NBU are preterm neonates according to a study done by Wagura et. Al in Kenyatta National Hospital, New-born Unit (3). The neonatal unit is made up of a Neonatal Intensive Care Unit (NICU), a Neonatal High Dependency Unit (NHDU), three rooms that nurse preterm babies, a Kangaroo Mother care room, and a Nursery for sick term babies. The focus of this study was in the NICU, NHDU, the rooms allocated for care of preterm babies, and the Kangaroo Mother Care Room.

4.3 Study Population

The study population included all preterm neonates <37 completed weeks and aged less than 28 days admitted at KNH newborn unit during the study period. This is because preterm neonates are more susceptible to skin impairment and are at a higher risk of mortality. Gestational age was calculated from the last day of normal menstrual period by Naegele's rule. This rule states that a pregnancy is 40 weeks or 280 days in duration (62). A correlation with clinical examination using the Ballard's score which evaluates a baby's appearance, skin texture, motor function, and reflexes to approximate the preterm gestational age was also carried out (63).

Based on the Naegel's rule, the proposition that a pregnancy is 40 weeks or 280 days in duration; this rule adds nine months and seven days to the first day of the last menstrual period (62). On the other hand, Ballard's score is obtained by the scores from neuromuscular and physical domains which are added to obtain a total score (63).

4.3.1 Inclusion Criteria

Preterm neonates (born at <37 completed weeks and less than 28days of life) admitted to the KNH newborn unit, whose mothers' consent were included. There are three categories of classifying premature newborns by gestational age of preterm birth. These are, extremely preterm (less than 28weeks), very preterm (28 to 32 weeks), and moderate to late preterm (32 to 37 weeks). Another way of classifying preterm new-borns is by their birth weight. There are three categories in this mode of classification. These are, extremely low birth weight (ELBW - <1000g), very low birth weight (VLBW - <1500g), low birth weight (LBW - <2500g).

For this study, the preterm babies were classified according to the gestational age. The mothers of the neonates recruited were included in the focused group discussions to assess their knowledge in skincare of preterm babies after obtaining informed and written consent from them. All the nurses on duty in the newborn unit, who consented, participated in a survey using a self-administered questionnaire assessing knowledge on skin care.

4.3.2 Exclusion Criteria

We excluded babies who were small for gestational age babies but born at term because their skin is considered mature; babies with significant comorbidities like congenital syndromes because they are at high risk of complications during hospital stay; babies with inborn skin conditions like Ichthyosis (Harlequins) and hemangiomas because there is skin impairment right from birth; and babies with birth-related injuries such as caput succedaneum, cephalohematoma, and bruising from malpresentations such as shoulder dystocia and face presentations.

We also excluded babies whose mothers did not give consent, mothers who were not able to sit through the entire duration of the focused group discussions because of their medical condition, and mothers of babies who met the exclusion criteria.

4.4 Limitation

There was a limitation in using weight as a mode of classification. This was because of challenges in distinguishing a true preterm baby from a term baby who is small for gestational age. However, this was mitigated by assessing the babies gestational ages and noting that babies born at term had a mature skin barrier function.

4.5 Sample Size Determination

The sample size for the preterm babies was calculated using the infinite population formula for sample size determination in prevalence studies. (Fischer's formula)

$$n = Z_{\alpha}^{2} p (1-p) / d^{2}$$

n = desired sample size

Z = standard normal value corresponding to 95% confidence interval (1.96)

D = desired degree of precision (0.05)

P = Proportion of babies with poor skin integrity (estimated conservative proportion of 26.6%)Sample population = 301

The estimated conservative proportion was adopted from a study conducted in a Jordanian neonatal intensive care unit, whereby 169 neonates were examined for skin injuries by Habiballah. L in 2017. They found that the prevalence of preterm skin injuries was 26.6% (33).

The quantitative data, which included the preterm neonates skin assessment and the nurses' survey, was collected consecutively until the sample size was achieved.

A census was conducted among the nurses working in the new-born unit, with the sample size calculated according to the total number of nurses in the New-born unit allowing a margin of error of 10% (64). The total number of nurses currently working in the New-born unit is about 85.

We conducted three focused group discussions among the mothers/carers with each group made up of 7-10 mothers/carers.

4.6 Sampling Procedure

Preterm neonates who met the inclusion criteria underwent consecutive sampling until the sample size is achieved. All the mothers of the babies included in the study were recruited by purposive sampling upon admission of the baby. Consent was sought post admission before the baby was assessed for any skin injury. The mothers/carers who participated in the focused group discussions during the period that their babies were in the unit were chosen by convenient sampling from the rooms allocated to preterm neonates while they did intermittent kangaroo

mother care. A census was conducted among the nurses working in the newborn unit and who gave consent to participate in the study.

4.7 Ethical Consideration

Approval to carry out the study was sought from the UON/KNH Ethics committee before undertaking the study. Informed consent was obtained from the study participants (mothers /carers and nurses), after thorough explanation about the study was done. In addition, this research did not interfere with treatment practices at admission. Emergency procedures, if required, was administered before recruitment of subjects to the study. The primary clinician was informed of any babies who were recruited in the study.

Patients' records were not interfered with and were treated with utmost care and confidentiality. They were returned to the respective storage areas for safekeeping after use for the study. Patients' files were not removed from the respective wards by the principal investigator or the research assistant. All information collected about the study subjects was treated with utmost confidentiality. Each questionnaire was checked to ensure that they did not contain personal identifiers to protect the confidentiality of the participants. The questionnaires were safely locked in a cabinet whose key was only accessible to the principal investigator and the research assistant. This protected the participants of the study and the information obtained from the study.

4.8 Study Period

The study was undertaken for a period of three months after ethical approval was obtained.

4.9 Study Variables

The dependent variable was impaired skin integrity (skin is damaged, vulnerable to injury or unable to heal normally), and the independent variables were gender, gestational ages, birth weight and factors affecting the skin integrity (phototherapy, radiant warmers, incubator care, hydration status, and invasive procedures among others). The skin lesions assessed were blisters, pustules, excoriation, rashes, and erythema.

Knowledge, perception, and practice of skincare among the nurses was assessed as a factor affecting skin integrity, and thus was an independent variable.

4.10 Outcome Measures

The aim of this study was to document the following outcomes:

The prevalence of impaired skin integrity (percentage of neonates with damaged skin, vulnerable to injury or unable to heal normally) and the factors associated with impaired skin integrity among preterm neonates in the newborn unit at Kenyatta National Hospital. This will increase awareness of factors associated with impaired skin integrity and allow the care givers in the neonatal unit to intervene in a timely manner and accordingly.

4.11 Data Collection

4.11.1 Study Tool

The study tools comprised a preterm neonatal skin assessment tool for the preterm neonates (Appendix II), a semi-structured questionnaire with for the nurses which allowed the respondents to explain their answers (Appendix IV), and a discussion guide for the focused group discussions used among the mothers (Appendix III).

The skin assessment tool was used to assess the skin integrity of the preterm neonates admitted to the newborn unit, the semi-structured questionnaire was used to assess knowledge and practices of preterm skin care among the nurses in the newborn unit, and the discussion guide was used to assess knowledge and current practice of preterm neonatal skin care among mothers/carers of the preterm neonates.

The skin assessment tool, based on the Neonatal Skin Condition Score tool (see Appendix II), was used to collect data on skin integrity of the preterm neonates weekly up to Day 14 of life (this tool was adopted to facilitate assessment of skin condition). It was developed, and clinically validated by the Associations of Women's Health, Obstetric and Neonatal Nurses of the United States (AWHONN) (30). The data was collected through direct observation.

Both the survey tool and the FGD guide were developed based on peer reviewed published research on neonatal skin care (65) to explain the observed findings. The questions were asked to comprehensively answer the objective on knowledge and practice of preterm neonate skin care.

4.11.2 Study Procedures

This study was carried out by the principal researcher and one clinical research assistant, a nurse, who was trained on the data collection tools. The principal researcher trained and supervised the work of the research assistant. The PI and RA conducted the focus group discussions among the mothers/carers. The study participants (preterm neonates and mothers/carers) were recruited on admission and consent obtained on the day of admission, or on any other day before commencing the study within 7days (Appendix 1a and 1b).

