UNIVERSITY OF NAIROBI

THE EFFECT OF NEWBORN CARE TRAINING AMONG HEALTH CARE WORKERS ON FEEDING PRACTICES IN VERY LOW BIRTH WEIGHT NEONATES IN KENYATTA NATIONAL HOSPITAL AND PUMWANI MATERNITY HOSPITAL: A BEFORE AND AFTER STUDY

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Declaration

This dissertation is my original work and has not been presented for the award of a degree in any other university. Where other people's work or my own has been used, this has been acknowledged and referenced in accordance with the University of Nairobi.

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DEDICATION

I would like to dedicate this work to the following people

1. To my late mother**, Mrs. Margret Nakasere Kawooya** who taught me to believe and work towards anything that I set out to do. It is my hope that I always make her proud

2. To my siblings **Joseph, Vicky, Solome** and **Kevin** and my father **Mr. Anthony Kawooya** who have been my number one supporters, my constant encouragement and source of strength.

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ABBREVIATIONS

AAP	American Academy of Pediatrics
BPD	Bronchopulmonary Dysplasia
CI	Confidence interval
CIN	Clinical Information Network
DBM	Donor Breast Milk
ETEF	Early enteral feeding
IUGR	Intrauterine Growth Restriction
IVF	Intravenous Fluid
KNH	Kenyatta National Hospital
LBW	Low birth weight
LTEF	Late Enteral Feeding
MoH	Ministry of Health
NEC	Necrotizing Enterocolitis
NEST	Newborn Essential Solutions and Technologies
OR	Odds Ratio
PMH	Pumwani Maternity Hospital
RCT	Randomized control trial
RDA	Recommended Dietary allowance
SGA	Small for gestation age
TPN	Total Parenteral Nutrition
VLBW	Very Low birth weight
WHO	World Health Organization

OPERATIONAL DEFINITIONS:

Very low birth weight neonate (VLBW) – Neonate with birth weight 1000gm – 1499gm

Stable neonate – Neonate without any of the following: convulsions, unconscious, severe respiratory distress evidenced by severe indrawing, or absent bowel sound(1)

Unstable neonate – Neonate with any of the following: convulsions, unconscious or severe respiratory distress evidenced by severe indrawing(1)

Enteral Feeding – Giving expressed breast milk by cup, nasogastric or oral gastric feeding

Early feeding – Feeding within the first 48 hours of life

Feeding Prescription - Feed plans on feeds to be administered to a patient written in the treatment chart, feeding chart, or newborn monitoring chart

Correct feeding prescription – A documented plan in the feeding chart of feeds that indicates amount (+/- 20%), type of feed, frequency of administration, and duration consistent with the Ministry of Health Guidelines (Either Basic Pediatric Protocols or Comprehensive Newborn Care Protocols)

The correct amount of feed for VLBW: A prescribed feed amount +/- 20% of the calculated volume

	Day 1	*Day 2*
Stable neonate	80mls of EBM per kg of body weight	100mls/kg/day in 8 divided feeds per day in 8 divided feeds
Unstable neonate	80mls/kg/day of 10% dextrose	70mls/kg/day of 10% dextrose with or without electrolytes dextrose Plus 30mls/kg/day of Expressed breast

	milk

Correct feed type:

	Day 1 of life	*Day 2 of life*
Stable neonate	Expressed breast milk	**EXPRESSED BREAST MILK (EBM)**
Unstable neonate	Intravenous dextrose 10%	10% dextrose with or without electrolytes And expressed breast milk

Correct Frequency of feeding on day 1:

EBM: Prescribed three hourly enteral feeds and 24 hour or intravenous hourly fluid (10% Dextrose) with prescription done per unit time

Correct feeding prescription:

A documented plan of feeds to be administered indicating correct amount. type of feed and correct timing.

In-correct feeding prescription:

A documented plan of feeds to be administered missing or having an incorrect field of any of the following: correct amount. type of feed and correct timing.

Parenteral feeding - administration of Intravenous fluid, partial or total parental nutrition.

Health care worker:

A person who is engaged directly in the improvement, safeguarding, or promotion of the Health of Very Low Birth Weight neonates.

Feeding practice:

The application of recommended approaches regarding timing of initiation of feeds, choice of feed, method of feed and amount of feed of Very Low Birth Weight neonates.

Newborn care training:

A 5-day training programme for disseminating the new Ministry of Health (MoH), Comprehensive Newborn Care Protocols'. The training package included lectures and practical sessions on feeding of small and sick newborns as well as identifying and managing common serious neonatal illnesses including prevention and management of early neonatal hypoglycemia, Neonatal Jaundice, Respiratory distress syndrome and Neonatal Resuscitation.

Training on feeding (Tailored for this study):

This was a half - day training adopted form the MoH Newborn care training. The training on feeding of a preterm neonate encompassed calculations of feeds and help people read and understand the current protocols and recommendations, filling feeding charts, expressing breast milk, fixing nasal and oral gastric tube and tube feeding.

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ABSTRACT

Background: Optimal nutrition in Very Low Birth Weight (VLBW) neonates is essential in decreasing mortality and long-term morbidities such as postnatal growth restriction and poor neurodevelopmental outcomes. Given appropriate nutrition, postnatal growth in preterm neonates should parallel that during the intrauterine period. Unfortunately, research done in the newborn units in Kenya showed that only about half of all admitted neonates receive appropriate feed volumes on their first day of life. Less than two-thirds had the right volume for Intravenous fluids, highlighting the need for strategies to remedy this. One of the strategies to address this challenge is ensuring that health workers have adequate knowledge in appropriate neonatal feeding practices.

Main objective: To determine the effect of the Newborn Care Training among health care workers on feeding practices in VLBW neonates in Kenyatta National Hospital (KNH) and Pumwani maternity hospital (PMH).

Study Design: This was a before and after intervention study.

Intervention: A 5-day Newborn Care Training of staff was conducted in the newborn units of KNH and PMH on 1st – 5th March 2021 and 22nd - 26th February 2021 for KNH and PMH respectively as part of ongoing national quality improvement programme. In addition, half day trainings with a focus on feeds were conducted to ensure all health care providers in the new-born units in both hospitals were trained.

Methodology: The study was conducted in the Newborn Unit (NBU) of Kenyatta National Hospital (KNH) and Pumwani Maternity Hospital (PMH); Data was extracted from REDCap data platform in both hospitals, KNH and PMH. This study had 16 time points – eight before the intervention (July 2020 – February 2021) and eight after the intervention (June 2021 – January 2022). Random sampling was used to select neonates at the individual time points, up to a sample size of 36 at each time point from both sites. We abstracted data on feed prescriptions made by health care workers for all VLBW neonates on their first day in the different time points in both pre- and post-interventional periods. Analysis used a balanced design in which the number of pre – training and post- training time points was equivalent. At each time point we calculated the proportion of correct feed prescriptions as a fraction of all the prescriptions at that time point. These proportions were then modelled using segmented beta regression.

Results: A total of 435 records met the inclusion criteria for the study. 181 in the pre-interventional period and 254 in the post interventional period. There were 38.1% (69/181) and 45% (115/254) correct prescriptions in the pre-intervention and post intervention period respectively (p value = 0.14). The intervention resulted in an improvement of the composite indicators for correctness of feed prescription +7.2% (-2.7 ,17.0), however, the difference between the two periods wasn't statistically different (p = 0.14). There was a significant decrease in the proportion of stable VLBW neonates on intravenous fluids from 72.6% to 54.5% (p = 0.05, effect size = -18.1%). In the segmental analysis, there was a decreasing trend of correctness of prescriptions before the training and immediately after the training there was step increase in the number of correct prescriptions. However, with longer post intervention time, the correctness of prescriptions plateaued from around the 2nd month. Two factors were significantly associated with correct feed prescription i.e., stability and the referral status of the child (p-values < 0.001 and 0.001 respectively).

Conclusions: There was no statistical effect of the newborn care training among heath care workers on feeding practices in VLBW neonates in KNH and PMH. There was a step increase in number of correct prescriptions, however the increase levels off at about 2 months after the intervention and remains at closely the same level after that. Neonates who were unstable and those who were referred from other health care centers were more likely to have a correct feed prescription compared to the rest of the VLBW neonates

Recommendations: Regular short focused in-service training on feeding of VLBW neonates should be conducted to improve correct feed prescriptions per the national and WHO guidelines in order to improve neonatal outcomes in newborn units.

CHAPTER 1. BACKGROUD

Preterm deliveries remain a significant burden both worldwide. More than 18 million preterm birth are recorded annually worldwide, and 96.7% of these occur in developing countries (2). Births before term account for 11.1% of the live births worldwide and 60% of these are in Sub-Saharan Africa and South Asia. (2)

In Kenya, 11% of all deliveries are preterm. Preterm infants account for 60 – 80% of neonatal deaths within the country, a significantly high burden. The majority are due to preventable causes such as insufficient feeding, inadequate attention to warmth, and infections.(2)

While in-utero, the placenta, through the umbilical cord, delivers required nutritional support to the unborn baby from the mother to fetus, and as the umbilical cord is cut after birth, this supply of continuous nutrition is also disrupted.(3) Hence, making the provision of nutrition to the newborn neonate a priority. In the case of stable Very Low Birth Weight (VLBW) neonates with no contraindications of enteral feeding, feeding ought to be initiated within the golden hour of birth with preference to expressed breast milk (EBM) or donor breast milk (DBM) by nasogastric tube (NGT)/ oral gastric tube (OGT).(4)

Nutritional needs also need to be addressed in those for whom immediate enteral feeds cannot be initiated. The fluid needs of the newly born infant will vary upon the gestational age at birth and insensible or sensible water losses. The aim of fluid provision is to deliver adequate calories, lipids and proteins; and counteract the continuing fluid losses. In VLBW (birthweigth1000- 1500 gram) newborn the initial fluid on day 1 is 80 ml/kg/day. (5) Besides, it has been shown that early (first 48hrs of life) initiation of enteral feeds in infants results in the achievement of maximum enteral feeding sooner and hence reduced the duration of stay in hospital.(6)

Optimal nutrition during this early life of an infant as a neonate is vital for its growth and development all through infancy and even into childhood. Adequate attention to feeding preterm infants has been shown to increase the chances of survival immediate and long-term wellbeing and health of an individual infant and of the population. (7)

In preterm infants, poor nutrition has been associated with more insufficient head growth. Constant small head size results in poor psychomotor and mental skills, greater cerebral palsy rates, and autism spectrum disorder.(8) Diminished weight and growth in VLBW neonates are substantially correlated with unfavorable neurodevelopmental consequences later on in life(9).

The prevention of early malnutrition is important given that sufficient postnatal growth has been correlated with the improvement of later neurodevelopment outcomes. Limiting extrauterine growth restriction helps prevent the need for rapid catch-up growth after the neonate has been discharged home, which has been linked to later undesirable metabolic consequences.(10)

Providing standard nutritional support is a challenging issue in managing of VLBW infants. Early proper nutrition is crucial not only for sufficient postnatal growth but also for decreasing complications such as neonatal sepsis and retinopathy of prematurity (10).

