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Missed opportunity for Nasal Continuous Positive Airway Pressure (NCPAP) in preterm neonates with Respiratory Distress Syndrome admitted at Kenyatta National Hospital, New Born Unit - A mixed method study.

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DECLARATION

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

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DEDICATION

To the God Almighty.

To my beloved parents and my husband whose support and encouragement meant everything.

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ABBREVIATIONS

BCPAP: Bubble Continuous Positive Airway Pressure

BPD: Broncho Pulmonary Dysplasia

CLD: Chronic Lung Disease

CPAP: Continuous Positive Airway Pressure

ELBW: Extremely Low Birth Weight

FGDs: Focus Group Discussions

FIO₂: Fractional of Inspired Oxygen

FRC: Functional Residual Capacity

GA: Gestational Age

II: In-depth Interviews

IPC: Infection and Prevention Control

KNH: Kenyatta National Hospital

LMICs: Lower and Middle-income Countries

MOH: Ministry Of Health

NBU: Newborn Unit

NIV: Noninvasive Ventilation

NNS: Neonatal Sepsis

O₂: Oxygen

PI: Principal Investigator

PPE: Personal Protective Equipment

RDS: Respiratory Distress Syndrome

SAS: Silverman Anderson Score

UON: University of Nairobi

WHO: World Health Organization

DEFINITION OF KEY TERMS

Preterm neonate - is a live birth that occurs before 37 completed weeks of pregnancy (WHO), divided into extremely preterm (<28 weeks), very preterm (28 to <32 weeks), moderate (32 to <34 weeks) to late preterm (34 to <37 weeks).

Neonatal mortality rate (NMR) – Probability that a child born in a specific year or period will die in the first 28 days of life if subject to age-specific mortality rates of that period, expressed per 1000 live births.

Under-five mortality rate (U5MR) – The probability of a child born in a specific year or period dying before reaching the age of 5 years, if subject to age-specific mortality rates of that period, expressed per 1000 live births.

RDS- is the major cause of respiratory distress in preterm infants primarily due to pulmonary surfactant deficiency in an immature lung.

CPAP- Continuous positive airway pressure is a noninvasive intervention for respiratory distress in newborns which applies positive pressure to the airways of a spontaneously breathing baby throughout the respiratory cycle.

Missed opportunity – lost a chance to be put on CPAP within 48 hours of life when clinically indicated due to CPAP unavailability or infrastructure challenges among many other reasons. (WHO)

ABSTRACT

Background: Respiratory distress syndrome (RDS) is the commonest complication of preterm infants and remains one of the major public health issues that contribute to neonatal mortality and morbidity, especially in Africa where 80% of neonatal mortality is estimated to be caused by preterm complications. Due to aggressive mechanical ventilation complications, a lot of strategies have been put in place to manage RDS and reduce its mortality including surfactant and less invasive modalities like continuous positive pressure (CPAP) ventilation. Nowadays, CPAP is the preferred mode of RDS treatment. However, CPAP is not easily accessible to every preterm infant in the low and middle-income countries (LMICs) and may be the case in Kenya.

Objectives: The objectives were to determine the proportion of preterm infants with RDS admitted to the newborn unit (NBU) at Kenyatta National Hospital (KNH) with a missed opportunity (within 48 hours of life) for CPAP, and to determine the barriers and facilitators of CPAP utilization.

Methodology: This was a hospital-based cross-sectional study that employed interactive explanatory concurrent mixed methods at the NBU in KNH. The study population was mainly preterm neonates (<37 weeks) within forty-eight hours of life who had signs of moderate respiratory distress (Silverman Anderson Score 4-6) or met the criteria for prophylactic CPAP (GA28-30 weeks or BW 1000g -1300g) from 28th July to 29th November 2021 (Quantitative arm). Participants who met the inclusion criteria were recruited consecutively until the desired sample size was reached. The qualitative arm was to determine the barriers and facilitators of CPAP utilization. The key informants were mainly; neonatologists, neonatal fellows, pediatric registrars, medical officers, nurses, and equipment nurse who utilize CPAP daily in their work from the newborn unit, procurement officer, and a biomedical engineer. These interviews happened from September to October 2021. Data was integrated by merging two data sets for analysis and a joint display was used whereby the quantitative and qualitative data were listed in different sections with an integrative statement.