Demographic information (information on mothers and babies) was recorded on admission. The preterm babies were classified into extreme preterm (aged less than 28weeks), very preterm (28 to 32weeks) and moderate to late preterm (32 to 37weeks).

The babies were also classified according to the birth weight into extremely low birth weight (ELBW - <1000g), very low birth weight (VLBW - <1500g), low birth weight (LBW - <2500g). The factors affecting skin integrity in each of the groups were assessed.

Skin assessment was done weekly from admission up to day 14 of life by direct observation and recorded on a skin assessment tool (based on the Neonatal Skin Condition Score tool) (Appendix 2).

All the nurses in the newborn unit were approached and explained the study. Those who gave consent participated in the survey. The nurses' survey was conducted daily, in blocks of eight hours each according to the nurses shifts to ensure highest response rate using a self-administered questionnaire with open ended questions for the nurses (see Appendix 3 and 4).

A discussion guide was then used to assess knowledge of mothers/ care givers on preterm babies' skincare during the hospital stay. The focused group discussions for the mothers/carers comprised of 7-10 participants. A diverse group of mothers were recruited. These were mothers to extreme preterm, very preterm, and moderate to late preterm neonates. We conducted 3 FGDs, one each month from the different rooms allocated for preterm neonates in the newborn unit.

The FGD sessions were conducted in a private space within NBU, and it was done in English and/or Swahili based on participant preferences. The FGDs were audio-recorded after participants provided informed consent.

The preterm skin assessments and the nurses survey were conducted simultaneously then the mothers/carers focused group discussions were conducted sequentially.

Every respondent was required to give consent before commencing with the study. Nonresponse issues were dealt with by ensuring confidentiality, and other ethical issues indicated in the consent form (Appendix 1). The quantitative data was collected on hard copies and then entered into one computer for ease of access during data management. The qualitative data was recorded using a recording device, then extracted and entered into a codebook.

4.12 Data Management and Analysis

The preterm babies' skin assessment findings were classified as Normal and not requiring intervention or Impaired and requiring intervention (A single score of 3 in any area or a

combined score of ≥ 6). This was adopted from the clinical guidelines of neonatal and infant care (66). The nurses survey findings were classified into three categories, knowledge, attitudes, and practice.

The quantitative data analysis was done using SPSS version 27. The data was analysed using descriptive statistics such as frequencies, and respective proportions were used for categorical variables such as the age of the preterm babies, and the demographic background of the respondents. Means, standard deviations and medians were presented for the continuous variables (the attributes of skin integrity). Univariate and multivariable analysis was done on the factors affecting skin integrity. Logistic regression was used to assess statistical significance of the factors associated with impaired skin integrity. All statistical tests were evaluated for statistical significance at a p value of 0.05.

The qualitative data was then collected and recorded from the focused group discussions. The data collection was direct, systematic and constant as it was collected by the same persons (Principal investigator and the research assistant). Recordings were done with a recording device during the FGD sessions, then they were extracted and saved electronically in a designated computer. The data was then coded into themes, and discussed thoroughly according to the study objectives by the principal investigator and the statistician as they went through the recordings. This was done to avoid errors, confusing information, or removing information that could alter the results.

The neonates' data collected was analyzed individually, and integration was done using explanations and direct reporting to explain the significance of the factors associated with impaired skin integrity, while correlating with the knowledge of mothers/carers and nurses. The qualitative data was used to explain the findings of the quantitative data and an interpretation of the integrated data was used to come up with recommendations on the care of preterm neonates' skin. The table below (Table 2) is a summary of the data and the analysis method used.

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Table 2: Data Analysis Summary

Study variables		Type of data	Analysis Method	Charts
Preterm Skin Assessment Tool				
	Demographics	Continuous	Mean (SD), Frequency	Tables
		Categorical	Frequency, Median IQR,	
	General examination of babies	Categorical	Frequency. Percentage	Tables, Bar charts
	Neonatal Skin Integrity (Adequate=, Inadequate=)	Discrete	Prevalence	Pie charts
Mothers/Carers' FDG Guide				
	Demographics	Continuous	Mean (SD), Frequency	Tables
		Categorical	Frequency, Median IQR,	
		Text	Codes and Themes	
Nurses' questionnaire				
	Demographics	Continuous	Mean (SD), Frequency	Tables
		Categorical	Frequency, Median IQR,	
	Knowledge (Adequate ≥50%, Inadequate <50%)	Nominal/ Continuous	Frequency. Percentage, Mean (SD)	Tables, Pie charts
	Attitude and Practice	Categorical	Frequency. Percentage	Tables
Factors affecting skin integrity			Logistic regression model. (Significant factors are set at $P < 0.05$).	Tables

4.13 Control of Errors and Bias

Only candidates who met the inclusion criteria were recruited to the study. The participants were selected by consecutive sampling for the preterm babies, and purposive sampling for the mothers. The questionnaires were pretested to reduce insensitive measure bias. The research assistant was trained on the study objectives and procedures prior to commencement of the study to minimize the absolute involvement of the researcher to reduce bias in questioning. In addition, the principal investigator assessed the responses given to the filled-out questionnaires daily and supervised data entry to ensure validity of the collected data.

CHAPTER FIVE: RESULTS

5.1 Study Participants Enrolment and characteristics

During our study, 310 eligible preterm neonates were identified. Out of the 310 preterm neonates, mothers of 299 preterm neonates gave consent for their babies to participate in the study. This number was within our sample size.

A total of 85 nurses in new-born unit were approached and the study explained to them. Out of the 85 nurses, 83 nurses gave consent to participate in the study.

We conducted skin assessments for 299 neonates and 83 surveys with nurses working at the Newborn unit to assess preterm skin care knowledge, practices, and attitudes. We then conducted 3 Focus Group discussions with mothers of preterm neonates.

The findings from neonates' skin assessments and the nurses' survey were then further explained by the findings from the mothers' FGD.
STUDY PROCEDURES



Figure 5: Flow Diagram showing the Study Procedures

5.1.1 Neonatal characteristics

Of the 299 neonates assessed, 170(57%) were male, median gestation age at birth was 32 (30-34) weeks, and median birth weight 1445(1200-1800), as shown below on Table 3.

Neonate characteristics (N=299)	Median (IQR), n (%)	
Sex		
Male	170(57)	
Female	129(43)	
Gestation (weeks)	32(30-34)	
<=28	31(11)	
29-32	137(48)	
33-37	120(42)	
Birth weight(grams)	1445(1200-1800)	
0 -1000	33(11)	
1001 -1500	130(44)	
1501_2500	126(42)	
2501-3500	10(3)	

Table 3: Neonatal Characteristics

5.1.2 Nurses' characteristics

The nurses who took part in this study were fairly young, median age 33(29-39) and majority were female 71(86%). Nearly half of them 37(45%) had diploma level training (KRCHN) and only 19(23%) were specialist NBU nurses as shown on Table 4.

Table 4:Nurses'	Characteristics
-----------------	-----------------

HCW demographics (N=83)	Median (IQR), n (%)	
Age	33 (29-39)	
Gender		
Female	71(86)	
Male	12(14)	
Qualifications		
Specialist NBU Nurse	19(23)	
BSN	27(32)	
KRCHN	37(45)	
Received specialized training		
Yes	14(17)	
No	69(83)	

*BSN – Bachelor of Science in Nursing, *KRCHN – Kenya Registered Community Health Nurse

5.1.3 Mothers/Carers' (FGD participant) characteristics

We conducted 3 focussed group discussions with 21 mothers of preterm children at Kenyatta National Hospital NBU. More than half, 11 (52%) were aged between 25 - 35 years old, 18 (86%) were educated above secondary level and 16 (76%) were multiparous.

5.2 QUANTITATIVE FINDINGS

5.2.1 Objective 1: Impaired skin prevalence

The following were our findings on local examination of the neonates. Of the 299 preterm neonates, more than half, 182(61%) had erythema, and 214(72%) had scaling. Other skin lesions noted were excoriations in 41(16%), blisters 6(2%) and pustules 1(0.3%) as shown in Figure 6.



Figure 6: Bar graph showing the skin lesions noted during skin assessments.