Adopting standardized feeding protocols has been recommended as a means to improve nutritional management and outcomes of VLBW infants. Prior studies on implementing feeding protocols that are standardized have shown improvement in nutritional outcomes, for instance reduced duration to reach maximum enteral feeds and decreased inconsistency in these outcomes. (11) The World Health Organization (WHO), to do this, has set out guidelines on the feeding of the VLBW neonate published in 2011 and then reviewed updated in 2017. (12)

In brief these guidelines recommend that VLBW infants should be fed om mothers' own milk and only if not available to use DBM of preterm formular milk; Plus, all should be given 10mls/kg/day of enteral feeds starting from day 1 of life with the remaining fluid requirement met by IV fluids. In addition, VLBW infants requiring intragastric tube feeding should be given bolus intermittent feeds.

In Kenya, guidelines for feeding VLBW neonates were revised in 2016 (Basic Pediatric protocols.(1) The same guidelines have been adopted in the new 2021 Ministry of Health guidelines for Comprehensive Newborn Care protocols yet to be published. In a study by Aluvaala *et al.*, it was shown that of all neonates on Intravenous fluids admitted in neonatal care facilities in

Kenya, only about half had an appropriate feed volume on their first day of life, and only 61.3% had a right volume for IV fluids. (13)

With an ever-increasing focus on improving healthcare to ensure greater access and higher quality, training programs have been established to teach health care professionals formal quality improvement approaches. In-service training has been described as a way to develop and sustain high-quality care.

Opiyo et al, in an interventional study to evaluate the effect of a health worker training on newborn resuscitation in Pumwani maternity hospital, demonstrated positive short-term effects on practice among the health care workers and these included significant reduction in frequency of harmful practices and improvement in performance of the initial steps of resuscitation with 66% adequate steps in the intervention group compared to 27% in the control group.

In 2020, the Ministry of Health in collaboration with Newborn Essential Solutions and Technologies (NEST) Kenya and KEMRI – Wellcome Trust Research Program (KWTRP), after release of the comprehensive newborn care protocols, rolled out a newborn care training package for health care workers. This package included training on feeding the small and sick newborns as well as identifying and managing common serious neonatal illnesses including prevention and management of early neonatal hypoglycemia, neonatal Jaundice, Respiratory distress syndrome, and Neonatal Resuscitation all underpinned on the principles of family centered care. What is still uncertain is the effect of this training on regards to feed prescription practices by health care workers for VLBW neonates.

CHAPTER 2: LITERATURE REVIEW

Neonates who are born premature embody a nutritional emergency that should be attended to as soon as they are born to prevent or reduce the development of deficits in nutrition that can lead to hypoglycemia, hypothermia and postnatal growth retardation. From a nutritional point of view, when caring for VLBW neonates, it should be kept in mind and consideration taken that promotion of their growth is attained by meeting their high nutrition needs, which are increased with the occurrence of co-morbidities.

Importance and Goals of optimal feeding VLBW infants

A nutritional approach that is aggressive has been advised and recommended to be able to limit the nutrient deficit secondary to the sharp interruption of placental supply plus also to avoid the development of a catabolic state, particularly in the early postnatal period. (14) However, actual nutrient and prescribed intakes often deviate, leading to cumulative protein and energy deficits. (15) The fear of metabolic intolerance, need for fluid restriction, feeding intolerance, inadequate nutrition protocols, and poor feed prescription practices represent the main barriers to providing appropriate nutrient intake to preterm neonates. (16)

As the preterm neonates' transitions from intrauterine to extrauterine life, they need to maintain their fluid balance, breathing and thermoregulation.

It has been showed that, in the first 6 weeks of life, the preterm infants' resting energy expenditure increases by 140% whereas that of term infants increases by 47% in the same time frame.(17) And with the increasing demand due to significant co-morbidities, nutrition support is demanding. The need for ventilator support and chronic lung disease development raises energy expenditure by 25% and 20%, respectively. In addition conditions such as cardiac disease, medications administration, neurological impairment and sepsis have been described to have an effect on energy needs.(18)

More profound knowledge regarding these points would allow for providing the proper quantity of specific essential nutrients, avoiding under exposure to certain nutrients plus individualize the nutritional care. The effectiveness of nutritional interventions depend on implementing standardized protocols of care and attention to individual nutritional priorities. (19)

<u>Impact of early feeding on the gut function of VLBW neonates.</u>

At 28 – 30 weeks gestation, peristalsis starts, whilst coordination of breathing, suck and swallow, begin at 32 – 34 weeks gestation. Swallowing of amniotic fluid nourishes the fetal intestine and prepares this organ for birth. The introduction of nutrients plus colonization of the gut by bacteria into the gut alter postnatal gastrointestinal and immunological growth. Preterm neonates have functional and anatomic restrictions to the tolerance and digestion of enteral feeds. Esophageal peristalsis is immature and bidirectional in these infants, with the forward movement of food to the stomach becoming developed close to term. Furthermore, Intestinal motor activity is also immature and disorganized in these infants compare to term Infants. Synchronized mature gastrointestinal motility and peristalsis with feeding develop in the preterm between 33 weeks of gestation to term. (20–22)

Early enteral feeding of VLBW neonates is also necessary to improve gut function. After birth, the adaptation of feeding in VLBW neonates involves significant postnatal adjustments in gut structure and function and intermediary metabolism. The motor function activity develops slowly and may limit tolerance of enteral feeds, although by 25 weeks gestation, the fetal intestine is structurally mature and can absorb milk feeds. (23)

After birth, enteral feeds appear to perform a critical function in activating development of the gut. Enteral feeding is a new experience to the newborn infant; by the end of pregnancy, the fetus is swallowing about 500 ml of amniotic fluid each day, providing up to 3 g of protein. This also contributes to fetal nutrition and may help to prepare the gut for extra uterine feeding. Evidence from animal studies – the rat model shows, exclusive intravenous feeding results in a decreased weight of the small intestine, pancreas, and oxyntic area of the stomach, which is associated with a significant reduction in small-intestinal DNA and a dramatic reduction in antral gastrin content. (23)

Even when nutrients are offered parenterally, lack of enteric feeds leads to reduced circulating gut peptides, lengthier transport of nutrients, enterocyte turnover, diminished bile acid secretion, and amplified vulnerability to infection because of the weakened barrier purpose of the intestinal epithelium, absence of establishment by normal commensal flora and colonization by pathogenic organisms.(23)

Furthermore, feeding appropriate feeding of VLBW neonates is associated with a reduction in their morbidity, reduction in hyperbilirubinemia due to the potentiated bile acid secretion, reduction in hypoglycemia and dehydration, improved immune function, reduced infections, and improved survival. (24,25)

Nutritional requirements for very low birth weight neonates

There is no patient who confronts a more serious need for optimal nutrition than the low birth weight (LBW) neonate, and this is due to their rapid rate of brain development and anabolic processes.(26)

Energy requirements

The total energy intake is a sum of energy needed for growth, basal metabolism, activity, and thermoregulation. The estimated daily energy requirement for VLBW neonates is 120kcal/kg/day with a resting energy expenditure/resting metabolic rate or 50kcal/kg, activity 15kcal/kg, thermoregulation/cold stress 10kcal/kg, growth 25kcal/kg, effect of feeding 8kcal/kg; fecal loss 12kcal/kg - 10% of intake (23)

Macronutrients

Carbohydrates: The lactase activity on the brush border is acquired later and is lower than maltase activity during the period of fetal life. The substantial pancreatic alpha-amylase activity occurs only a number of months later after the baby is born. Besides, intestinal hydrolysis of lactose is reduced in LBW infants through the initial newborn period. Through the initial days after birth, the prematurely born newborn has a decreased capability to hydrolyze lactose.

The neonate is prepared to handle the hydrolysis of glucose oligosaccharides, maltose and sucrose. And from a point of view that is practical, lactose, which also holds advantageous special effects on the absorption of minerals and composition of gut flora, should be the key source of carbohydrates in the diet of the LBW infants. The daily requirement of carbohydrates for a VLBW neonate is 10 – 15g/kg and should provide 35 – 40% of total calories.(26) Colostrum contains a rich amount of lactose, about 4g/dl of milk. Highlighting the fact that expressed breast milk in the first 3 days of the newborn preterm neonate's life is more than enough to provide the necessary needs for the baby. (27,28)

Proteins: Four primary considerations affect the quality and quantity of protein to be given to VLBW neonates: (1) necessities for normal growth (2) supplies for maintenance, (3) energy intake and (4) development of amino acid metabolism and renal function or more precisely energy available for growth.

Besides a very high intake of proteins might lead to harmful buildup of amino acids, ammonia and urea in VLBW infants for the reason that several enzyme pathways are immature and VLBW neonates have a low glomerular filtration rate. Provided that energy intake is adequate, studies on amino acid metabolism showed that optimal protein intake for LBW neonates fed orally is around 3 – 4 g (500mg nitrogen) per kilo body weight per day. With this level, it can provide 7 – 16% of daily calories. Essential amino acids should constitute 53% of nitrogen intake.(26)

Colostrum provides about 3g/dl of protein. It is rich in immunoglobulins, especially secretory IgA, which may protect against the viruses and bacteria present in the birth canal and associated with other human contacts. These properties make it much more superior to any other form of feeding for newborn preterm neonates in the first days of life. (27,28)

Fats: Fat malabsorption is common in VLBW infants. Fat absorption increases with the rise in gestational age. Unsaturated fatty acids, like linoleic and oleic acids, are better absorbed than their saturated equivalent, stearic acid. Besides, the bile acid pool and the production rate are lower in preterm neonates than in full-term neonates. As a result, the concentration of bile salt present in duodenal fluid in LBW infants is often lower than the critical micellar concentration; this could justify the poor absorption of long-chain saturated fatty acids. An additional reason for fat malabsorption in VLBW neonates is the minimal activity of pancreatic lipase subsequently resulting in diminished duodenal hydrolysis of triglycerides.(26)

Human breast milk has an active bile salt-stimulated lipase, contributing close to 50% of the overall lipase and esterase activity present in the duodenum of preterm neonates. Long-chain fatty acids, found richly in human milk, are important for brain and retina development during the first days of life. Fat should provide 30 -50% of total caloric intake, and this gives a daily requirement of 5 – 9g/kg. (26) Colostrum provides 12 - 15g/l of fat in the first 48 hours of life, making it very sufficient to provide for the preterm neonate's caloric requirements. Besides this, colostrum also enables the establishing of Lactobacillus Bifidus flora present in the gastro-intestinal tract plus even the passage of meconium. (27,28)

Micronutrients:

Minerals and vitamins: Preterm neonates fed on unfortified human breast milk or term formulas can develop signs of osteopenia or even obvious rickets. The pathogenesis of skeletal lesions is frequently a result of several factors. Insufficient phosphorus, calcium, and poor vitamin D status all have been fingered out. Due to the low phosphorus and calcium intake, preterm neonates fed on human breast milk retain only 20 – 25mg phosphorus and calcium per kilogram body weight per day, which corresponds to 20% of the calcium and 30% of the phosphorus intrauterine accumulation rate. (26,28)

Colostrum is a rich source of fat-soluble vitamin A, Vitamin E and carotenoids, all essential for their pro-enzymatic activities and antioxidants benefits to the preterm neonate. The aqueous human colostrum impedes the polymorphonuclear leukocytes' oxygen metabolic and enzymatic activities that are vital in the response to acute inflammation, supporting the idea that human breast milk is anti-inflammatory. (27)

Type of feed to give VLBW in the first 48 hours:

The first choice of feed for stable VLBW neonates is the mother's own colostrum or expressed breast milk (EBM). The next choice to this is donor breast milk (DBM), and the last is preterm formula milk. The EBM should be fresh, if not provided, previously frozen milk is preferred.