Results: A total of one hundred and sixty-seven term neonates were reviewed and analyzed. Fifty six of these children (33.5% [95% CI 59.0% - 73.2%]) missed the opportunity to receive NCPAP. Missed opportunity for prophylactic group and Silverman Anderson Score group was 44.7 (34.1% - 55.9%) and 24.2 (16.5% - 33.9%) respectively. Twenty key informants were interviewed and the facilitators of NCPAP use reported were: i) the training and mentorship of health workers, ii) availability of NCPAP machines, iii) KNH being a referral hospital and conditions of referrals, iv) global evidence that NCPAP use is beneficial, v) development of

technology, and vi) there was a need for NCPAP use. Barriers to NCPAP use were mainly: i) the inadequate number of NCPAP machines, ii) inadequate training and mentorship, iii) inadequate and inappropriate size of NCPAP consumables, iii) staff shortage, iv) faulty CPAP and v) long servicing turnaround time, vi) long cleaning turnaround time, vi) infrastructure challenges e.g. limited space in the unit, and vii) insufficient utilities like oxygen outlet points.

Conclusion: The proportion of the missed opportunity for NCPAP at the NBU in KNH was found to be high (33.5%). Barriers to NCPAP use were mainly related to medical products and technologies, health workforce related challenges, and service delivery. We recommend the provision of more NCPAP machines, human resource support, frequent training/CMEs/mentorship, infrastructure improvement, the adequate and appropriate size of consumables, and promotion of family-centered care to support more preterm neonates in need and also for the quality of care improvement.

CHAPTER 1- INTRODUCTION

1.1 Background

The first twenty-eight (28) days of life has the highest chance of death in a lifetime. Globally 1/3 of all neonates die on the first day while three-quarters (¾) die in only the first 7 days. A child born in sub-Saharan Africa and Asia has a 20 times higher risk of death than in Australia and New Zealand. In 2019, 2.4 million neonates died globally and about 80% of deaths occurred from those regions (1)(2).

Inequity exists in the health care system worldwide. For instance, it is projected that 2/31 countries in sub-Saharan Africa will achieve sustainable development goals(SDG) 3 by 2030 while 5/31 will achieve only under-five mortality reduction goals among others if a slow move on mortality reduction continues(3).

Prematurity is a global health problem and the main cause of neonatal mortality. Premature and small for gestational age neonates have a fifteen times higher risk of death than other neonates(2)(4). Roughly 15 million infants are born prematurely annually; respiratory complications kill more than one million neonates. In 2018, prematurity complications accounted for 1/3 (35%) of them, respiratory distress syndrome being the commonest complications in 50% of cases(5)(4). Eighty percent (80%) of neonatal deaths in Africa are estimated to be caused by the high number of preterm births/LBW and its complications(2).

In Kenya 2018, the neonatal mortality rate (NMR) was at 19.6/1000 live births, mostly due to prematurity complications 28 % and intrapartum-related complications 29% (6). In a study conducted in 2013 from five Kenyan hospitals, 38% of admissions were low birth weight infants with a 68% mortality rate (7). At Kisii Teaching and Referral Hospital in 2015, RDS was the common reason for admission for preterm neonates at 56.6% with 73.15% of the overall deaths caused by RDS(8).

KNH was found to have the highest prevalence of preterm births at 18.3% in the maternity unit in 2014 compared to world health organization (WHO) estimates with a worldwide prevalence range between 5-18% (9), and in 2018 overall neonatal mortality rate due to prematurity complication in KNH was 87.5% mostly likely due to lack of respiratory support(10). RDS almost occurs exclusively in preterm infants. Its occurrence and severity are inversely proportional to gestational age mainly due to immature lung and surfactant deficiency (11).