These skin lesions noted on skin assessment were then scored on each baby using the skin assessment tool, Neonatal Skin Integrity Score (NSIS). Impaired skin integrity was defined as a score of 3 in any of the individual categories, or a total score of ≥ 6 in all the categories. According to the NSIS, no preterm baby had very dry skin or extensive breakdown. Only 3(1%) had erythema visible >50% of skin surface area as shown inTable 5.

Neonatal skin integrity sco	ore
Dryness	
Normal	53(18%)
Dry skin	246(82%)
Very dry skin	0(0%)
Erythema	
No evidence	99(33%)
Visible<50%	197(66%)
Visible>50%	3(1%)
Breakdown	
None evident	168(56%)
Small	131(44%)
Extensive	0(0%)

 Table 5: Findings according to the Neonatal Skin Integrity Score

We found 70 babies had impaired skin integrity. The prevalence of impaired skin integrity was therefore 23.4% (70/299, 95%CI: 18.6-28.2%) as seen in Figure 7.



Figure 7: Pie Chart Showing the Prevalence of impaired skin integrity.

5.2.2 Objective 2: Management Interventions

This group of preterm neonates received several interventions at the Newborn unit; 198 (66%) had phototherapy, 69(23%) were in NICU, 246(82%) required radiant warmers while about half, 153(51%) were on incubator care. Invasive procedures were common in almost all the neonates as documented in 290(97%). The use of adhesives was also common and was seen in 296(99%), while alcohol and antiseptics 299(100%) use was reported in all the babies. Figure 8 illustrates the distribution of the various interventions amongst neonates admitted to the NBU.



Figure 8: Bar graph showing the management interventions employed.

Factors associated with impaired neonatal skin conditions.

We conducted both bivariable and multivariable analysis to assess the factors associated with neonatal skin conditions. Logistic regression was done to determine factors that were significantly associated with skin integrity impairment of the newborns admitted in newborn unit. Variables with a p value <0.05 were considered significant.

Kangaroo mother care (**COR** 0.42, 95% **CI**: 0.16-0.89, **AOR** 0.39, 95% **CI**: 0.14-0.94, (p=0.008)) was significantly associated with impaired skin integrity as shown in Table 6. Preterm babies who received kangaroo mother care had 58% lower odds of having impaired skin integrity compared to preterm babies who did not receive KMC.

The other variables, phototherapy, radiant warmer, incubator care, NICU care, use of adhesives, alcohol cleansers and invasive procedures were found to have no statistical significance to the impairment of skin integrity in the preterm neonates.

Variable	Non	Impaired	COR (95% CI)	p value	AOR (95% CI)	p value
(Neonatal	impaired	skin				
characteristics)	skin	integrity				
	integrity	(N=70)				
Condor	(N=229)					
Eomolo	00(77)	30(23)	1(Deference)		1(Poforonco)	
Mala	120(76)	30(23)	1(Reference)	0.056	$\frac{1}{105(0.6, 1.85)}$	0.853
Niale Disthusicht	130(70)	40(24)	1.01(0.39-1.74)	0.930	1.03(0.0-1.83)	0.835
Dirtiiweigiit (grams)						
(grams)	25(76)	8(24)	1(Reference)		1(Reference)	
1001 -1500	99(76)	31(24)	0.97(0.4-2.38)	0.962	1(100000000000000000000000000000000000	0.718
1501 2500	96(77)	30(23)	0.97(0.12.30)	0.959	1.2(0.15 5.22)	0.298
2501-3500	9(90)	1910)	0.34(0.03-3.17)	0.349	0.67(0.06-7.69)	0.250
Cestation age)()0)	1710)	0.5+(0.05 5.17)	0.547	0.07(0.00 7.05)	0.757
(weeks)						
<=28 weeks	25(81)	6(19)	1(Reference)		1(Reference)	
29-32 weeks	102(74)	35(26)	1.41(0.37-5.35)	0.611	1.5(0.35-6.37)	0.581
33-37 weeks	92(77)	28(23)	0.90(0.23-3.43)	0.879	0.85(0.18-4.18)	0.857
Variable	Normal	Impaired	COR (95% CI)	p value	AOR (95% CI)	p value
(Management	Skin	Skin	, , ,	•		-
interventions)	Integrity	Integrity				
	(N=229)	(N=70)				
Phototherapy						
No	82(81)	19(19)	1(Reference)		1(Reference)	
Yes	147(74)	51(26)	1.52(0.84-2.76)	0.162	1.34(0.71-2.55)	0.370
Neonatal						
Intensive Care						
No	179(78)	51(22)	1(Reference)		1(Reference)	
Ves	50(72)	10(28)	1(Reference)	0.357	1(100000000000000000000000000000000000	0.618
105	30(72)	1)(20)	2.52)	0.337	1.17(0.57-2.58)	0.018
Radiant Warmer			,			
No	44(83)	9(17)	1(Reference)		1(Reference)	
Yes	185(75)	61(25)	1.65 (0.74 -	0.199	2.08(0.87-4.99)	0.101
			3.50)			
Incubator Care						
No	113(77)	33(23)	1(Reference)		1(Reference)	
Yes	116(76)	37(24)	1.09 (0.64-1.87)	0.747	1.06(0.52-2.15)	0.870
Invasive						
procedures	202(77)	(7(00)				
INO N	223(77)	67(23)	1(Reference)	0.120	I(Reference)	0.055
Yes	0(0/)	3(23)	0.40 (0.12-1.33)	0.139	0.28(0.07-1.03)	0.065
Kangaroo Mother Care						

No	120(81)	29(19)	1(Reference)		1(Reference)	
Yes	109(73)	41(27)	0.42(0.16-0.89)	0.008	0.39(0.14-0.94)	0.046

COR - Crude Odds Ratio, AOR - Adjusted Odds Ratio, CI - Confidence Interval

Note: *Use of alcohol/antiseptic cleansers, and use of adhesives, were omitted since all neonates had the intervention.

5.2.3 Nurses' Survey

5.2.3.1 Nurses' knowledge on preterm skin care

Most nurses recognized that preterm skin needs specialized care, 64(77%) and slightly more than half 46(55%) acknowledge that skin care practice is dependent on neonate age.

The majority of the nurses, 69(83%) reported never receiving training on preterm skin care. Only less than a quarter, 18(22%) of the nurses reported training mothers on preterm skin care and almost half 41(49%) of the nurses did the daily preterm skin care.

Use of adhesives and invasive procedures we commonly cited as having an impact on the preterm skin by 82(99%) of nurses. Notably, few nurses, 29(35%) reported that KMC has an impact on preterm skin care. Table 7 gives a summary of the nurses' knowledge parameters.

Nurses Knowledge (N=83)	n (%)
Does preterm skin need specialized care	
Yes	64(77%)
No	19(23%)
Does skin care practice differ based on	
neonate age	
Yes	46(55%)
No	37(45%)
Do the following practices have an impact	
on the skin	
Phototherapy	
Yes	74(89%)
No	5(6%)
I don't know	4(5%)
NICU care	
Yes	70(84%)

~ ~	11(10)
No	11(13%)
I don't know	2(3%)
Radiant warmer	
Yes	72(87%)
No	10(12%)
I don't know	1(1%)
Incubator care	
Yes	54(65%)
No	24(29%)
I don't know	5(6%)
Invasive procedures	
Yes	82(99%)
No	0(0%)
I don't know	1(1%)
Alcohol and antiseptics	
Yes	61(74%)
No	16(19%)
I don't know	6(7%)
Adhesives	
Yes	82(99%)
No	0(0%)
I don't know	1(1%)
КМС	
Yes	29(35%)
No	46(55%)
I don't know	8(10%)
Do nurses train mothers on preterm skin	
care	
Yes	18(22%)
No	65(78%)
Who does daily preterm skin care	
Nurses	41(49%)
Mothers	23(28%)
Both	19(23%)

5.2.3.2 Nurses attitude towards preterm skin care

All the nurses recognized that it is important to teach mothers on preterm skin care and nearly all of them 80(96%) recommended that preterm skin care be included in standard protocols. They felt that training the mothers on preterm skin care was important since the mothers were the primary caregivers, and it would improve baby outcomes faster. In addition, more than half 54(65%) believed that the current preterm skin care practices were inadequate. They further justified that practices were inadequate for the following reasons: they were not adequately

trained on preterm skin care and the unit did not have protocols on preterm skin care thus no uniformity in practice, there were no preterm friendly adhesives and sometimes invasive procedures such as cannulation were not done at the right sites predisposing the neonates to skin injuries. The majority of the nurses 76(92%) believed that appropriate preterm skin care practices had an impact on morbidity and mortality. Table 8 gives a summary of the nurses' perception parameters.