Expressed breast milk has several advantages for preterm neonates. These include effects on infants' host protection, sensory-neural growth, gastro-intestinal development, and some aspects of nutritional status. (29) Colostrum that mothers produced within the first 1-3 days of delivery has been associated with a reduction in nosocomial infection incidence in premature infants. However using fresh milk is preferred due to the exhaustion of commensals, immune cells and factors, plus enzymatic action that follows freezing. (28)

VLBW neonates who received an exclusively human milk-based feed have considerably lower rates of necrotizing enterocolitis(NEC) than those who take formula or human milk with a bovine milk-based fortifier. (28)

In a randomized control trial (RCT), Cristofalo et al. reported that preterm newborns who receive an exclusively human milk diet have a lesser incidence of Necrotizing enterocolitis (21% *versus* 3%, $p = 0.08$) contrasted to neonates who receive bovine milk-based preterm formula. (30) Using human donor milk *vs* preterm formula as an alternative for mother's milk does not lower rates of necrotizing enterocolitis. (30)

Cost-effectiveness analysis has also showed that the use of exclusively human milk-based products results in a briefer length of hospital stay (less by 3.9 days in a neonatal intensive care unit (NICU)) and savings of 8167 dollars per premature neonate ($p < 0.0001$) for the reason that there was reduction in NEC. (31)

For unstable VLBW neonates or those who have contraindications to enteral feeding, fluid, and nutritional requirements must be met with intravenous 10% dextrose, the strength of dextrose that provides a near physiological glucose infusion rate (GIR) of 4-6mg/kg/min equivalent to endogenous hepatic glucose. Plus, when available, total or partial parenteral nutrition and trophic enteral feeds should be initiated within 1 – 2 hours of birth.(32)

<u>Initiation and volume of feeds in VLBW neonates</u>

Early enteral feeding in stable VLBW neonates has been shown to result in earlier achievement of maximum feeds and reduces the period of hospitalization (6.5 ± 1.5 vs 10.1 ± 4.1 days; mean difference –3.6 [–4.5 to –2.7]; $p < 0.001$) with no increased risk of feed intolerance or necrotizing enterocolitis (NEC) (33). It is now a primary objective while feeding VLBW neonates to get to maximum enteral feeding in the shortest period of time whilst maintaining optimal growth and nutrition and preventing the harmful outcomes of rapid feeding progression. (12)

Early feeding for VLBW neonates is appropriate for their growth and development. In a Cochrane review (4 RCTs, 588 babies), Morgan *et al.* contrasted slow day-to-day increments (from 15 – 20 mL/kg/day) *versus* fast day to day increments of enteral feed quantity (from 30 – 35mL/kg/day). He reported that neonates in the slow-rate-of-advancement group showed a statistically significantly extended period to return to birth weight. (34) In a Cochrane review (4 RCTs, 588 neonates) that compared slow day-to-day increments (extending from 15 – 20mL/kg/day) *as opposed to* fast day-to-day increments of enteral feeding volume (extending from 30 – 35mL/kg/day) Fast increment did not increase the risk of NEC (pooled RR 0.97 (95% CI 0.54, 1.74)), or interruption of feeds (pooled RR 1.29 (95% CI 0.90, 1.85)) or mortality (pooled RR 1.41 (95% CI 0.81, 2.74)), The different trials independently reported that the fast daily increment group recovered their birth weight and reached maximum feeds sooner. (35)

All VLBW neonates should be started on enteral feeds, ideally initiated within 1 – 2 hours of delivery as expressed breast milk. This recommendation has an exception for sick/unstable neonates who should be started on intravenous fluids and consider parenteral nutrition with added trophic feeds if enteral nutrition is delayed. (12)

Trophic feeds are minimal amounts of milk feeds (10 – 15mL/kg/day), and they should be started preferably within 24 hours after birth. If maternal or donor milk is not available by 24 – 48 hours, formular milk should be considered. (24)

In a systematic review (9 trials, 754 VLBW neonates), the actual quantity of trophic feeds varied from 10 – 25mL/kg/day; and onset from day one of life onwards. Early introduction of trophic feeds contrasted to fasting had a non-significant proclivity towards reaching maximum feeds sooner (mean difference of 1.05 days (95% CI −2.61, 0.51)) and no difference in Necrotizing enterocolitis.(34)

The World Health Organization currently recommends that on the first day of life, VLBW neonates should be given 80ml/kg of EBM or if unstable same amount of Intravenous fluids with an additional 10mls/kg/day of trophic enteral feeds, preferably expressed breast milk, starting from the 1st 2 hours of life. And in VLBW neonates who require to be fed by an alternate oral feeding method or given intragastric tube feeds, feed amounts can be increased by up to 30 ml/kg/day with cautious monitoring for intolerance of feeds. (36)

Contraindications for early enteral feeding in VLBW neonates:

A couple of conditions make enteral feeding not feasible. Among these are congenital gastrointestinal malformations, such as atresia, gastrointestinal pathologies such as suspected or confirmed NEC, and any obstruction evidence perforation, or paralytic ileus. Plus, breast milk intolerance, e.g., enzyme deficiencies like galactosemia, also pose a contraindication to enteral feeding with it recommended. (24)

The following are not contraindications for trophic feeds; Respiratory distress, perinatal asphyxia, neonatal sepsis, hypotension, ventilation, glucose levels and umbilical lines (24,34)

Method of feeding for VLBW neonates:

VLBW neonates needing intragastric tube feeding must be given bolus intermittent feeds. Bolus or intermittent feeding, unlike continuous intragastric tube feeding, does not need syringe pumps or other infusion pumps. A Cochrane meta-analysis showed that the continuous nasogastric feeding method resulted in a long time to reach maximum enteral feeding (weighted mean difference 3 days, with no change in growth or occurrence of NEC.(37)

In those VLBW infants who need to be given intragastric tube feeding, the intragastric tube may be placed either by the oral or nasal route, depending upon healthcare providers' preferences. (36)

Furthermore, in a randomized, time series and cross over study by Chen *et al*, it was noted that reduction in the amount of gastric residuals was lower in the prone position, demonstrating the effect of gravity on appropriate feeding and helping health care professionals perform the appropriate positioning of preterm infants.(38) Dawson et al. in a Cochrane review compared push set against gravity for intermittent bolus gavage tube feeding of premature and LBW neonates. They found that only one small study had a trend towards higher respiratory rate at 10 to 30 minutes following push gavage feeding. There was no statistical difference in the time taken to give the feeds regardless of the method used. (34)

Impact of training of health care personnel on their practice

With an ever-increasing focus on improving healthcare to ensure greater access and higher quality, training programs have been established to teach health care professionals and students formal quality improvement approaches. Various training methods and approaches have been researched, including university courses, printed resources, distance learning, online modules, simulations, and role-play. Though, active learning strategies, where participants put quality improvement into practice, are considered to be more effective than educational classroom styles only. (39)

Training of health workers as a team has been shown to impact health care team processes and patient outcomes, both simulation and classroom-based team-training interventions can improve teamwork processes (e.g., communication, coordination, and cooperation), and implementation has been associated with improvements in patient safety outcomes. The critical element defining team-training is that the learning activity focuses on developing, refining, and reinforcing knowledge, skills or attitudes that underlie effective teamwork behaviors such as communication, coordination, and collaboration(40)

In-service training is a way to develop and sustain high-quality care. For healthcare systems that have yet to develop a strong specialty workforce, this in-service training can be steered towards improving the skills or retraining existing health professionals to offer the healthcare system with competent health care personnel.(41)

Opiyo et al, in an interventional study to evaluate the effect of a health worker training on newborn resuscitation in Pumwani maternity hospital, demonstrated positive short-term effects on practice among the health care workers and these included significant reduction in frequency of harmful practices and improvement in performance of the initial steps of resuscitation with 66% adequate steps in the intervention group compared to 27% in the control group.(42)

In another pre – post interventional study evaluating a neonatal resuscitation training program for health care professionals in Tanzania, the need for continuous in-service training was demonstrated as essential to provide confidence in health care professional to initiate care and improve newborn outcomes. (43)

The Kenya Ministry of Health has employed Pre-service and in-service training to promote change in practice and improve skills. For instance, through the Emergency Triage and Treatment for Very sick children (ETAT+) training, Health care professionals, through lectures, simulations, and practical sessions, receive knowledge and skills to be able to improve the quality of services they deliver. (44)

However, disparity in practice and data demonstrates how seldom best evidence is dependably implemented inside complex health care systems, with their numerous competing demands. Inevitably, the process of quality improvement starts with small-scale testing changes, for instance, ensuring the medications and feeds are prescribed correctly, among other things. These early steps are vital and essential parts of the improvement journey. (45)

There is a significant increase in best practices after the education of health care professionals. A systematic review on the effect of health professional training in breastfeeding on hospital practices by Jesus *et al.;* showed that training health care professionals have been effective in improving their knowledge, skill, and practice. (46)

Amsalu et al. demonstrated that training of health care workers as an intervention had a significant impact on the practice in a quasi-experimental pre- and post-study. After a training on the interventional newborn care package that comprised of Helping Babies Breathe, Essential Care for Every Baby and Essential Care for Small Babies, the fraction of newly born babies who received 2 or more essential newborn care practices (early breastfeeding, skin-to-skin contact and dry cord care) improved from 19.9% to 94.7%. (47)

The effect of training health care workers has also been noted to have subsequent effects to the outcome of their practice. Okara et al, in assessing the effect of newborn resuscitation training on the prevalence of perinatal asphyxia in Kisii teaching and referral hospital, reports that focused neonatal resuscitation training resulted in a substantial improvements in the Apgar scores of babies.(48)

In a randomized clinical trial, Taddei et al., following exposing health care workers to Well start-Santos Lactation Center Course, noted that the fraction of newborns that were breast-fed in the first 6 hours of life improved from 41% to 53%. Improvements were also noticed in the fraction of mothers who got assistance and support to breastfeed their babies from hospital personnel. (49) All this highlights the uptake of best practices after clinical pre-service and in-service training of health care personnel.

However, in a systematic review by Rowe et al on effectiveness of strategies to improve health care provider practice in low-income and middle-income countries, it was noted that training alone typically had moderate effects, whereas combining training and supervision had larger effect than using one strategy alone.(50)

Study justification, Utility and Objectives.

Study justification.

Of all deaths among inborn neonates in hospitals in Kenya, 22% occur among Very Low Birth Weight Neonates. Besides 18.5% of all deliveries in Kenyatta National Hospital are preterm births. Most of these deaths have been noted to be due to insufficient feeding, inadequate attention to warmth, and infections. (2,51) Early appropriate nutrition is vital not only for adequate postnatal growth but also for reducing complications, for instance, sepsis.