In the high-income countries, due to aggressive mechanical ventilation complications like barotrauma and chronic lung disease, a lot of strategies have been put in place to manage RDS and reduce its mortality. These include surfactant and less invasive modalities like continuous positive airway pressure. CPAP has been shown to work effectively in the treatment of RDS as well as reducing chronic lung diseases hence it is currently the preferred mode of RDS treatment. Ventilation and surfactant are used when they are needed (12). CPAP tends to reduce RDS mortality and the need for mechanical ventilation by almost a half. In lower and middle-income countries; mechanical ventilation, surfactant, and CPAP are not easily accessible to every preterm infant in need(12).

There have been a lot of efforts in limited settings to scale up NCPAP use by using improvised and low-cost bubble NCPAP machines to improve neonatal survival. (14)(29) Despite CPAP being a promising procedure, there are still barriers to its implementation in the sub-Saharan health care system in contrast to the modern world where it is widely available, some of the challenges being insufficient equipment and consumables, turnover and staffing shortage, and lack of staff training among others (13)(14). Moreover; limited space in the newborn units, low CPAP-patient ratio, skilled staff turnover, and electricity interferences were the main problems in Kenya by Nabwera et al in 2018 (15).

A slow reduction in neonatal mortality has been observed worldwide and global progress in child survival and health cannot be achieved without addressing preterm births and their complications, thus WHO strongly recommended the use of CPAP in preterm infants. Although RDS is commonly seen in preterm infants, it occurs in all three leading causes of neonatal mortality namely neonatal sepsis, intrapartum-related complications, and prematurity. So focusing on effective intervention for RDS would decrease neonatal mortality in LMICs(16). Missed opportunity for CPAP is defined as neonates who lose the chance to be put on CPAP when clinically indicated due to CPAP unavailability or infrastructure challenges among many other reasons. Therefore, it is very important to understand the barriers to CPAP use in our settings.

Missed opportunity for CPAP in developed countries would mean those who met criteria for CPAP but other interventions were done instead; like mechanical ventilation (17). In LMICs, the missed opportunity for CPAP is common due to CPAP unavailability or infrastructure constraints among others (15)(18).

A study done in KNH by Nganga et al, in 2016 revealed that 56.9% of preterm infants were eligible for CPAP but did not get it, the reasons behind this were not captured in this study. Missed opportunities in KNH remain unclear with gaps that limit the understanding of what could be the reasons behind a missed opportunity for CPAP (19).

This study aimed to find out the proportion and factors associated with a missed opportunity for CPAP in preterm infants admitted in the newborn unit, KNH.

CHAPTER 2 - LITERATURE REVIEW

2.1 INTRODUCTION

2.1.1 RDS in preterm infants

RDS is the commonest etiology of respiratory distress in preterm infants primarily due to lung immaturity and surfactant deficiency (20)(21).

The preterm neonate is a live birth that occurs before 37 completed weeks of pregnancy according to WHO. It is divided into late preterm (34 to <37 weeks), moderate preterm (32 to <34 weeks), very preterm (28 to <32 weeks), and extremely preterm (<28 weeks). Prematurity may be due to spontaneous causes mostly due to inflammation or infections, hemorrhage, or uteroplacental ischemia and it can be clinically indicated due to different fetal or maternal indications. However multiple factors are associated, lower social-economic status being one of them (4) (22).

Preterm neonates are associated with long term complications like chronic lung disease (CLD) and intellectual impairment, in addition to increased morbidity and mortality due to RDS among other complications (9). RDS commonly occurs in preterm infants due to biochemical and morphological immaturity mainly surfactant. It is inversely proportional to gestational age and about 80% occurs in those <28 weeks and 15-30% in those 32-36weeks. However RDS may also occur in term infants due to different conditions, intrapartum related complications being some of them (23).