Nurses attitude (N=83)	n (%)
Do you think current skin care practice is adequate	
Yes	29(35)
No	54(65)
Do you think preterm skincare should be included in the standard protocols	
Yes	80(96)
No	3(4)
Do you think it is important to teach mothers about skincare for preterm babies?	
Yes	83(100)
No	0(0)
Do you think appropriate skincare in preterm neonates has an impact on morbidity/mortality	
Yes	76(92)
No	7(8)

Table 8: Nurses' perception on preterm skin care

5.2.3.3 Nurses preterm skin care practices

Only a small number, 10(12%) of nurses reported not routinely assessing preterm skin. 76(95%) of the nurses confirmed the absence of a skin care protocol in the newborn unit.

Those that reported training mothers predominantly mentioned two topics; they taught mothers on doing three-hourly turning of the neonates and cleaning with warm water and cotton.

Majority of them 57(70%) reported that the first preterm bath would be done between day 2-4 and that nothing was applied on the skin after the bath.

More than half of the nurses reported that the preterm babies on incubator, phototherapy or radiant warmer care did not need any specialized skin care procedures; 44(54%), 49(60%),

47(57%) respectively. Those who reported that the babies need specialized skin care mentioned humidity checks in the incubator, temperature regulation, regular turning of the baby and monitoring for dehydration. Table 9 gives a summary of the nurses' practice parameters.

Nurses preterm skin care practices	N	n (%)
Do you routinely assess the skin of preterm babies during daily nursing care	83	
Yes		73(88)
No		10(12)
Do you have a protocol for preterm skincare in the newborn unit	80	
Yes		4(5)
No		76(95)
Age at preterm first bath	82	
Day1		14(17)
Day 2-4		57(70)
Day 7		2(2)
Not given a bath		9(11)
What do you use to clean the skin of a preterm baby	82	
Cloth and water		66(80)
water		14(17)
Chlorhexidine		1(1)
Soap and water		1(1)
Special skin care practices for babies on the following management plans	82	
Incubator		
Yes		38(46)
No		44(54)
Phototherapy		
Yes		33(40)
No		49(60)
Radiant warmer		
Yes		35(43)
No		47(57)

Table 9: Nurses' practice of preterm skin care

5.3 QUALITATIVE FINDINGS

5.3.1 Mothers/Carers' Knowledge, attitudes, and practice

Mothers/Carers' knowledge of preterm skin integrity

Mothers who participated in this study acknowledged that the preterm baby skin is delicate and needs care. Some of their observations were: the skin peels easily, the skin could easily be irritated if not cared for gently.

"I have noticed that since their skin is still premature, when they are exposed, their body temperature drops very quickly."

(Participant 2, FGD 3)

"It should be cared for in a special way by using light items because if you use rough objects, you may affect their skin by maybe turning reddish ... Like a soft piece of cloth, Cleaning them with soft materials" (**Participant 1, FGD 2**)

Mothers' experiences and practices caring for the preterm baby skin.

The most common skin care practice reported by mothers was cleaning with warm water and cotton. They reported having learnt this from the nurses or other mothers.

This confirms the fact that only few nurses reported that they train mothers on skin care and the main topic of training was on cleaning the skin with warm water and cotton.

"When I first came, I didn't know cleaning should be done with a cotton. I found my sister (referring to a fellow mother) using it and she told me that's how they have been doing it. It was not made clear to me that the baby should be cleaned with the cotton, I found people doing that. I asked the neighbor who told me that's how they have been cleaning the babies, I wasn't informed on how to go about it." **Participant 1, FGD 2**)

Participant 2: "Worst case scenario, you are not even guided by the nurse on what to do. I was guided by her (referring to a fellow mother).

Participant 6: Even me, I was shown by her.

Participant 2: So, you are a first-time mother, you don't know where to start, you are just being told to do this and that. And with premature babies, you can be scared to care for them because they are very delicate. So, some negligence on the part of

providers who are with us, they are supposed to educate you step by step on how to care for the baby." (Participant 2&6, FGD 1)

Mothers expressed the need to get feedback or information from the health care workers regarding changes in the baby's skin. They felt that often they would go away with questions or sometimes they would be told to ask the next provider.

"I would like it that when I come to visit my baby, if I meet the doctor or the nurse they should explain to me the situation of the baby's skin, why, what needs to be done, and if it's going to change. At least I be told about my baby's skin so that I don't have questions from time to time of which I can't get answers" (**Participant 6, FGD 1**)

Mothers felt that while medical procedures were important, they were also harmful to the skin. In some cases, they alluded to health care workers not being keen/careful while doing the procedures. Some of the procedures include the use of adhesives to secure feeding tubes, intravenous cannulation sites, CPAP injuries and use of monitors that are often strapped on the neonate leg.

"You can find that they have injected everywhere when looking for veins. So, they end up injecting the same place that is swollen. The doctor would even send me away when doing the injection because I felt so bad ... It (injection site) would swell and become a wound ... It made me stressed." (**Participant 3, FGD 1**)

"Is there anything better that can be used, instead of the tags they have, taking them off is stuck on the baby. Sometimes it is put in such a way it is close to the eye when they plug in the feeding tube. So, is there anything else that can be used, because when you take it off as well, it leaves some redness and rash on the skin. (**Participant 4, FGD 1**)

Some mothers reported not feeling that the health care workers were providing adequate skin care like in this case. They were concerned that intravenous cannulas were not removed as soon as medication doses were completed and attributed this to causing blisters.

"Sometimes you find the medicine in the syringe got depleted but it's not taken off. I think partly it is the reason for the blisters. It can stay for 3 to 4 days before it's taken off" (*Participant 5, FGD 2*)

Training gap

All the nurses reported that there is a need to train mother on preterm skin care. The mothers agreed that they need to be trained.

": It's important to be trained because when caring for the baby you will not have many questions. You will have knowledge of how the skin should be handled" (*Participant 6, FGD* 2)

"For the pre-terms, their skin wouldn't have grown until 9 months, so, it is good that we are educated. But there are mothers who don't know anything about the care, they don't know the difference between a healthy skin and unhealthy one" (**Participant 4, FGD 1**)

"I think we should be educated on how to care for the baby when we take them home. This is because there are those of us who once we are discharged, we go home and start using soap on them. so, we should be taught how to take care of them when at home." (Participant 7, FGD 1)

Also, while training is important, there were few nurses who reported that they trained mothers and mainly on cleaning the skin. This was confirmed by the mothers.

"We are only told how to change the diapers, to wash hands when changing the diaper and after changing the diaper, and how to clean by wiping. Nothing else." (*Participant 3, FGD 1*)

During the FGD, mothers had several questions and often felt unsure about their current skin care practices. Some of the mothers wanted to know if the current cleaning (use of warm water and cotton) is adequate or if they needed to moisturize the skin after cleaning.

5.4 INTERGRATED FINDINGS

Quantitative Findings	Qualitative Findings	Mixed methods inference				
Domain 1: Prevalence						
The prevalence of impaired skin integrity was 23.4%. Most common forms of skin impairment: Scaling 72% Erythema 61%	Mothers' knowledge on skin integrity "It should be cared for in a special way by using light items because if you use rough objects, you may affect their skin by maybe turning reddish Like a soft piece of cloth, Cleaning them with soft materials" (Participant 1, FGD 2) "Though the skin looks like it is still peeling off. When you touch the skin, it feels dry and is peeling off. The skin is till shedding off, that is what I have been observing up to now." (Participant 6, FGD 1)	Scaling and erythema were common observations among preterm infants. This was confirmed by the mothers' observations.				