A recent 2015 study by Aluvaala *et al.* showed that of all neonates on IV fluids admitted in neonatal care facilities in Kenya, only about half had an appropriate feed volume on their first day of life, and only 61.3% had a right volume for IV fluids. (13) With the background of the 2016 Basic Pediatric protocols (1) and the new yet-to-be-published 2021 Ministry of Health guidelines for Comprehensive Newborn Care protocols, this study aims to determine the effect of newborn care training on feeding practices among very low birthweight admitted neonates.

Utility of the study:

In 2020, Newborn Essential Solutions and Technologies (NEST) Kenya and KEMRI – Wellcome Trust Research Program (KWTRP) in collaboration with the Ministry of Health (MoH), after release of the comprehensive newborn care protocols, rolled out a Newborn care training package for health care workers.

Findings of this research are expected to provide knowledge and evidence on the need for training of health care workers in this setting and its effect on health worker practice to be able to reduce the current neonatal mortality rate. Training is an essential part of improving knowledge and skill in among health care workers thus giving every single neonate better care and thus better outcomes.

Results will also be used to inform policy on how best to forge ways to improve nutrition in VLBW neonates as an essential element in decreasing mortality and long-term morbidities such as postnatal growth restriction and poor neurodevelopmental outcomes. Plus also forging ways to address knowledge decay that occurs with time after training.

Research question.

What is the effect of newborn care training on feeding practices among very low birth weight Neonates in Kenyatta National Hospital and Pumwani Maternity Hospital?

Objectives.

Main objective:

- To determine the effect of the newborn care training among health care workers on early feeding practices of VLBW neonates in Kenyatta National Hospital (KNH) and Pumwani Maternity Hospital (PMH).

Specific objectives:

- To determine the effect of the newborn care training among health care workers on correctness of feed prescriptions for VLBW neonates in KNH and PMH.
- To determine factors associated with correct feed prescription among VLBW neonates admitted in NBU of KNH and PMH.

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CHAPTER 3: METHODOLOGY

Study design

Before and after retrospective study. We used an interrupted time series (ITS) model of analysis to compare variations before and after the intervention in the group that is exposed. The ITS analysis is one of the more robust observational designs as it has control for the secular trends presents in health system outcomes. It considers the aspect of time as an influence to changing trends on the impact of interventions to improve quality of health systems as compared to some rigorous quasi-experimental designs observational study designs.

Study sites

The study's designated areas were the NBU of Kenyatta National Hospital (KNH) and PMH. KNH is the largest public hospital in Kenya. KNH serves as a teaching hospital for the University of Nairobi, Faculty of Heath Sciences. It is also the largest referral facility in East and Central Africa. It is also the main tertiary referral hospital in Kenya; therefore, this hospital has a wide catchment of patients as it receives referrals from all over the country.

The Newborn unit of the KNH admits over 100 babies per month, mostly delivered in the hospital, with some referred from other hospitals over the country. In KNH 18.5% of all deliveries are preterm. Medical officers or Paediatric Residents prescribe medications and feeds for these babies within the unit under consultant pediatricians and neonatologists' guidance. With an average of about 5 doctors and 12 nurses per work shift. A 5-day Newborn Care Training of staff in the NBU in KNH was conducted on 1st – 5th March 2021 as part of ongoing national quality improvement programme.

Pumwani Maternity Hospital (PMH) is an obstetric and referral hospital. It is largest largest maternity hospitals in East and Central Africa. The NBU in PMH admits on average about 250 neonates per month. Feeds for these babies are prescribed by clinical officers, medical officers under the guidance of Pediatricians. The 5-day Newborn Care Training of staff in the NBU in PMH was conducted on 22nd - 26th February 2021 for PMH as part of ongoing national quality improvement programme. PMH also runs donor human milk bank unlike KNH which has none.

Both KNH and PMH newborn units are in the Clinical Information Network (CIN). CIN is a project implemented in 22 hospitals in Kenya. It is collaborative partnership between. The implementing hospital, MoH, KEMRI-Wellcome Trust and Kenya Paediatric association. It aims at improving quality of data and their utilization in improving performance of health care providers by providing regular audit feedbacks to the hospitals (52). PMH and KNH joined CIN in January 2014 and January 2020 respectively.

In the NBU of both KNH and PMH, continuous monitoring of patient clinical status feeds and medications are documented using a comprehensive newborn monitoring chart. The care of neonates in both KNH and PMH currently follows the national guidelines using the 2016 Basic Pediatric Protocol (1) or the Comprehensive Newborn Care Protocols. These two protocols provide similar guidance regarding calculation for the feeds for the VLBW small and sick newborns. Both hospitals are implementing the NEST program and were trained in the training for dissemination of the Comprehensive Newborn protocols.

Routine data collection occurs at the point at which every patient is discharged. The inpatient paper records are extracted directly into a non-commercial electronic tool called REDCap by a trained data clerk. The data clerks use a standardized operational procedure manual for data extraction that forms the basis of their training.(44,52). The complete data comprises clinical and treatment data focused on admission events, feeds, specific medications during the admission period, and discharge data.

All data are afterwards shared with a central network analysis team are de-identified. R statistical software has been installed on a hospital computer that each data clerk uses. Through a meta-programming process, R software autogenerates code that is used for running on-site quality checks daily. It then cleans and records data to enable indicator measurement and recording.

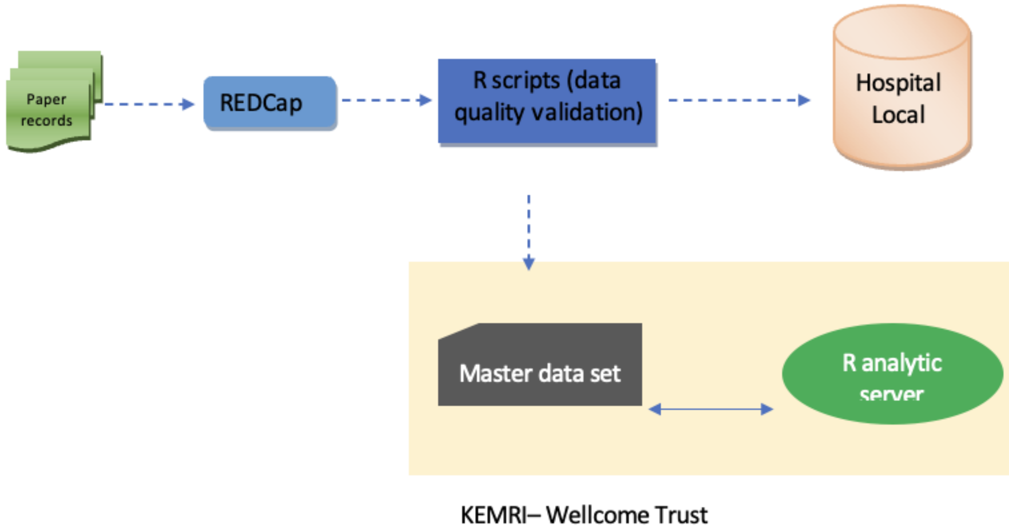

Figure 1: Informatics framework of data entry and storage

As summarized in figure 1, the data collected by the data clerk passes through a validation process using the pre-programmed field validation rules in the REDCap tool as it is entered. In PMH the data are stored in the local REDCap server in the data clerks' machine and de-identified data stored in the KEMRI Wellcome Trust Research Programme (KWTRP). However, the data from KNH is stored directly in the KNH hospital server. As part of CIN data quality assurance, all out of range values give an alert to the date clerk to check the records. At KEMRI an ARO checks quality of data and communicates to the data clerk for any errors detected. Further, every 3 months 5% of the records are selected and re-entered in REDCap to check for concordance. The concordance has range from 85-92%(44). The number of the medical records entered are compared with the NBU daily bed return that captures all admissions and discharges to allow recognition of any missing records.

This proposed study utilized the data stored in the local REDCap servers within the hospitals.

Study period

The study period was eight months pre-intervention (July 2022 - February 2021), 1 month of intervention, eight months post intervention (June 2021 – January 2022) This allowed collection of eight time points in both pre and post-intervention periods all one month long.

Study population

The study population comprised databases of neonates with birth weight 1000gm - 1499gm admitted within the first 12 hours of life into the newborn unit of KNH and PMH during the period of data collection.

Inclusion criteria

- Medical records entered in the RedCap database
- Database of neonates with birth weight 1000gm – 1499gm
- Database of neonates admitted within the first 12 hours of life in the newborn unit of KNH and PMH

Exclusion criteria

We excluded data of neonates with any of the following conditions:

- VLBW neonates with contraindications to enteral feeding, e.g., necrotizing enterocolitis, gastroschisis, and intestinal obstruction documented in the medical records
- Neonates given breast milk substitutes

Intervention

The main 5- day training (commonly dubbed as NEST training) took place in February/March 2021 as a part of a five-day training run by the Ministry of Health in collaboration with Newborn Essential Solutions and Technologies (NEST) Kenya and KEMRI – Wellcome Trust Research Program (KWTRP). We developed a tailored 5- day training programme, that was adapted from the NEST training, on feeding the VLBW. We provided this training to the HCWs working in the NBU of the two hospitals who had not attended the NEST training. In KNH we trained 19 health care workers on 28th March, 2021, and in PMH we trained 15 health care workers on 4th June, 2021 and this ensured 100% coverage in PMH and 8% coverage in KNH hospital.

The training was part of a newborn care training package that, included feeding the small and sick newborns as well as identifying and managing common serious neonatal illnesses including prevention and management of early neonatal hypoglycemia, neonatal Jaundice, Respiratory distress syndrome, and Neonatal Resuscitation all underpinned on the principles of family centered care.

Those who could not attend the five-day training attended a half day training on the feeding of small and sick newborn infants, a section within the five-day training, but these trainings (one in each of the study facilities) were specifically conducted by the author and targeted to this study. This five-day training for each facility had the same content and materials that the main training had in regards to feeding of the small and sick newborn infant including calculations of feeds and help people read and understand the current protocols and recommendations, filling the feeding charts, expressing breast milk, fixing nasal or oral gastric tube (NGT or OGT), and tube feeding underpinned on the framework of family centered care. We conducted the half day trainings in collaboration with NEST Kenya.

Sampling

Sample size

Sample size calculation was done through simulation methods as recommended for interrupted time series designs.(53) Using this formular below, the estimated the time point sample size was calculated. The size that is associated with the change in slope of the outcome (β_3) if a power of 80% is to be achieved.

$$\boldsymbol{Y_i = \beta_0 + \beta_1 * time_i + \beta_2 * intervention_i + \beta_3 * time\ after\ intervention_i + e_i}$$

Where:

Y_i – denotes the average event rate.

$time_i$ – indicates time points from the pre to post – intervention periods.

$time\ after\ intervention$ – denotes number of time points after the intervention is implemented.

β_1 – indicates underling (secular) trend

β_2 – indicates the change in level

β_3 – indicates the change in trend/slope

In this study assuming the baseline event rate (50%(54)) as a constant throughout the pre – intervention period and increases to 80% at the end of the study.

We fitted a segmented autoregressive model of order one (AR) with the outcome (Y_i) assuming beta distribution; due to the bounded nature of event rates between 0 and 1.

Varying sample sizes (which were to be collected per time point), depending on an effect size of 30%, the sample size was achieved which would result in an approximate power of 80%, fitting 1000 models and reporting the number of times slope change parameter is significant.