Surfactant is a surface-acting material that lowers the surface tension of a fluid; pulmonary surfactant is an amphiphilic complex of specific lipids, proteins, and carbohydrates secreted by type 2 pneumocytes. Surfactant is synthesized and secreted between 23 weeks and 32 weeks in a saccular stage of lung development, mature surfactant levels are present after 34 weeks of gestational age. Its components are synthesized in the endoplasmic reticulum of type II alveolar cells and transported through the Golgi apparatus to the lamellar bodies, where they are packaged and stored. Lamellar bodies appear in the cytoplasm at about 23 weeks gestation. These bodies are secreted by exocytosis into the surface water layer lining the alveolar airspace, where the surfactant forms a meshwork of tubular myelin. Tubular myelin then generates the phospholipids that provide the material for a monolayer at the air-liquid interface on the alveolus that lowers surface tension.

Surfactant is mainly made up of phospholipids (Phosphatidylcholine by seventy percent (70%)), proteins, and ions. Dipalmitoylphosphatidyl choline is the primary surface-active material found in surfactant. Surfactant-associated proteins (apoproteins), SP-A and SP-D are small and hydrophilic proteins that are involved in host defense while SP-B and SP-C are extremely hydrophobic proteins. The function of SP-B is storage, reprocessing, and secretion of surfactant in type 2 respiratory epithelial cells and SP-C is the most hydrophobic protein in the surfactant. Surfactant increases before birth due to increased synthesis, then surfactant secretion increases during and immediately after birth. (11)

Surfactant reduces surface tension and prevents alveoli collapse during expiration to facilitate adequate ventilation. It also increases local pulmonary defense mechanisms; surfactant deficiency increases the pressure required to open alveoli thus there is alveoli instability leading to collapse and atelectasis, which further causes; lung injury, inflammation, pulmonary edema, and low functional residual capacity as a result. All interfere with surfactant function and production resulting in RDS (24).

2.1.2 RDS diagnosis

Usually, signs and symptoms of RDS manifest in 4-6 hours after birth and become severe in 1 to 2 days if left untreated. RDS severity depends on clinical signs and laboratory findings. The Silverman Anderson score (SAS) was developed in the 19th century and consists of 5 signs which show a degree of respiratory severity. Later it was mainly adopted in LMICs where blood gas machines and x-rays are not widely available. Therefore, clinical findings are the key in these settings and SAS helps in sorting out children who need respiratory support more than others. SAS is done by grading the signs of respiratory distress where if none of each of the respiratory signs shown in table 1 is present then zero is given if the mild sign of respiratory distress then one is given and two are given when there are severe respiratory distress signs. The accumulation of grading gives zero to ten in total, ten being the most severe form of severe respiratory distress. (25)

Table 1. Silverman Anderson score (20) (25)

	Upper chest movement	Lower chest retractions	Xiphoid retractions	Nares dilation	Expiratory grunt
Grade 1	Synchronized	None	None	None	None
Grade 2	Lag on inspiration	Just visible	Just visible	Just visible	Heard with stethoscope
Grade 3	Seesaw	Easily seen	Easily seen	Easily seen	Heard by ear

Mild RDS is when SAS is 1-3, moderate RDS (CPAP indication) SAS 4-6 and severe RDS (impending respiratory failure) SAS 7-10.

Blood gas analysis usually shows hypercarbia, hypoxemia with respiratory acidosis, and metabolic acidosis depending on RDS severity whereas air Bronchograms, reticulonodular ground glass appearance, and atelectasis are commonly seen on chest x-ray (23).

2.1.3 RDS management (CPAP)

It is figured that if respiratory distress, neonatal sepsis, kangaroo mother care, and nutrition are well taken care of, preterm-related deaths can be decreased by 70 % (2).