Table 10: Integration of quantitative and qualitative findings

Quantitative Findings	Qualitative Findings	Mixed method inference				
Domain 2: Experiences						
Use of medical devices and invasive procedures Observed use of adhesives 99%, Observed invasive procedures 97%, 99% Nurses believe adhesives and invasive procedures have impact in skin impairment. Nurses also added that it would be to have some preterm friendly devices such as adhesives that will not irritate their delicate skin	Mothers were concerned about medical devices and invasive procedures. When they strap the head. When you take it off, it comes off with hair, and it is very painful making the baby cry a lot. (Participant 7, FGD 3) the baby monitors really press against their skin, you find that the baby is left with a depression. (Participant 4, FGD 1) "You can find that they have injected everywhere when looking for veins. So, they end up injecting the same place that is swollen. The doctor would even send me away when doing the injection because I felt so bad It (injection site) would swell and become a wound It made me stressed." (Participant 3, FGD 1) Sometimes it (feeding tube) is put in such a way it is close to the eye when they plug in the feeding tube. So, is there anything else that can be used, because when you take it off as well, it leaves some redness and rash on the skin." (Participant 4, FGD	The use of adhesives and invasive procedures was common among preterm infants, and nurses were concerned they lead to skin impairment. Mothers expressed similar concerns.				
Domain 3: Training Gap						
Only 17% of nurses had been trained in preterm skin care. Only 22% of nurses reported training mothers on preterm skin care.	": It's important to be trained because when caring for the baby you will not have many questions. You will have knowledge of how the skin should be handled"	It was quite evident that majority of nurses had not been trained thus they did not train mothers.				

	"We are only told how to change the diapers. To wash hands when changing the diaper and after changing the diaper, you also wash the hands. And, how to clean, by wiping. Nothing else."	
Domain 4: Skin Care Practice	(1 unicipani 3, 1 OD 1)	
65% of nurses reported that skin care practices were not adequate. They further noted that the mainly train mothers on cleaning the preterm skin with water and cotton wool.	"I can say they don't give proper care. True like number five has said, the medicine could be depleted but they leave the needle intact, or when the baby is put under the blue lights you might find the sockets are not fitted properly. Then they take the baby off hastily and even some hair peels off." (Participant 2, FGD 2) "In caring for the baby's skin, I use soft cloth to wipe the skin, so that I don't bruise the skin. I don't use oil on my baby because I applied it once and noted rashes on the skin, so I stopped, and it went away." (Participant 1, FGD 3) "We have been informed that we should not use cleaning wipes, and that we should not apply oil on their skin we should use cotton and water for cleaning." (Participant 2, FGD 2)	Mothers confirmed what had been suggested by healthcare providers on inadequacies in preterm skin care. One common practice that everyone seemed to be most aware of is the use of water and cotton wool to clean.

CHAPTER SIX: DISCUSSION

6.1 Discussion

In this study, we set out to assess the prevalence and the factors associated with impaired skin integrity. We found the prevalence of impaired skin integrity among preterm babies admitted in KNH newborn unit was 23.4%. This was comparable to the prevalence of skin injuries in a study carried out in a neonatal intensive care unit Jordan, that was reported as 26.6% (33). The study in Jordan focused on adhesive skin injuries. This prevalence of preterm skin impairment was lower than a period prevalence of 41.1%, in a study conducted in Australia and New Zealand among preterm neonates admitted to 3 newborn units, with acquired skin injury (26). The difference in the prevalence of preterm skin injuries between our study and the other two studies can be attributed to the difference in duration of the studies, and the difference in the resource settings. The two studies were conducted for a longer duration, and in high resource settings, compared to the prevalence in our study which was conducted for a duration of three months, and in a low/middle income resource setting.

In our study, the preterm neonates at KNH newborn unit were exposed to different management interventions during the duration of the study. We found that phototherapy, NICU stay, and use of radiant warmer were not associated with increased odds of skin injury. This is comparable to the studies done in New Zealand and Australia by August. D et al, and in Jordan by Laila H et al, whereby the skin impairment was reported to have been caused by medical devices and use of adhesives(26,33). The skin assessment tool used in our study assessed types and extent of skin integrity impairment. The spectrum of skin lesions noted in this study included scaling and erythema. There is a paucity of studies reporting specific skin lesions noted in impaired skin integrity.

Out of all the management interventions employed, the only factor found to have statistical significance with impaired skin integrity was kangaroo mother care, whereby preterm babies who received kangaroo mother care had 58% lower odds of having impaired skin integrity. This is probably because kangaroo mother care improved skin condition of preterm neonates by transferring normal flora from mothers' skin to babies' skin, thus improving their immunity, as alluded to by findings from a study by Adisasmitas et al. in North Jakarta(52).

In our study, we found that nurses were aware that preterm skin requires special care, and that it was important to train mothers on this. However, 76(95%) of them confirmed that there is no protocol on the care of preterm skin. This can be compared to a study in a teaching hospital in Malaysia, conducted by Mohamed Z. et al, whereby a knowledge gap was revealed in terms of theoretical and practical application of preterm skin care(58). They also noted that the nurses' duration of working in the newborn unit, or the neonatal intensive care unit (more than 5years) was not a predictor of better preterm skin care practice by the nurses(58). In another study in Brazil, conducted by Delgado B.S et al, nurses' knowledge and experiences of preterm skin care were assessed. In this study, the nurses' responses indicated great capacity in terms of their knowledge and experience in terms of preterm neonatal skin care. There was great concern in use of medical devices and procedures that would predispose the preterm skin to any form of injury(60).

In our study, we found that the knowledge and attitudes of both mothers/carers and nurses was noted to be good, and this may have contributed to the low prevalence of impaired skin integrity that was found. However, the gap noted on the practice of preterm skin care may have contributed to the prevalence of impaired skin integrity.

6.2 Strengths

This study has several strengths that include the study design, which was a mixed methodology of both quantitative and qualitative methods. This method provided strengths that offset weaknesses of both qualitative and quantitative research. This served to improve the validity of the study findings.

This study was unique as it was carried out in an urban setting and in a tertiary facility (Level 6 Hospital) in Kenya. This setting provided the highest level of care to the preterm neonates, thus ideal in terms of availability of resources and quality of care.

This is the first study of its kind in our set up documenting prevalence of impairment of skin integrity in preterm neonates and the factors that affect skin integrity. This study lays a foundation upon which further studies can be conducted tin different settings.

This study conducted in a tertiary hospital (Level 6 National referral Hospital) which serves a large population of patients from different parts of the country.

6.3 Limitations

There was a delay in getting approval from the KNH-UoN ethics committee after submission of the study proposal. This resulted in limited time for data collection. Lack of a second person doing skin assessments of the preterm neonates alongside the primary investigator may have brought in some bias to the findings.

6.4 Dissemination of Study Findings

The results of the study will be presented to the KNH Pediatrics unit, which includes pediatric wards, pediatric emergency unit, and newborn unit through a formal meeting where a copy of the same will be provided. The results will be presented to the University of Nairobi, Pediatrics and Child Health department through a poster presentation. A manuscript would be prepared for journal publication.

6.5 Application of Study Findings

The period prevalence and knowledge of the factors associated with impaired skin integrity of preterm neonates' findings will allow the neonatal unit to develop measures and guidelines to ensure the protection of skin integrity of babies in KNH and other New-born units in the country.

CHAPTER SEVEN: CONLUSION AND RECOMMENDATION

7.1 Conclusion

The prevalence of impaired skin integrity was 23.4%, and the skin lesions noted were dryness with scaling, and erythema.

The factor that was found to be significantly associated with skin impairment was kangaroo mother care, and it had a protective effect.

Knowledge and attitude were good for both nurses and mothers, and this may have contributed to the somewhat low prevalence in impaired skin integrity. However, we noted that there was a gap in the practice due to lack of training for both nurses and mothers/carers. There is therefore a need for training for the nurses who work in the newborn unit and for the mothers/carers whose preterm babies are admitted to the newborn unit, on the appropriate care of the preterm skin.

7.2 Recommendation

Standard operating protocol/guidelines can be developed on preterm skin care based on available and approved preterm skin-care guidelines. This would help improve the care of preterm skin in the newborn unit, and further reduce the prevalence of impaired skin integrity.

Continuous medical education on preterm skin care can be done in the new-born unit. This would ensure that all the staff are up to date on the care of preterm neonates' skin. It would also ensure standardized practice of preterm skin care among all the care givers in the newborn unit.

There can be peer support groups formed among mothers. This means that mothers whose babies have been in the newborn unit longer, and who have been trained on the skin care of their preterm babies, can then teach mothers whose babies are newly admitted into the newborn unit about the care of their preterm babies' skin.