With this we obtained 36 VLBW neonates at every data/time point.

And regarding interrupted time series designs we had 8 observations before and after the intervention, and with a size of 36 at every time point, we had 288 VLBW neonates as the sample size in the pre-intervention and post intervention periods, making a total of 576medical records of VLBW neonates as the sample size for the study.

Sampling method

The pre-intervention and post-intervention periods had 8 months each. Each time point was 1 month long. The number of records of VLBW neonates to be include in each time period were proportional to the total admissions in each study site. We included all records at every time point from both sites.

Data collection, management, and analysis

Data collection:

Data in the pre-intervention and post-intervention period were extracted by the principal investigator with the help of the CIN data clerks in both hospitals from the REDCap data platform from the server in KNH and PMH.

In regards to KNH, some of the data in the pre-intervention period (November 2020 and December 2020) had not been entered in the REDCap Platform, in the period before the unit joined the Clinical Information Network. After the hospital approval was obtained, we obtained all medical records from the records department in KNH of VLBW neonates admitted in the NBU within the months whose data was not recorded and updated the REDCap database. Then extracted the whole data set afterwards from the REDCap database.

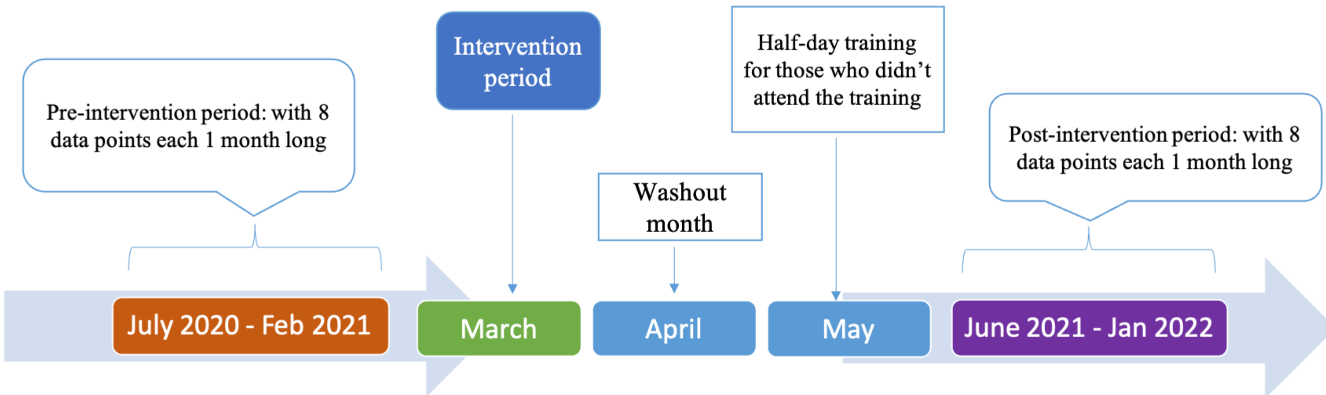

Figure 2: Figure showing the study scheme

The principal investigator collected the data from all VLBW neonates who meet the inclusion and exclusion criteria at every time point for both pre- and post-intervention periods. These data were extracted from the local REDCap data platform/serve at the study site into using R-scripts in pre-programmed computer programme made to capture all the variables required for this study.

The following data was collected; biodata, maternal factors, clinical features on admission, Diagnosis, feeding plan indicating the fluid type, volume, frequency, and duration of feeds on day of admission, feeding plan showing the fluid type, volume, frequency, and time of feeds on the next day after admission. (See paper questionnaire (Appendix 4))

<u>Quality control</u>

Quality control measures and standard operating procedures were always adhered to during this research. The principal investigator did the data collection and crosschecks to ensure the validity of collected data and that correct sampling techniques are being used.

All out of range values were checked and confirmed from the paper records. The 5% of the records were selected in the pre-intervention and post-intervention, re-entered in REDCap by the principle investigator together with the KEMRI team to check for concordance.

Data storage and security

All records were de-identified, and each record were given a unique study number to maintain the patients' confidentiality.

The principal investigator was responsible for storing all study data including the data extracted from CIN database. These data were accessible to the principal investigator and the study statistician only. These measures ensured that patient confidentiality was always maintained.

Data management and analysis

The data collected were all quantitative data. They were reviewed to identify any errors or omissions before being put into the R software for analysis. Categorical data was represented using frequency distributions, percentages and tabulated.

Nominal categorical variables: Gender, birth weight, Delivery mode, place of birth, Place of admission, resuscitation at birth (by BVM ventilation and/or Chest compressions), HIV serostatus of the mother, stable or unstable neonates, Diagnosis, and referral.

Ordinal categorical variables: Gestation, age of mother, Parity of mother
Continuous data is presented using medians or mean and interquartile ranges (IQR) or standard deviation (S.D.) with minimum and maximum limits of respective ranges defined.

1st specific objective:
An interrupted time series model was fitted to examine the effect of the newborn care training on the feeding practices among health care workers in VLBW neonates. The analysis used a balanced design in which the number of pre – training and post- training time points was equivalent. Our pre-intervention period considered data collected from July 2020 to February 2021 while the post intervention period will consider data from June 2021 – January 2022. At each time point we calculated the proportion of correct feed prescriptions as a fraction of all the prescriptions at that time point. These proportions was then modelled using segmented beta regression.

The proportion of correct feed prescriptions before and after the intervention was compared using chi-square, giving odds ratios considering a p-value of -0.05 as significant

2nd specific objective:

Looking at the characteristics of the study population of the patients before and after the intervention, tests of associations were applied.

Outcome measures:

1st specific objective

The proportion of patients with correct feed prescription – this is a composite indicator (correct timing, correct type and volume) on day 1

2nd specific objective

For the pre intervention and post intervention periods, associations between correct feed prescriptions and variables including Gender, Delivery mode, Place of birth, Place of admission, Stable or Unstable neonates, Diagnosis, referral, gestation, age of mother, Parity of mother, and mode of delivery

Ethical considerations

The study was undertaken after approval from the Department of Paediatrics and Child Health, University of Nairobi and the KNH scientific and ethical committee. The principal investigator also sought a waiver of individual consent from the KNH-UoN ERC for the study.

We also sought authorization from Kenyatta National Hospital and Pumwani Maternity Hospital to access data collected from the REDCap Platform for these NBUs.

We observed strict confidentiality throughout the entire study period, held in trust by participating investigator. The Study records were given study identification numbers, and the principal investigator and statistician recorded no personal identification data. Information concerning the individual study findings were not released to any unauthorized third party.

And lastly, no financial implication was transferred to patients/participants in this study

Dissemination of study findings:

The overall study findings will be availed to the neonatologists and staff running the newborn unit of KNH and PMH to disseminate the knowledge gained about the effect of training on practice, thereby contributing to the improvement of care delivered to this subset of children.

The principal investigator will present the study findings to the University of Nairobi Department of Pediatrics and Child Health academic staff and students to fulfil the Master of Medicine Program requirements.

CHAPTER 4: RESULTS

Patient flow Chart showing how patients were selected

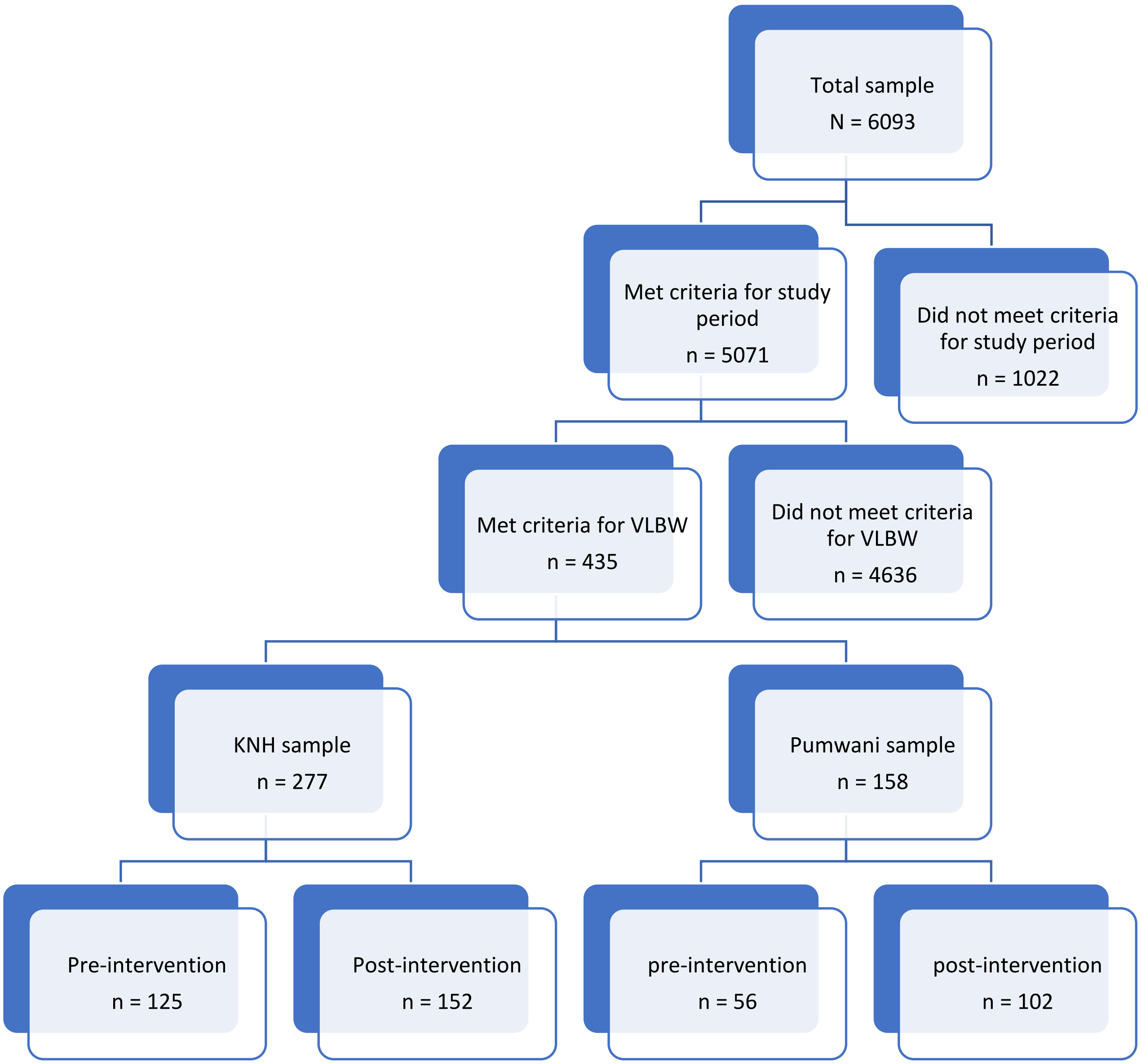

Figure 3: Flow chart showing how study participants were selected from the total data

In total we were able to get a samples size of 181 pre-intervention (62% of the calculated sample size) and 254 post intervention (88% on the calculated sample size).