CPAP is an easy and effective treatment proven modality that can be used in the reduction of RDS morbidity and mortality in preterm infants; CPAP consists of a gas source, nasal or mask airway interface, and a pressure generating source (20). Studies in the modern world have shown that CPAP halved the demand for invasive ventilation and preterm deaths as well as reduction of mechanical ventilation complications (12).

Commonly used CPAP modes are ventilator-derived CPAP (V-CPAP) and bubble CPAP (B-CPAP). Their pressure originates from different sources. In V-CPAP, an adjustment of a valve gives variable airflow resistance while in B-CPAP; pressure in the circuit is appreciated by immersing the expiratory tubing in water to a certain depth. It consists of gas flow source, oxygen air blender, humidifier, and the respiratory circuit (26).

CPAP maintains positive airway pressure in a spontaneously breathing baby, which prevents atelectasis, improves functional residual capacity due to recruitment of collapsed alveoli, chest wall stability, improves work of breathing; increases surface area for gaseous exchange and thus improves oxygenation (27). CPAP recruits collapsed alveoli and thus lowers the fraction of inspired oxygen needed which decreases oxygen toxicity, risk of airway damage, and reduces mechanical ventilation rates (28).

Improvised or simple and low cost effective bubble CPAP machines are commonly used in low constrained settings to reduce missed opportunity for NCPAP and improve neonatal outcomes due to its affordability and efficacy. (14)(29)

2.1.4 CPAP efficacy

A few studies done in LMICs showed improved survival with CPAP use although it is not widely available in these countries.

Thukral et al systematically reviewed the safety and efficacy of CPAP in LMICs. They analyzed 4 observational studies with 66% neonatal mortality reduction, one study showed 50% mechanical ventilation reduction rates while the proportion of CPAP failure ranged from 20-40% in 8 studies. Researchers concluded that CPAP was effective and safe in LMICs (30).

Rezzonico et al measured the effect of BCPAP usage on neonatal deaths in NICU Nicaragua. Two hundred and thirty (2006) and 383(2008) neonates participated in pre-CPAP and Post-CPAP intervention. Intubation rates halved from 72% to 39%, CPAP use increased from 27% to 61% and the death rate halved from 40% to 23%. Researchers emphasized CPAP usage in LMICS due to its efficacy and ease of use (31).

Okello et al, 2019 retrospectively studied the effect of BCPAP introduction on the neonates <1500 g in Uganda. Three hundred seventy-seven (377) VLBW infants were selected; 158 in Pre –CPAP era (missed the opportunity for NCPAP) 2015-2016 and 219 in the Post-CPAP era in 2016-2017.

Thirty nine percent (62/158) in the Pre-CPAP era died versus 26.5% (58/219, $P = 0.012$) in the post-CPAP era. In general, the mortality decreased by 44% (OR 0.56, 95% CI 0.36–0.86, $P = 0.01$). Researchers believed that resource-appropriate and specialized neonatal care addresses appropriately healthcare provision challenges in LMICs with the potential to decrease neonatal deaths. Therefore, the usage of low-cost BCPAP (relatively affordable and simple) could have a big impact on neonatal mortality globally (12).

Mwatha et al conducted a randomized control trial to determine and implement BCPAP efficacy and its outcomes compared to oxygen therapy in preterm neonates with respiratory distress in Tanzania at a tertiary hospital in 2020. In this study, 48 babies were recruited 25 on BCPAP and 23 on oxygen. There was higher survival in the BCPAP group 77.3% (17/22) vs. the oxygen group 47.8% (11/23). The neonates managed with BCPAP had 52% less risk of death (crude HR 0.48, 95% CI = 0.16–1.43). Consequently, this research presented a 30% survival improvement with BCPAP (21).