STUDY TIMELINE/WORK PLAN

	2022										
	Jan	Feb	Mar	Apr- Sept	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	April 23
Literature review and concept presentation											
WrittenresearchProposaland1stsubmissiontoKNH-REC											
2 nd submission and corrections											
Final submission and expected approval											
Data collection											
Data analysis											
Report writing											
Submission of report											

BUDGET

S/N	Particular	Description	unit	Unit price in KShs	Total costs in KShs
1	Computer	Laptop	Own	-	0
2	Printer	Laser jet	Own	-	0
3	Proposal Development	Printing, Photocopying, Binding of proposal drafts	6	500	3000
4	Data collection tools	Questionnaires	150	30	4500
		Neonatal Data collection tool	400	30	12000
		Focused group discussion guides	40	10	400
		Recording tools	2	10,000	20,000
5	Data collection	Research Assistant,	1	10,000	40,000
6	Data Analysis	Statistician services	1	90,000	90,000
7	Typing, Photocopying, Printing and Binding Of Final Draft		6	1000	6,000
8	Poster Presentation		1	5000	5,000
9	Contingency 15%				19,000
	Total				204,400

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APPENDICES

Appendix I(a): Consent Form for Mothers/Careers Participating in the Study

Participant Identification Number: ______ Date: _____

Research Title: A study assessing the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted to the newborn unit at Kenyatta National Hospital.

Investigator: **Dr Sinikka Rono**, Postgraduate student, Department of Pediatrics and Child Health, University of Nairobi.

Supervisors:

Dr Jacqueline Oliwa, Lecturer, Department of Pediatrics and Child Health, University of Nairobi.

Dr Martin Aluvaala, Lecturer, Department of Pediatrics and Child Health, University of Nairobi.

Introduction

We are requesting you to participate in this research study to determine the prevalence and factors affecting skin integrity among preterm neonates admitted to the newborn unit at Kenyatta National Hospital. This consent form is going to give you information that will help you decide on whether you are going to take part in this study.

Skin integrity refers to skin health. A skin integrity issue might mean the skin is damaged, vulnerable to injury or unable to heal normally. This study aims to find out the magnitude of impaired skin integrity, how most babies present and the factors that affect normal skin integrity, to increase awareness to help recognize it early and prevent it.

Benefits:

The results of this study will help make decisions on the provision of better care to neonates admitted to the Kenyatta National Hospital newborn unit. The information collected will be shared with the Kenyatta National Hospital, Department of Pediatrics, Newborn Unit and the University of Nairobi Department of Pediatrics to help inform policies on the care of skin in preterm neonates.

Risks: We are going to take some personal information from you to help in our research. You are advised to only answer those that you are comfortable doing so. No personal details will be released to the public that may identify you or your baby.

Procedure:

Once you sign this form to give consent for you and your baby to be part of this study, an initial assessment of the baby's skin will be done. Further assessment of the skin will be done every week while in the ward. There will be no invasive procedure done on the baby during the assessment. A full physical examination will also be done on your baby and recorded. The attending clinician will review the results. In addition, if you consent to this form, you will be required to participate in a focus group discussion together with other mothers.

Confidentiality

We will treat all the information obtained from you with the utmost confidentiality. No names will be used in the research tool. We will not publish or discuss any information collected that may identify either you or your baby.

Recruitment and compensation

It is voluntary to participate in this study and there will be no compensation offered. You are free to withdraw your participation from the study if you wish.

Problems or Questions:

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, **Dr Rono Sinikka** by calling **0723720603**. If you have any questions about your rights as a research participant, you can contact the Kenyatta National Hospital Ethics and Research Committee (**KNH/UoN- ERC**) by calling 2726300 **Ext. 44355**. To contact my supervisors:

Dr. Jacquie Oliwa: 0722 854812; joliwa@uonbi.ac.ke

Dr. Martin Aluvaala: 0722 217 034; jaluvaala@uonbi.ac.ke

Participant's Statement:

I.....having received adequate information regarding the study research, risks, and benefits hereby AGREE / DISAGREE (Cross out as appropriate) to participate in the study with my baby. I understand that our participation is fully voluntary and that I am free to withdraw at any time. I have been given adequate opportunity to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Caregiver's Signature: Date:

Witness: Date:

I..... declare that I have adequately explained to the above participant, the study procedure, risks, and benefits and given him /her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Interviewer's name:Date:Date:

Appendix I(b): Ilani Ya Mlinzi Wa Mtoto Kushiriki Katika Utafiti

Namba tambulishi ya mshiriki: _____

Tarehe: ___

Mada ya Utafiti: Utafiti wa kutathmini kipindi cha maambukizi na mambo yanayohusiana na kuharibika kwa uadilifu wa ngozi miongoni mwa watoto waliozaliwa kabla ya wakati wao kulazwa katika kitengo cha watoto waliozaliwa katika Hospitali ya Kitaifa ya Kenyatta. Jina la Mtafiti: Daktari Sinikka Rono, mwanafunzi wa shahada ya juu ya uuguzi wa watoto katika chuo kikuu cha Nairobi.

Wasimamizi

Dk. Jacquie Oliwa, Mkufunzi katika chuo kikuu cha Nairobi.

Dk. Martin Aluvaala, Mkufunzi katika chuo kikuu cha Nairobi.

Kauli ya Mtafiti

Tunakuomba ushiriki katika utafiti huu ili kubaini maambukizi na mambo yanayoathiri uadilifu wa ngozi miongoni mwa watoto wachanga waliozaliwa kabla ya wakati wao kulazwa katika kitengo cha watoto waliozaliwa katika Hospitali ya Kitaifa ya Kenyatta. Fomu hii ya idhini itakupa maelezo ambayo yatakusaidia kuamua kama utashiriki katika utafiti huu.

Mwanzo wa Mada

Uadilifu wa ngozi unahusu afya ya ngozi. Suala la uadilifu wa ngozi linaweza kumaanisha kuwa ngozi imeharibika, inaweza kujeruhiwa au haiwezi kupona kawaida. Utafiti huu unalenga kujua ukubwa wa unyogovu wa uadilifu wa ngozi, jinsi watoto wengi wanavyojitokeza na mambo yanayoathiri uadilifu wa kawaida wa ngozi, ili kuongeza ufahamu wa kusaidia kuitambua mapema na kuizuia.

Utaratibu wa Utafiti

Mara tu unapotia saini fomu hii ili kutoa idhini kwa wewe na mtoto wako kuwa sehemu ya utafiti huu, tathmini ya awali ya ngozi ya mtoto itafanywa. Tathmini zaidi ya ngozi itafanywa kila wiki wakati wa wodi. Hakutakuwa na utaratibu wa uvamizi unaofanywa kwa mtoto wakati wa tathmini. Uchunguzi kamili wa kimwili pia utafanywa kwa mtoto wako na kurekodiwa. Matokeo yatapitiwa na daktari anayehudhuria. Zaidi ya hayo, ukikubali fomu hii, utahitajika kujaza dodoso utakayopewa, na baadaye kushiriki katika majadiliano ya kikundi pamoja na akina mama wengine.

Faida ya Utafiti

Matokeo ya utafiti huu yatasaidia kufanya maamuzi juu ya utoaji wa huduma bora kwa watoto wachanga waliolazwa katika kitengo cha watoto waliozaliwa katika Hospitali ya Kitaifa ya Kenyatta. Taarifa zitakazokusanywa zitashirikishwa kwa Hospitali ya Kitaifa ya Kenyatta, Idara ya Madaktari wa Watoto, Kitengo cha Watoto Waliozaliwa na Idara ya Magonjwa ya Watoto ya Chuo Kikuu cha Nairobi ili kusaidia kuarifu sera za utunzaji wa ngozi kwa watoto wachanga waliozaliwa kabla ya wakati.

Hatari

Tutachukua taarifa za kibinafsi kutoka kwako ili kusaidia katika utafiti wetu. Unashauriwa kujibu yale tu ambayo unastarehesha kufanya hivyo. Hakuna maelezo ya kibinafsi yatatolewa kwa umma ambayo yanaweza kukutambulisha wewe au mtoto wako.