Characteristics of the study population

A total of 435 records met the inclusion criteria for the study. 181 in the pre-interventional period and 254 in the post interventional period. From these, data was abstracted for this study

Demographic and clinical characteristics

Pre-intervention

In the pre-intervention, 53.0% (96/181) of the babies were females while the rest were males. The proportion of children weighing less than or equal to 1250 grams was 53.0% (96/181) while the rest weighed above 1250 grams. The median weight of the children in the pre-intervention period was 1210 grams with an interquartile range of 230 grams. The mean weight was 1230 grams.

Post-intervention

In the post-intervention, 53.9% (137/254) of the babies were males while 45.7% (116/254) were females. The remaining babies did not have their gender indicated. The proportion of children weighing less than or equal to 1250 grams was 50.0% (n = 127 while the rest weighed above 1250 grams. The median weight of the children in the post-intervention period was 1252 grams with an interquartile range of 280 grams. The mean weight of these babies was 1240 grams. Table 1 summarizes the socio-demographic characteristics of the population.

Comparison of the pre – intervention and post intervention period characteristics

The neonatal and maternal biomedical characteristics were not significantly different. The neonatal clinical characteristics including HIV sero-exposure, Mode of delivery and child with convulsions were similar in the pre-intervention and post intervention, any difference could have been by chance. However, there was less documentation in post intervention period, resulting to the difference in these neonatal characteristics being statistically different.

Some neonatal clinical characteristics were statistically different on both intervention period, and these included, neonates who were referred ($p = 0.04$), neonates with difficulty in breathing ($p = 0.03$) and neonates with apnea (0.01). The gestation age recorded was considered unreliable, so no further analysis was done regarding this variable. Ballard’s scoring should have been done but its not routinely done in the study sites.

Table 1: Table showing the Demographic and clinical characteristics of babies in the study

Variable	**Pre-intervention**		**Post-intervention**		**P-value**
Children characteristics	Frequency N = 181	Percent (%)	Frequency N = 255	Percent (%)	
Median Birth weight (IQR)	1210gms (230)	_	1325gms (230)	_	0.51
Weight categories: <=1250 grams >1250 grams	96 85	53.0 47.0	127 127	50.0 50.0	0.60
Gender: Female Male Not indicated	96 85	53.0 47.0	116 137 1	45.7 53.9 0.3	0.17
Gestational age at birth: 28-34 weeks >34 weeks Non-determinate	120 14 47	69.3 7.7 26.0	191 15 48	75.2 5.9 18.9	0.13
Maternal characteristics					
Parity of the mother: Primigravida Multigravida	42 139	23.2 76.8	64 190	33.7 66.3	0.72
Age of the mother: <20 years 20-30 years 30-40 years >40 year	31 105 43 2	17.1 58.0 23.8 1.1	33 136 81 4	13.0 53.5 31.9 1.6	0.24
Clinical characteristics					
Sero-exposed: Yes No Not indicated	8 153 20	4.3 84.5 11.2	13 210 31	5.1 82.7 12.2	0.72
Referral: Yes No Not indicated	32 122 27	17.7 67.4 14.9	66 147 41	26.0 57.9 16.1	**0.04**
Difficulty in breathing: Yes No Not indicated	117 54 10	64.6 29.8 5.6	187 49 18	73.6 19.3 7.1	**0.03**
Mode of delivery: C-section Normal (SVD) Breech Not indicated	63 108 9 1	34.8 59.7 5.0 0.5	90 148 13 3	35.4 58.3 5.1 1.2	0.92
Child had apnea: Yes No Not indicated	15 154 12	8.3 85.1 6.6	26 207 21	10.2 81.5 8.3	**0.01**
Child had convulsions: Yes No Not indicated	1 158 22	0.6 87.3 12.3	2 231 21	0.8 90.9 8.3	0.38

Objective 1: To determine the effect of newborn care training among health care workers on the correctness of feed prescriptions

There were 38.1% (69/181) and 45% (115/254) correct prescriptions in the pre-intervention and post intervention period respectively. The intervention produced an improvement of the composite indicators for correctness of feed prescription +7.2% (-2.7 ,17.0), however, the difference between the two periods wasn't statistically different (p = 0.14).

Table 2: Overall correctness of feed prescriptions between pre- and post-intervention period

Composite Indicator	Pre-intervention N = 181	Post-intervention N = 254	P-value	Effect size (95% CI)
Correct prescriptions: Yes **No**	69/181 (38.1%) 112/181 (61.9%)	115/254 (45.3%) 139/254 (54.7%)	0.14	+7.2% (-2.7 ,17.0)

We performed exploratory analysis to determine the effect of the training on the individual indicators (table 3 and 4)

Table 3: Effect Indicators of feed prescriptions between pre- and post-intervention period

Indicator	Pre-intervention N = 181	Post-intervention N = 254	P-value	Effect size (95% CI)
Correct volume of feeds: Yes No	101/181 (55.8%) 80/181 (44.2%)	143/254 (56.3%) 111/254 (43.7%	**1.00**	**+0.5% (-9.4, 10.4)**
Correct type of feed: Yes No	94/181 (51.9%) 87/181 (48.9%)	138/254 (54.3%) 116/254 (45.7%)	**0.69**	**+2.4% (-7.5, 12.4)**

Even though there was an effect size increase of +0.5% (-9.4, 10.4) and +2.4% (-7.5, 12.4) for correct volume and type of feed prescribed respectively, there was no significant difference between the pre-intervention and post-intervention periods, p – values 1.00 and 0.69 respectively.

Table 4: Effect Indicators of feed prescriptions between pre- and post-intervention period for stable and unstable babies

Indicator	Pre-intervention	Post-intervention	P-value	Effect size (95% CI)
Type of feeds given to unstable babies on Day 1	**N = 119**	**N = 188**		
IVF	88/119 (74%)	131/188 (69.7%	0.50	-4.3%
Oral feeds (trophic feeds not included)	15/119 (12.6%)	19/188 (10.1%)	0.62	-2.5%
Type of feeds given to stable babies	**N = 62**	**N = 66**		
Stable babies on oral feeds:	20/62 (32.3%)	14/66 (21.2%)	0.22	-11.1%
Stable babies on IVFs:	45 (72.6%)	36 (54.5%)	**0.05**	**-18.1%**

In the pre-intervention period, 74% (n = 88) unstable babies were on intravenous fluids. In the post-intervention period, 69.7% (n = 131) of the unstable babies were on intravenous fluids, a 4.3% reduction. Unstable babies were also prescribed oral feeds on day one despite not being recommended. The proportion of those prescribed oral feeds on day one was 12.6% (n = 15) and 10.1% (n = 19) in the pre-intervention and post-intervention periods respectively, a 2.5% reduction.

The feeding recommendation of strictly oral feeds (expressed breast milk) for stable babies on day one was also not adhered to. This study showed that only 32.3% (n = 20) of the stable babies were given oral feeds on day 1 in the pre-intervention period while 21.2% (n = 14) were give oral feeds in the post-intervention period, an 11.1% reduction. Stable babies given intravenous fluids on day one accounted for 72.6% (n = 45) in the pre-intervention period and 54.5% (n = 36) in the post-intervention period, a significant reduction of 18.1% (table 4).

<u>Interrupted time series (ITS) analysis</u>

ITS model was used to analyze whether the positive changes observed in performance and the slope of change observed over time after intervention were statistically significant compared to the performance before the intervention.

The figure 2 shows the time series of proportions of correct prescriptions per 4 weeks period, the blue vertical line represents the time of the intervention and the horizontal red line represents the trend. There was a decreasing trend before the training, and immediately after the training there was step increase in the number of correct prescriptions. However, with increase in time after the intervention, the correctness of prescriptions plateaued from around the 2nd month.

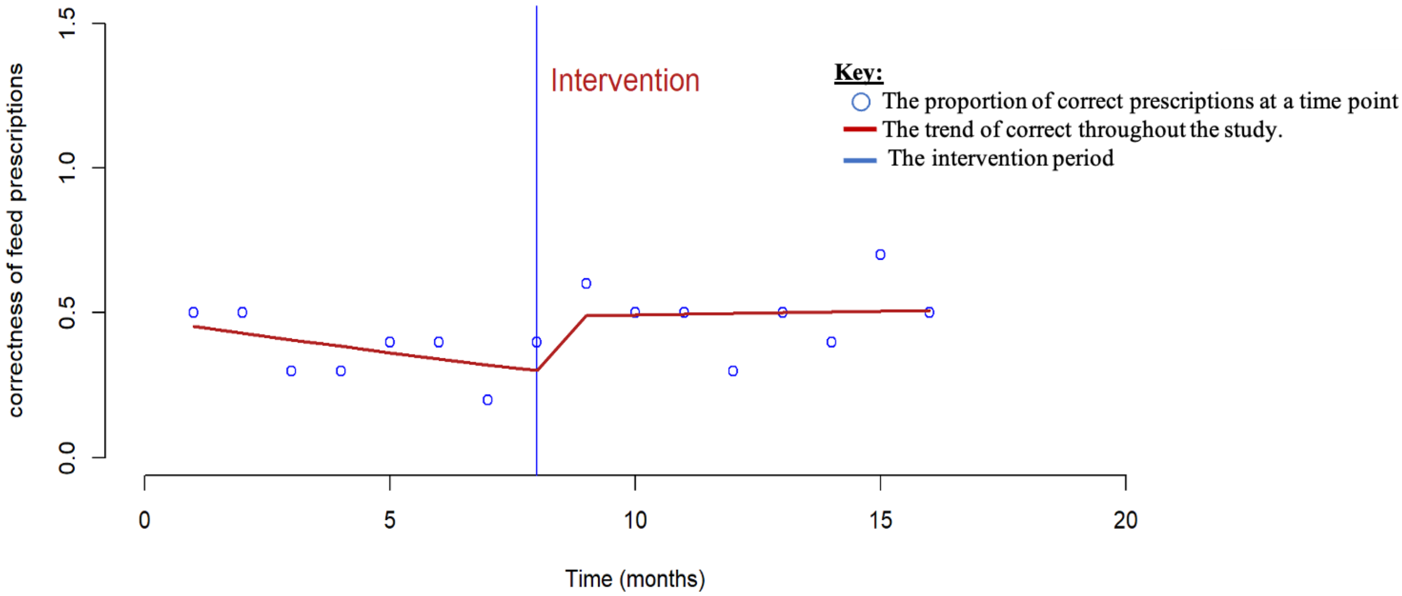

Figure 4: Graphical presentation the effect of training on correctness of feed prescription among VLBW neonates

The segmented regression analysis presented here looks at the effect of time during the study.

The intercept as shown in the table 5 below, estimates the baseline level of the outcome, mean number of correct prescriptions per patient per 1 month period, at time zero. Time looks at the effect of time from the beginning of the study to the end. With every 1 month change in time the prescription correctness decreased by a factor of 0.1.

However, With the introduction of the training prescription correctness increased by a factor of 0.80. With an odds ratio of 2.22 (0.04, 182.2). which was not statistically significant with a p value of 0.70 and with very wide confidence interval 0.04, 182.2 indicating lower precision possibly due to a small sample size and hence greater uncertainty. But with time after the intervention, prescription correctness increased at a factor of 0.10, with one unit increase in time the slope was increasing giving a positive estimate. However, that was as well not statistically significant P = 0.82 with a wide confidence interval 0.45, 2.78 as well.