Table 2. Summary of the Literature review on CPAP Efficacy

Author/Year	Study objective	Design	Sample	Results
Thukral et al, LMICs in 2015	Efficacy and safety of CPAP in LMICs	Systematic reviews	13 papers	Four observational studies with 66% neonatal mortality reduction, a single study showed 50% mechanical ventilation reduction, CPAP failure ranged from 20% to 40% in 8 studies Researchers found CPAP to be effective and safe in LMICs and a need for further studies of high quality.
Rezzonico et al, In BCH, NICU Nicaragua 2015	measured the effect of BCPAP usage on neonatal deaths in pre-CPAP and Post-CPAP intervention (a period with the promotion of its use to reduce mechanical ventilation rates as a result)	Prospective pre-and post-intervention study.	230(2006) and 383(2008) neonates participated	Intubation rates halved from 72 to 39% and BCPAP use increased from 27-61%, death rate halved from 40% to 23%. Researchers emphasized CPAP to be used in LMICS due to its efficacy and ease of use.
Okello et Al, Mbale Regional Referral Hospital, Uganda 2019	Studied the effect of BCPAP introduction on neonates <1500 g	Retrospective observational study	377 VLBW infants 158 in Pre – CPAP 2015-2016 219 in Post-CPAP in 2016-2017	Thirty nine percent (62/158) in Pre-CPAP died versus 26.5% (58/219) in post-CPAP. Mortality decreased by 44%
Mwatha et al, Tertiary hospital in Tanzania 2020	To determine and implement BCPAP efficacy and its outcomes vs. oxygen therapy in preterm neonates with RDS.	randomized control trial	48 babies, 25 on BCPAP while 23 on oxygen.	Higher survival in the BCPAP group 77.3% (17/22) vs. the oxygen group 47.8% (11/23). Neonates managed with BCPAP had a 52% lower risk of death.

2.1.5 Efficacy of Bubble CPAP in LMICs and Kenya

A lot of progress has been made as far as respiratory support is concerned for preterm neonates, NCPAP is cost-effective respiratory support. Improvised bubble CPAP has also gained an audience in low limited settings due to its affordability and the fact that it can be locally assembled. Reviews in the region have been done to evaluate its efficacy and the results are quite encouraging.

In 2015, Bhatti et al compared the J-CPAP-variable flow and Bubble CPAP failure rates in preterm infants with respiratory distress in India. There was no difference in failure rates between the two types of CPAP machines, with a sample size of 170 neonates. (32) Chisti et al. 2015, evaluated whether BCPAP use has better outcomes compared with standard oxygen therapies using randomized control trial in Bangladesh. Thirty-five percent received BCPAP while low flow oxygen therapy was received by thirty percent of participants, six percent of the BCPAP group had treatment failure compared to twenty-four percent in low flow o2 therapy. Only four percent died in the BCPAP group compared to fifteen percent in the control group.(33)

A systematic review by Martin et al in LMICS, studied BCPAP efficacy with RDS, 3 studies found that BCPAP reduces invasive ventilation by half, 3 other studies showed no difference in mortality comparing BCPAP and Ventilator CPAP, Moreover, a meta-analysis of treatment failure showed a lower failure rate in the bubble CPAP groups.(34)

A systematic review by Kinshella et al, 2020 in SSA showed survival rates of using pumani CPAP to be between fifty-six to seventy-one percent in 2 studies, and 5 studies showed fifty-two to eighty-five percent survival with improvised bubble CPAP using the water bottle method.(13)

Myhre et al, 2016 looked at the effect of using low-cost BCPAP as a treatment for premature infants with RDS at AIC Kijabe Hospital in Kenya before and after the introduction of BCPAP. They enrolled 46 neonates in the Pre-CPAP period from 2007- 2009 versus 72 in the Post BCPAP period in 2009-2011; then compared survival rates of 61% vs. 85% for Pre-CPAP and post CPAP group respectively. In addition, there were fewer infants referred in the post-CPAP period 4% vs. 17% in the Pre-CPAP group. They recommended that BCPAP use be expanded to all Kenyan hospitals that have preterm infants as their clients. (27) A longitudinal study on preterm infants at the AIC Kijabe Hospital in Kenya by Omoding et al, 2012 also has shown CPAP to be effective with no major complications observed during the period of the study (23).