Usiri

Tutashughulikia taarifa zote zilizopatikana kutoka kwako kwa usiri wa hali ya juu. Hakuna majina yatatumika katika zana ya utafiti. Matokeo yote tutakayopata kwa utafiti yatawekwa siri. Tutawajusa wakubwa wa kitengo cha watoto katika hospitali kuu ya Kenyatta na chou kikuu cha Nairobi kuhusu matokeo ya utafiti. Hatutachapisha au kujadili taarifa yoyote iliyokusanywa ambayo inaweza kukutambulisha wewe au mtoto wako.

Kijitolea na fidia

Ni kwa hiari kushiriki katika utafiti huu na hakutakuwa na fidia itakayotolewa. Uko huru kuondoa ushiriki wako kutoka kwa utafiti ikiwa unataka, na wakati wowote bila tashwishi yoyote.

Matatizo au Maswali:

Ukiwahi kuwa na maswali yoyote kuhusu utafiti au kuhusu matumizi ya matokeo unaweza kuwasiliana na mpelelezi mkuu, **Dk. Rono Sinikka** kwa kupiga simu **0723720603**. **Barua Pepe: snixrono@gmail.com.** Ikiwa una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na Hospitali Kuu ya Kenyatta. Kamati ya Maadili na Utafiti ya Hospitali (**KNH/UoN- ERC**) kwa kupiga simu Tel. (254-020) 2726300-9 Ext 44355. Barua Pepe: uonknh erc@uonbi.ac.ke

Ili kuwasiliana na wasimamizi:

Dr. Jacquie Oliwa: 0722 854812; joliwa@uonbi.ac.ke

Dr. Martin Aluvaala: 0722 217 034; jaluvaala@uonbi.ac.ke

Kauli ya mlinzi wa mtoto/Kauli ya Mshiriki:

Mimi...... baada ya kupokea taarifa za kutosha kuhusu utafiti, hatari, manufaa kwa hili NAKUBALI/SIKUKUBALI (Kumbuka inavyofaa) kushiriki. katika masomo na mtoto wangu. Ninaelewa kuwa ushiriki wetu ni wa hiari kabisa na kwamba niko huru kujiondoa wakati wowote. Nimepewa nafasi ya kutosha kuuliza maswali na kutafuta ufafanuzi juu ya utafiti na haya yameshughulikiwa kwa njia ya kuridhisha.

Sahihi ya mlinzi wa mtoto: _____ Tarehe: _____

Alama ya kidole gumba cha mlezi

(Alama ya kidole gumba itatumika ikiwa mlezi hawezi kutia sahihi)

Sahihi ya shahidi: _____ Tarehe: _____

Mimi kutangaza kwamba nimemweleza mshiriki hapo juu vya kutosha, utaratibu wa utafiti, hatari, na manufaa na kumpa muda wa kuuliza maswali na kutafuta ufafanuzi kuhusu utafiti. Nimejibu maswali yote yaliyoulizwa kwa uwezo wangu wote.

Sahihi ya mtafiti: _____ Tarehe:_____

Appendix I(c): Consent Form for Nurses Participating in the Study

Participant Identification Number:

Date:

Research Title: A study assessing the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted to the newborn unit at Kenyatta National Hospital.

Investigator: Dr Sinikka Rono, Postgraduate student, Department of Paediatrics and Child Health, University of Nairobi.

Supervisors:

Dr Jacquei Oliwa, Lecturer, Department of Pediatrics and Child Health, University of Nairobi. **Dr Martin Aluvaala**, Lecturer, Department of Pediatrics and Child Health, University of Nairobi.

Introduction

We are requesting you to participate in this research study to determine the prevalence and factors affecting skin integrity among preterm neonates admitted to the newborn unit at Kenyatta National Hospital. This consent form is going to give you information that will help you decide on whether you are going to take part in this study.

Skin integrity refers to skin health. A skin integrity issue might mean the skin is damaged, vulnerable to injury or unable to heal normally. This study aims to find out the magnitude of impaired skin integrity, how most babies present and the factors that affect normal skin integrity, to increase awareness to help recognize it early and prevent it.

Benefits:

The results of this study will help make decisions on the provision of better care to neonates admitted to the Kenyatta National Hospital newborn unit. The information collected will be shared with the Kenyatta National Hospital, Department of Paediatrics, Newborn Unit and the University of Nairobi department of paediatrics to help inform policies on the care of skin in preterm neonates.

Risks: We are going to take some personal information from you to help in our research. You are advised to only answer those that you are comfortable doing so. No personal details will be released to the public that may identify you.

Procedure:

Once you sign this form to give consent to be part of this study, you will be given a survey form to fill out to the best of your knowledge.

Confidentiality

We will treat all the information obtained from you with the utmost confidentiality. No names will be used in the research tool. We will not publish or discuss any information collected that may identify you.

Recruitment and compensation

It is voluntary to participate in this study and there will be no compensation offered. You are free to withdraw your participation from the study if you wish at any point without consequence.

Problems or Questions:

If you ever have any questions about the study or the use of the results, you can contact the principal investigator, **Dr Rono Sinikka** by calling **0723720603**. If you have any questions about your rights as a research participant, you can contact the Kenyatta National Hospital Ethics and Research Committee (**KNH/UoN- ERC**) by calling 2726300 **Ext. 44355**.
Participant's Statement:

I.....having received adequate information regarding the study research, risks, and benefits hereby AGREE / DISAGREE (Cross out as appropriate) to participate in the study with my baby. I understand that our participation is voluntary and that I am free to withdraw at any time. I have been given adequate opportunities to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Nurse's Signature: Date:

Witness: Date:

I..... declare that I have adequately explained to the above participant, the study procedure, risks, and benefits and given him /her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Interviewer's name:Date:Date:

Appendix II: Neonatal Skin Conditions Score

Participant Identification Number: _____ Date: _____

Study title: A study assessing the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted to the newborn unit at Kenyatta National Hospital.

2.0 Study nur	nber				
2.0 Date:(dd/	mm/yy)				
2.0 Neonate	Information				
Date of	Date of birth				
Gesta	Gestational age at birth				
2.1 Se	2.1 Sex Male () Female ()				
2.2 Ag	2.2 Age (day of life)				
2.3 Es	2.3 Estimated gestation at birth(weeks)				
2.4 Bi	2.4 Birth weight(grams)				
2.5 Da	2.5 Date of admission				
2.6 Da	2.6 Date of discharge				
2.7 D	2.7 Duration of Hospital stay				
2.8 G	2.8 General exam				
a)	Pallor	Mild	Moderate	Severe	
b)	Jaundice	Yes	No		
c)	Edema	Yes	No		
	If yes specify site				
d)	d) Hydration status				
i.	Well hydr	ated		Yes	No
ii.	Mild Dehy	dration		Yes	No
iii	. Moderate	dehydration		Yes	No
iv	. Severe del	nydration		Yes	No

2.9 Local examination of skin (tick appropriately

1.	Blisters	Yes	No
2.	Pustules	Yes	No
3.	Excoriation	Yes	No
4.	Erythema	Yes	No
5.	Scaling	Yes	No
6.	Any others (s	pecify)	

2.10 Management interventions done (Circle appropriately to all that apply)

		Week	Week 1		Week 2	
a.	Phototherapy	Yes	No	Yes	No	
b.	Neonatal Intensive Care Unit	Yes	No	Yes	No	
c.	Radiant Warmer	Yes	No	Yes	No	
d.	Incubator Care	Yes	No	Yes	No	
e.	Invasive procedures	Yes	No	Yes	No	
f.	Use of alcohol/antiseptic cleansers	Yes	No	Yes	No	
g.	Use of Adhesives	Yes	No	Yes	No	
h.	Kangaroo Mother Care	Yes	No	Yes	No	

2.11 Neonatal Skin Conditions Score

Criteria	Description	Score	Score
		1	2
Dryness	Normal, no signs of dry skin		
	Dry skin with visible scaling		
	Very dry skin with cracking and/or fissures present *		
Erythema	No evidence of erythema		
	Visible erythema (< 50% body surface)		
	Visible erythema (>50% body surface) *		
Breakdown	None evident		
	Small and/or localized areas		
	Extensive		
Total Score			

Note: Perfect score = 3, worst score = 9

Appendix III(a): Focus Group Discussion Guide Questions for Mothers

Participants Identification Number: _____ Date: _____

Study title: A study assessing the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted to the newborn unit at Kenyatta National Hospital.