Table 5: Showing the Segmented regression analysis

Variable	Estimate	OR (95% CI)	P - value
Intercept	-0.10		
Time	-0.1	0.91 (0.44, 1.75)	0.78
Intervention (training)	0.80	2.22 (0.04, 182.2)	0.70
Time after intervention	0.10	1.11 (0.45, 2.78)	0.82

<u>Objective 2: To determine factors associated with correct feed prescription among VLBW neonates admitted in NBU of KNH and PMH.</u>

Table 6: Patient factors associated with prescription correctness

Variable		Prescriptions			
		Correct (ref) N = 184	Incorrect N = 251	Crude OR (95% CI)	p-value
Gender:	**Female (ref)**	86 (40.4%)	127 (59.6%)		
	Male	98 (44.1%)	124 (55.9%)	0.86 (0.59, 1.25)	0.43
Child is stable:	**Yes (ref)**	4 (3.1%)	124 (96.9%)		
	No	180 (58.6%)	127 (41.4%)	0.02 (0.008, 0.06)	<0.001
Referral: *	**No (ref)**	125 (46.5%)	144 (53.5%)		
	Yes	27 (27.6%)	71 (72.4%)	2.28 (1.38, 3.78)	0.001
Place of admission:	**KNH**	119 (52.4%)	158 (47.6%)		
	Pumwani	65 (41.1%)	93 (58.9%)	1.1 (0.73, 1.60)	0.71
Method of delivery: *					
	CS (ref)	67 (43.8%)	86 (56.2%)		
	SVD	108 (42.2%)	148 (57.8%)	1.07 (0.71, 1.60)	0.75
Gestational age: *					
	28-34 weeks (ref)	142 (45.7%)	169 (54.3%)		
	>34 weeks	9 (31%)	20 (69%)	1.87 (0.82, 4.23)	0.13

- The total doesn't add up to the N value of 184 or 251 due to missing data

In this bi-variable analysis, because the training had had no effect on prescription correctness, we combined both data from the pre and post intervention periods. From table 6 above, only two factors were significantly associated with correct feed prescription i.e., stability and the referral status of the child with p-values< 0.001 and 0.001 at 5% significance level respectively.

Babies who were not stable were 98% less likely to get incorrect feeds compared to babies who were stable OR 0.02 (0.008, 0.06). In terms of referral status, babies who were referred were 2.28 times more likely to get incorrect feed prescriptions compared to those who had not been referred OR 2.28 (1.38, 3.78).

Multivariable analysis

Under multivariable analysis, we did a stepwise selection using Akaike's Information Criteria (AIC). The final model had 2 variables namely referral status and place of admission. Babies who were referred were 2.20 times more likely to get incorrect feed prescriptions compared to the ones who had not been referred after adjusting for place of admission and stability of the child. Babies who were admitted at Pumwani Maternity Hospital were 2.13 times more likely to get incorrect feeds compared to those admitted at KNH. Unstable babies were 98% less likely to get incorrect feeds compared to stable babies after adjusting for referral status and place of admission (Table 7).

Table 7: Table showing factors associated with correct feed prescriptions

Variable		**Prescriptions**			
		Correct (ref) **N = 184**	**Incorrect** **N = 251**	Adjusted OR (95% CI)	p-value
Child is stable:	**Yes (ref)**	4 (3.1%)	124 (96.9%)		
	No	180 (58.6%)	127 (41.4%)	0.02 (0.006, 0.056)	<0.001
Referral:	**No (ref)**	125 (46.5%)	144 (53.5%)		
	Yes	27 (27.6%)	71 (72.4%)	2.20 (1.23, 3.98)	0.008
Place of admission:	**KNH**	119 (52.4%)	158 (47.6%)		
	Pumwani	65 (41.1%)	93 (58.9%)	2.13 (1.23, 3.72)	0.007

CHAPTER 5: DISCUSSION

This study adds to the growing evidence that training is an intervention in a resource limited set up in improving practice and as an element of strengthening broader health systems that result to improved quality of care. (47–49,55). In this study, the Newborn care training didn't result in a significant increase in correct prescriptions, from 38% to 45%, but had a significant decrease the proportion of stable VLBW neonates on intravenous fluids from 72.6% to 54.5% ($p = 0.05$, effect size = -18.1%).

In low - middle income countries, training is often used to improve health care provider performance and reduce the burden that is caused by poor quality healthcare. Although there was marginal improvement after training in this study, the effect was not significant and did not persist over time. This could be explained by the fact that data for the study was not collected shortly after the training because not all health care workers were trained. The interval of 3 months could have led to knowledge decay and improvement could be attributed to the people trained in the half day trainings in May and another training organized by NEST in July 2021.

Arguably the follow up period was short to have resulted in any change in Quality of care. Ayieko et al in research to improve quality of care for pneumonia found that it took 9 months for improve quality of care after training.(56) This supports the notion that while training creates awareness of best practices, translation of the knowledge into practice requires attention to be paid to enablers for change eg audit and feedback and incentives. (57,58)

There was a slight improvement in prescription of correct volume of feeds and there was also an improvement regards to correct type of feed prescribed by health care workers although both of them, were not statistically significant.

The proportion of Unstable neonates on IVF and enteral feeds reduced though this was affected by increase in the proportion of non- determinate (missing and unclear) records in the post intervention period.

This study adds the effect of time to impact of training on practice. In our results, we note that there was a step increase in number of correct prescriptions, however the increase levels off at about 2 months after the intervention and remains at closely the same level up to the 8^{th} month. This is in close agreement with a systematic review done by Ahmed *et al* on knowledge and skill level among health care workers after a cardiopulmonary training, it was noted that even though skills decayed within about 2 weeks after the training, knowledge retention started to decline between 1 month and 6 months after training. In most of the studies involving health care workers, skills were at pre- training levels 4 to 6 months after the training and complete decay of skills and knowledge by 1 year. (59)

A study by Okara et al reports substantial increase in neonatal resuscitation skills performance after a focused neonatal resuscitation training.(48) However, unlike our study, this study looked at the short term, 3 months evaluation after the training. And hence could not evaluate the effect of time on knowledge and skill decay.

Even though in this study we noted that with one unit increase in time decreased the odds of correct prescriptions by 9% (OR 0.91 (95% CI 0.44, 1.75) and neonates who were prescribed post intervention were prescribed 2.22 time more correctly compared to those who undergo the training; however, these results might have been by chance because they were not statistically significant. And this could have been affected by the large number of infants in the post intervention period who were prescribed feeds under the leveled off period.

In this study, we also note that neonates who were referred from other units were significantly more likely to have a correct feed prescription compared to those who were not referred. This could be explained by the more attention given to babies who are referred from other hospitals because they tend to be sicker than those born within. In addition, neonates who were unstable were significantly more likely to have correct feed prescription compared to those who were stable and admitted at Pumwani Maternity Hospital were 2.13 times more likely to get incorrect feeds compared to those admitted at KNH.

These findings have implications in regards to the care of VLBW neonates in our hospitals, first is the need for continuous regular in-service training of health care workers within the newborn units to keep practice of evidence-based guidelines for better outcomes. Secondly, as Rowe et al notes that combining different simple strategies is more effective in improving health care provider practice, training health care workers alone may not be sufficient for them to put in to practice evidence-based practices.(50) Even though knowledge is the foundation of any skill, the investigation that knowledge is not enough to maintain good practice for a long period of time highlights a higher challenge.

These findings may also highlight as a surrogate, the disorganization of our health care system. With constant rotation of people form one unit to another plus limited specialization of cadres of nurses and doctors within the newborn units. Within this study, we note that the NBU in KNH received new resident doctors who came in from other general pediatric units around the months of August 2021, and December 2021. This creates an institutional loss of knowledge and memory every time they are moved from the unit to other units and then new staff brought into these units.

This study also has implications both at the individual hospital level to keep on training staff repeatedly and at the national level channeling human and financial resources on to staff training and other methods to reduce knowledge decay.

Our study emphasizes the benefits of short focused training to improve practice among health care workers in newborn units, however recommends that need for reinforcement through regular in-service re-trainings and also use of a combination of different training strategies like educational outreach visits, on-site training, incorporating clinical practice plus combining training with supervision to improve health care provider practice.

Future studies should hence focus on the optimal time frame required for re-training of health care workers within hospitals. This will help achieve the NEST 360 desired outcome of the reduction of neonatal mortality rate by 50% by 2030 in Kenya.

STUDY STRENGTHS

This study shows the effect of newborn care training among health care workers on feeding practices in VLBW neonates as a way of improving neonatal outcomes in KNH and PMH. It serves as good evidence of what can be achieved in these hospitals and other hospitals within similar settings.

The study as well shows the relationship between time and knowledge decay. Knowledge is the foundation of any skill or practice but it is not enough to maintain good practice.

The study allowed us to look at more outcomes at the same time, correct feed prescription, number of VLBW neonates admitted in KNH and PMH and documentations practice before and after the training.

The study had a retrospective aspect and was from records, which made it cheap and feasible, since very few resources were used. We didn’t require research assistants to do the study.

The study is also reproducible and generalizable. Any other hospital can reproduce the study using the same study methodology and get comparable results.

The results can be used to implement changes in KNH and PMH and any other hospital in the CIN or within similar settings.

STUDY LIMITATIONS

Randomization could not be achieved for a quasi-experiment hence association cannot be studied. There is also no control over the data that is entered into RedCap platform since it is collected and entered by another party.

The outcome of the study may be affected by other extraneous factors for instance prescribers attending continuous medical Education sessions, or other educational sessions other than the intervention of interest.

The knowledge pick-up rate among health care workers who attended the main newborn care training and those in the tailored half day training could have differed, being affected by factors like fatigue and information overload in the longer training.

The washout periods for health care workers who attended the main newborn care training and those in the tailored half day training was different, and even though this was due to the approvals that had to be sought before the half day trainings were done, this could have affected the outcome.

Some prescribers may change and hence some people who make the prescriptions may not be the ones who are trained; hence the intervention may not be informative in this case. This has been reduced by training 80% of the health care workers who are certain to be consistent within the unit for a period of 6 months during the post intervention period.

The gestation age recorded was considered unreliable, so no further analysis was done regarding this variable. Ballard's scoring should have been done but it's not routinely done in the study sites.

This was a retrospective study that used recorded data and there we found a lot of missing data. However, of note, to be able to reduce this, at every data point, files with missing data were not recruited in the study. But this affected the study, we were not able to achieve 100% of sample size, only getting 62% in the pre-intervention period, and 88% in the post intervention period, and this reduced the power of the study.

CONCLUSION

This study reports that there was no statistical effect of the newborn care training among heath care workers on feeding practices in VLBW neonates in KNH and PMH.

In our results, we note that there was a step increase in number of correct prescriptions, however the increase levels off at about 2 months after the intervention and remains at closely the same level after that.

There was a statistically borderline reduction in the number of stable VLBW neonates prescribed IVF after the training.

Neonates who were unstable and those who were referred from other health care centers were more likely to have a correct feed prescription compared to the rest of the VLBW neonates.

RECOMMENDATIONS

Regular short focused in-service training on feeding of VLBW neonates should be conducted to improve documentation and correct feed prescriptions per the national and WHO guidelines in order to improve neonatal outcomes in newborn units.