Table 3. Summary of the Literature review on Bubble CPAP Efficacy

Author/Year	Study objective	Design	Sample	Results
Bhatti et al, India in 2015	Nasal Jet-CPAP (variable flow) versus Bubble-CPAP in preterm infants with respiratory distress.	A randomized controlled trial	170 neonates	There was no difference in failure rates between the two types of CPAP machines. Jet CPAP/BCPAP had Twenty-nine percent versus twenty-one percent failure rates respectively.
Chisti et al, Bangladesh, 2015	Assessed whether BCPAP use has better outcomes compared with standard O ₂ therapies.	A randomized controlled trial	225 children	Six percent of the BCPAP group had treatment failure compared to twenty-four percent in low flow O ₂ therapy. Only four percent died in the CPAP group compared to fifteen percent in the control group
Martin et al, LMICs, 2014	Bubble CPAP efficacy in neonatal care in LMICs	A systematic review	14 studies	Studies found that BCPAP reduces invasive ventilation by half. Studies showed no difference in mortality comparing BCPAP and Ventilator CPAP. Treatment failure rate was lower in the bubble CPAP groups.

Kinshella et al, Sub-Saharan Africa 2020	Barriers and facilitators to implementing bubble CPAP to improve neonatal health.	A systematic review	17 studies	Pumani CPAP had an efficacy of 56-71% in just 2 studies while improvised bubble CPAP had 52-85% efficacy in 5 studies.
Myhre et al, AIC Kijabe Hospital Nursery, Kenya 2016	Looked at the effect of using low-cost BCPAP as a treatment for premature infants with RDS before and after its introduction.	Retrospective study	118 neonates enrolled 46 neonates in Pre-CPAP period 2007-2009, 72 in the post – CPAP 2009-2011	Sixty-one percent vs. 85% for post CPAP group /Pre-CPAP infants survived respectively. Fewer infants were referred in post CPAP period 4% vs. 17%Pre-CPAP group from AIC Kijabe Hospital.

2.1.6 Missed opportunities for non-invasive ventilation

Though there is increasing evidence of CPAP safety, CPAP use hasn't yet been scaled up especially in our setting. Currently, there are limited studies on the proportion and factors associated with missing an opportunity for CPAP in patients with RDS in LMICs including Kenya. Therefore, there are few studies done in LMICs on missed opportunity for CPAP which found that; missed opportunity is common due to CPAP unavailability or infrastructure constraints among others (15)(18).

In 2008, Sweet et Al did an observational study on opportunities missed for noninvasive positive pressure ventilation in COPD or CHF patients at St. Paul's teaching Hospital, Canada. He determined patients who experienced exacerbations and met the criteria for noninvasive positive pressure ventilation trial but were emergently intubated and mechanically ventilated. Fifty nine patients met the criteria for NPPV, 33.9% (20) received a trial of NPPV while 39 (66%) did not get a chance for an NPPV trial but were intubated instead. Researchers concluded that the NPPV use should be improved since about 2/3 met the criteria for NPPV but didn't receive it (17).

In 2009, Gregory et al carried out a survey of physicians and respiratory therapists on the usage of Noninvasive ventilation in the Veterans Affairs health- care system, USA. NIV was considered as a first-line choice for CHF and COPD, but the perceived use was less. Furthermore, 29% of physicians ($P < 0.001$) and 64% of respiratory therapists responded that NIV was used less than 50% of the time when indicated. Therefore, there were minimal rates of perceived efficacy and underuse of NIV as their major findings (35).