We are requesting you to participate in this research study to determine the prevalence and factors affecting skin integrity among preterm neonates admitted to the newborn unit at Kenyatta National Hospital. We will treat all the information obtained from you with the utmost confidentiality. No names will be used in the research tool. We will not publish or discuss any information collected that may identify either you or your baby. Please be as honest as possible. Thank you.

Number of participants.....

Age groups

- \circ <25 years
- o 25-35 years
- o 35-45 years
- \circ >45 years

Level of Education

- o None
- Primary Level
- Secondary level
- Tertiary level

Parity

- \circ Primigravida
- o Multipara

Guide Questions

- 1. What have been your experiences caring for newborn skin in premature babies?
- 2. Do you think the skin of premature babies need special care? What kind of care?
- 3. How do you normally care for the newborn baby's skin? How do you clean? with what? how often? what do you apply and how often?
- Do you observe the nurses doing any special procedures to protect the skin of the newborn babies? Give examples.

PROBES

- 5. Do you think the current skin care practice is adequate? Why or why not?
- 6. Do you think it is important to learn about care of skin of a preterm neonate? If yes, give details.
- 7. Have you received any information while here on how to care for newborn skin? From whom exactly? If yes, what information were you given? Do you feel like you now know enough? What else would you like to know?
- What are some of the lesions that appear in a baby's skin that would make you worry?
 Probes Types of lesions
- 9. What are some of the procedures they have seen being done that may jeopardize baby's skin? Probes -

Appendix III(b): Maswali ya Mwongozo wa Majadiliano ya Kikundi kwa Akina Mama

Nambari ya Utambulisho wa Washiriki: _____

Tarehe:

Kichwa cha utafiti: Utafiti unaotathmini maambukizi ya kipindi na mambo yanayohusiana na uadilifu wa ngozi ulioharibika miongoni mwa watoto wachanga waliozaliwa kabla ya wakati waliolazwa katika kitengo cha watoto wachanga katika Hospitali ya Kitaifa ya Kenyatta. Tutashughulikia habari zote zilizopatikana kutoka kwako kwa usiri mkubwa. Hakuna majina yatakayotumika katika chombo cha utafiti. Hatutachapisha au kujadili habari yoyote iliyokusanywa ambayo inaweza kutambua ama wewe au mtoto wako. Tafadhali kuwa mkweli iwezekanavyo. Asante.

Idadi ya washiriki.....

Makundi ya umri

o < miaka 25

o miaka 25-35

o miaka 35-45

o miaka >45

Ngazi ya Elimu

o Hakuna

- o Ngazi ya Msingi
- o Ngazi ya Sekondari
- o Ngazi ya juu

Parity

- o Primigravida
- o Multipara

Maswali ya Mwongozo

1. Uzoefu wako wa kutunza ngozi ya watoto wachanga kwa watoto wanaozaliwa kabla ya wakati?

2. Je, unadhani ngozi ya watoto wanaozaliwa kabla ya wakati inahitaji uangalizi maalum? Utunzaji wa aina gani?

3. Kwa kawaida unatunzaje ngozi ya mtoto mchanga? Unasafishaje? na nini? mara ngapi? Unapaka nini ukishamsafisha mtoto? Na mara ngapi?

4. Je, unawaona wauguzi wakifanya taratibu zozote maalumu za kulinda ngozi za watoto wachanga? Toa mifano

UCHUNGUZI

5. Je, unadhani mazoezi ya sasa ya utunzaji wa ngozi yanatosha? Kwa nini au kwa nini?

6. Je, unadhani ni muhimu kujifunza kuhusu utunzaji wa ngozi ya mtoto mchanga kabla ya wakati? Ikiwa ndio, toa maelezo

7. Je, umepata taarifa yoyote ukiwa hapa kuhusu namna ya kutunza ngozi ya watoto wachanga? Kutoka kwa nani hasa? Kama ndiyo, ulipewa taarifa gani? Unahisi kama sasa unajua vya kutosha? Nini kingine ungependa kujua?

8. Ni baadhi ya vidonda vinavyojitokeza kwenye ngozi ya mtoto ambavyo vitakufanya uwe na wasiwasi? Uchunguzi - Aina za vidonda

9. Ni baadhi ya taratibu ambazo wameona zikifanywa ambazo zinaweza kuhatarisha ngozi ya mtoto? Uchunguzi -

Appendix IV: Survey tool for Nurses

Study title: A study assessing the period prevalence and factors associated with impaired skin integrity amongst preterm newborns admitted in new born unit at Kenyatta National Hospital.

We are requesting you to participate in this research study to determine the prevalence and factors affecting skin integrity among preterm neonates admitted in the newborn unit at Kenyatta National Hospital. We will treat all the information obtained from you with utmost confidentiality. No names will be used in the research tool. We will not publish or discuss any information collected that may identify either you or your baby. Please be as honest as possible. Thank you.

Study number Date: **Biodata** Nursing Staff Characteristics 3.1 What is your age in years?..... 3.2 What is your sex? Female () Male () 3.3 What is your qualifications? KRCHN Nurse () 0 BSc Nurse () 0 Specialist NBU Nurse () 0 3.4 How long have you worked in the newborn unit (in years)?..... 3.5 Have you received specialized training on the care of preterm' skin? Yes () No() If yes, how long ago did you receive the training?..... 3.6 Who does the daily care of skin in the preterm babies in the Newborn Unit? Nurses 0 Mothers/Carers \cap 3.7 Do you train mothers on the basic skin care of a preterm newborn? No() Yes () If yes, give details.....

Knowledge of Skin Care Among Nurses

3.8 Are you aware that the skin of a preterm baby requires specialized care?

Yes () No ()

3.9 Does skincare practice differ according to the age of the preterm neonate?

Yes No

If yes, give details.....

3.10List the common characteristics of impaired skin integrity in preterm babies.....

3.11 Do the following practices have an impact on the skin of a preterm baby?

0	Phototherapy	Yes	No	I don't know
0	Neonatal Intensive Care Unit care	Yes	No	I don't know
0	Radiant Warmer	Yes	No	I don't know
0	Incubator Care	Yes	No	I don't know
0	Invasive procedures	Yes	No	I don't know
0	Use of alcohol/antiseptic cleansers	Yes	No	I don't know
0	Use of Adhesives	Yes	No	I don't know
0	Kangaroo Mother Care	Yes	No	I don't know

The attitude of Nurses toward Preterm Skin Care

3.12 Do you think the current skincare practice is adequate?

Yes No

The practice of Preterm Skin Care

3.16 Do you routinely assess the skin of preterm babies during daily nursing care?

No

Yes No If yes, specify what you would look for, and what you would worry about.....

3.17 Do you have a protocol for preterm skincare in the newborn unit?

If yes, give details of what it entails.....

3.18 At what age do you give a preterm baby its first bath?

Yes

- o Day 1
- Day 2-4
- Day 7(week)
- Not given a bath

3.19 What do you use to clean the skin of a preterm baby?

- Cloth and water
- Water
- Chlorhexidine and Water
- Soap and Water
- Others(specify).....

3.20 What do you apply to the baby's skin after cleaning?.....

- 3.21 Are there special skincare practices for babies on the following management plans?
 - Babies on incubator care.....
 - Babies on phototherapy.....
 - Babies on radiant warmers.....

THANK YOU FOR AGREEING TO PARTICIPATE IN THIS STUDY. WE WILL SHARE THE FINDINGS AND CONCLUSIONS ONCE THE STUDY IS COMPLETE.

KNH-UON ERC APPROVAL



- Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <u>https://research-portal.nacosti.go.ke</u> and also obtain other clearances needed.

Yours sincerely,

R . DR. BEATRICE K.M. AMUGUNE SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN The Senior Director, CS, KNH The Assistant Director, Health Information Dept., KNH The Chairperson, KNH- UoN ERC The Chair, Dept. of Paediatrics and Child Health, UoN Supervisors: Dr. Boniface O. Osano, Dept. of Paediatrics and Child Health, UoN Prof. Grace Irimu, Dept. of Paediatrics and Child Health, UoN

Protect to discover