Reinforcing training with other evidence-based methods to encourage and maintain correct practice among health care workers.

An adequately powered, randomized control trial is required to study what impact this form of training has on mortality in a resource constrained setting.

STUDY BUDGET:

Category	Remarks	Units	Unit Cost (KShs)	Total (KShs)
Proposal Development	Printing drafts	1000 pages	5	5,000
	Proposal Copies	10 copies	500	5,000
	KNH – UoN ERC processing fee	1	3,000	3,000
Data Collection	Stationery Packs (Pens, Paper and Study Definitions)	10	100	1000
	External hard drive	1	15000	15000
Thesis Write Up	Computer Services			30,000
Data Analysis	Printing drafts	1000 pages	5	5,000
	Statistician	1	30000	30,000
Thesis Write Up	Printing Thesis	Ten copies	1500	15,000
	Contingency funds			50,000
	Total			**161,000**

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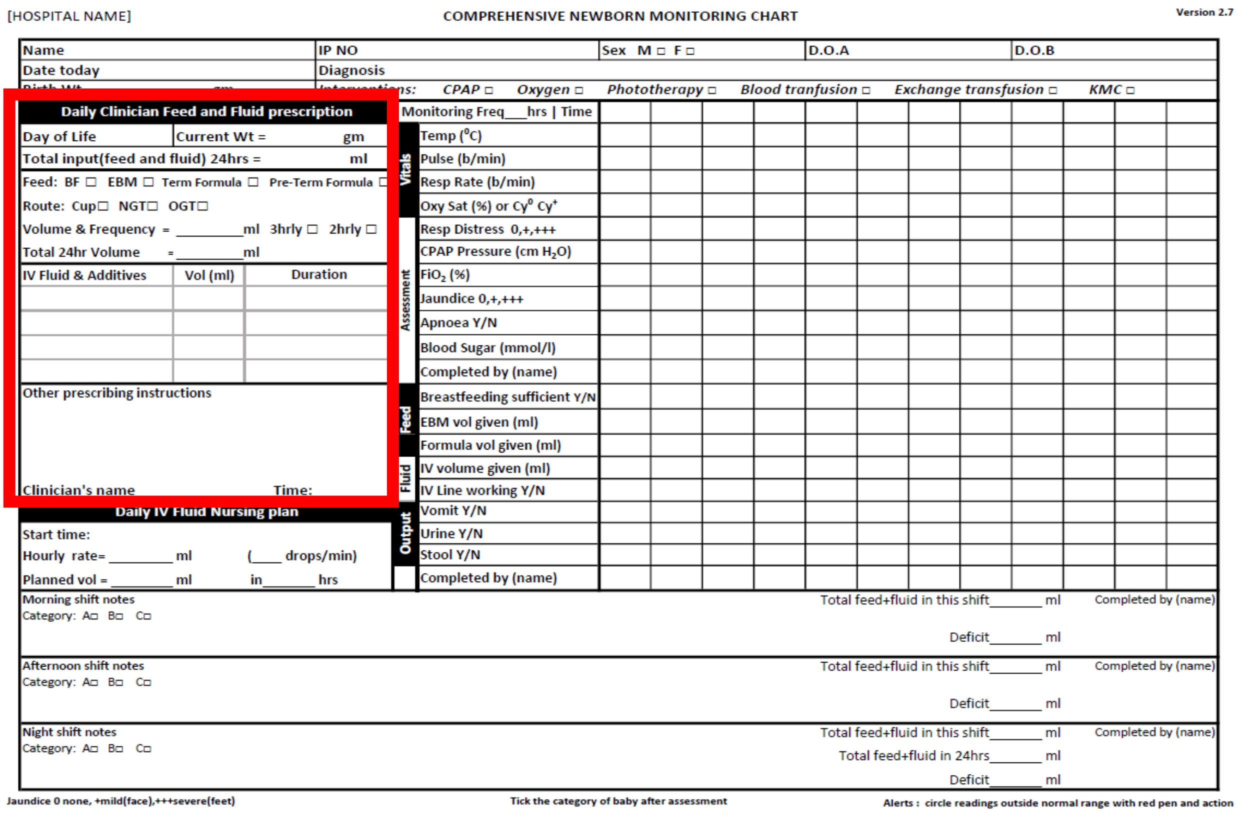
APPENDICES

Appendix 1: Comprehensive Monitoring Chart


[HOSPITAL NAME]

COMPREHENSIVE NEWBORN MONITORING CHART

Version 2.7

Name | IP NO | Sex M □ F □ | D.O.A | D.O.B

Date today | Diagnosis

Birth Wt ___ gm | Interventions: CPAP □ Oxygen □ Phototherapy □ Blood tranfusion □ Exchange transfusion □ KMC □

Daily Clinician Feed and Fluid prescription

Day of Life | Current Wt = gm

Total input(feed and fluid) 24hrs = ml

Feed: BF □ EBM □ Term Formula □ Pre-Term Formula □

Route: Cup□ NGT□ OGT□

Volume & Frequency = ________ml 3hrly □ 2hrly □

Total 24hr Volume = ________ml

IV Fluid & Additives	Vol (ml)	Duration

Other prescribing instructions

Clinician's name Time:

Daily IV Fluid Nursing plan

Start time:

Hourly rate= ________ ml (____ drops/min)

Planned vol = ________ ml in________ hrs

Monitoring Freq___hrs | Time

Vitals: Temp (^0C); Pulse (b/min); Resp Rate (b/min); Oxy Sat (%) or Cy^0 Cy^+

Assessment: Resp Distress 0,+,+++; CPAP Pressure (cm H_2O); FiO_2 (%); Jaundice 0,+,+++; Apnoea Y/N; Blood Sugar (mmol/l); Completed by (name)

Feed: Breastfeeding sufficient Y/N; EBM vol given (ml); Formula vol given (ml)

Fluid: IV volume given (ml); IV Line working Y/N

Output: Vomit Y/N; Urine Y/N; Stool Y/N; Completed by (name)

Morning shift notes
Category: A□ B□ C□
Total feed+fluid in this shift_______ ml Completed by (name)
Deficit_______ ml

Afternoon shift notes
Category: A□ B□ C□
Total feed+fluid in this shift_______ ml Completed by (name)
Deficit_______ ml

Night shift notes
Category: A□ B□ C□
Total feed+fluid in this shift_______ ml Completed by (name)
Total feed+fluid in 24hrs_______ ml
Deficit_______ ml

Jaundice 0 none, +mild(face),+++severe(feet)

Tick the category of baby after assessment

Alerts : circle readings outside normal range with red pen and action

The information about prescription of feeds and fluids as shown in the comprehensive monitoring chart as shown I the figure 4 above, in the section highlighted by the red box. This is the information that after being put in the REDCap Platform plus other demographic data, will be extracted for this study.

Appendix 1: **<u>Questionnaire (for both Pre and Post Intervention periods)</u>**

Demographic data:

Unique Code: ……………………………

Date of Birth: …………………………….

Time of Birth: …………………………...

Date of Admission: ……………………...

Time of Admission: ……………………..

Sex: …………………………………

Gestation: …………………………...

Birth weight: …………………………

Delivery mode:

a) SVD
b) Breech
c) C/S
d) Vacuum
e) Forceps

Resuscitation at birth (by BVM ventilation and/or Chest compressions):

a) Yes
b) No

Delivered in Kenyatta National Hospital:

a) Yes
b) No

Age of mother in years:

a) < 20 years
b) 20 – 30 years
c) 30 – 40 years
d) >40 years

Parity of mother:

a) Primigravidae
b) Multigravida

HIV serostatus of mother at any point during the gestation:

a) Positive

b) Negative

Any of the following at admission:

a) Convulsions
b) Unconscious,
c) Severe respiratory distress evidenced by severe indrawing,
d) Absent bowel sounds

What is the Diagnosis at admission?

a) Birth asphyxia
b) Preterm
c) Neonatal sepsis
d) Meconium aspiration
e) Multiple deliveries
f) Newborn RDS
g) Jaundice
h) Meningitis
i) Birthweight < 2kg

j) Others (specify)………….

Feeding Prescription on day 1 of life:

What type of feed was prescribed?

a) Breastfeeding
b) Expressed breast milk
c) Preterm formula
d) Intravenous fluids
e) TPN
f) Others (specify)………

What route of feeding was prescribed?

a) Cup
b) NGT
c) OGT
d) Intravenous

What volume of feed/fluid was prescribed on day 1 of life?

…………………………………………………………………………………………

…………..

Frequency of feed:

a) 3 hourly
b) 2 hourly
c) Modified bolus
d) Continuous

Total 24-hour feed or fluids volume prescribed:

…………………………………………………………………………………………

Feeding Prescription on day 2 of life:

What type of feed was prescribed?

a) Breastfeeding
b) Expressed breast milk
c) Preterm formula
d) IV fluids

If the fluid is prescribed, how much fluid was prescribed 24-hour fluids volume prescribed?

………………………………………………………………………………………….

What was the route of feeding prescribed?

a) Cup
b) NGT
c) OGT
d) Intravenous

How much volume of feed was prescribed on day 2 of life?

………………………………………………………………………………………………
…

What was the frequency of feed prescribed?

a) Three hourly
b) Two hourly
c) Modified bolus
d) Continuous

What was the total 24-hour feed and fluids volume on day 2 of life?

………………………………………………………………………………………………
…

Appendix 2: <u>Turnitin Similarity and Plagiarism Report</u>

THE EFFECT OF NEWBORN CARE TRAINING AMONG HEALTH CARE WORKERS ON FEEDING PRACTICES IN VLBW NEONATES IN KNH AND PMH: A BEFORE AND AFTER ST

by Allan Kayiza

Submission date: 29-Apr-2022 05:34AM (UTC+0300)
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Appendix 3: UoN/KNH Ethics and Research Committee Approval letter

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
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Tel:(254-020) 2726300 Ext 44355

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Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/403

28th October, 2021

KENYATTA NATIONAL HOSPITAL
APPROVED
28 OCT 2021
KNH/UoN-ERC
P.O. Box 20723-00202 NAIROBI

Dr. Allan Kayiza
Reg. No.H58/34293/2019
Dept. of Paediatrics and Child Health
Faculty of Health Sciences
University of Nairobi

Dear Dr. Kayiza

RESEARCH PROPOSAL: THE IMPACT OF NEWBORN CARE TRAINING AMONG HEALTHCARE WORKERS ON FEEDING PRACTICES IN VERY LOW BIRTH WEIGHT NEONATES IN KENYATTA NATIONAL HOSPITAL AND PUMWANI MATERNITY HOSPITAL: A BEFORE AND AFTER STUDY (P294/04/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P294/04/2021.** The approval period is 28th October 2021 – 27th October 2022.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours
v. 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.

Protect to discover

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

Yours sincerely

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

c.c. The Dean-Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Department of Paediatrics and Child Health, UoN
Supervisor: Prof. Irimu Grace, Dept. of Paediatrics and Child Health, UoN
Prof. Dalton Wamalwa, Dept. of Paediatrics and Child Health, UoN
Dr. Paul Laigong, Dept. of Paediatrics and Child Health, UoN
Dr. Wairimu Kimani, Dept. of Paediatrics and Child Health, KNH

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