In 2016, Kondwani et al conducted a prospective non-randomized sample study in Malawi at Queen Elizabeth Central Hospital on BCPAP efficacy in RDS management in which 87 neonates were enrolled, 62 infants were managed with BCPAP while 25 were put on oxygen therapy (due to unavailability of CPAP). Seventy one percent (44/62) who were managed with BCPAP survived versus only 11/25 (44.0%) in the oxygen group. Sixty five percent (19/29) VLBW Infants in the BCPAP group were discharged versus only 15.4% (1/13) in the oxygen group. Sixty-one percent (16/26) of those with neonatal sepsis who received BCPAP were discharged, while none of 7 neonates with neonatal sepsis in the missed opportunity group survived. This paper showed a 27% survival difference with BCPAP use and 28% missed opportunity for BCPAP. The researchers recommended BCPAP implementation in the developing world since it could scale down neonatal deaths (28).

Nganga et al in 2016 did a descriptive study on the Clinical profile and audit of RDS management in preterm infants at KNH. Two hundred and six (206) preterm neonates were enrolled. The majority of whom were clinically candidates for CPAP but 56.9% didn't receive CPAP despite being eligible

(19).

Table 4: Summary of the Literature review on Missed opportunities for CPAP

Author/Year	Study objective	Design	Sample	Results
Sweet et al, St. Paul's teaching Hospital, Canada 2008	Opportunities missed for non-invasive positive pressure ventilation in COPD or CHF patients	Retrospective observational study	59 patients	Fifty nine patients met the criteria for NPPV, 33.9% (20) received a trial of NPPV while 39 (66%) did not get a chance for an NPPV trial but were intubated instead.
Gregory et Al, Veterans Affairs health- care system, USA 2009	carried out a survey of physicians and respiratory therapists on the usage of NIV Also, NIV was considered as a first-line choice for CHF and COPD	Survey	192 participants	Twenty nine percent of physicians ($P < .001$) and 64% of respiratory therapists responded that NIV was used $< 50\%$ of the time when indicated Therefore, there were minimal rates of perceived efficacy and underuse of NIV as their major findings.
Kondwani et al, QECH, Malawi 2016	BCPAP efficacy in RDS management	Prospective non-randomized study	87 neonates	Sixty two infants received BCPAP while 25 (28%) missed the opportunity for CPAP and were put on O_2 (due to unavailability of CPAP) 71.0% (44/62) (95% CI: 59-81%) ($p=0.018$) who were managed with BCPAP survived while only 11/25 (44.0%) in the O_2 group survived.
Nganga et al, KNH.2016	Clinical profile and audit of RDS management in preterm infants	Descriptive cross-sectional study.	206 preterm neonates were enrolled	The majority of enrolled neonates had SAS 4-6 but 56.9% didn't receive CPAP despite being eligible.

2.1.7 Limitation factors and facilitators to NCPAP use and accessibility

Szymon et al designed a survey to determine the accessibility and limiting factors of non-invasive mechanical ventilation in the regions and worldwide targeted members of European society and ERS national delegates using survey monkey in 2018. One hundred and sixty one responses from forty-six countries were collected. In High Income Economies, NIV compensation in chronic respiratory failure management were reimbursed by insurance ($p < 0.0001$) while in Lower and Middle Income Economies, the use of chronic NIV is not reimbursed which shows the urgency for advocacy. Therefore, financial constraints were the driving factor for NIV use (36). b

In a regional survey done on the usage of NIV in the USA in 2006, Maheshwari et al received replies from 71/82 (88%) directors of respiratory care in Rhode Island and Massachusetts at acute care hospitals. The overall usage for NIV was 20% and lower utilization rates were due to inadequate equipment, respiratory therapist training, and lack of physician knowledge. Therefore, educational programs at individual institutions were recommended to improve utilization rates (37).

In India, Dewez et al in 2018 found that the barriers faced were mainly limited staff numbers to handle and monitor neonates on CPAP or to start CPAP, less equipment and consumables compared to the number in need, poor support by health care administration, and infrastructure challenges among others (38). The same barriers were also found in Sub-Saharan Africa in a systematic review by Kinshella et al in 2020. Understaffing and turn over affected training on CPAP use and supply was not reliable in 5 studies. Donor sustainability, leadership challenges, and motivation were also mentioned. However some challenges were partially solved by mentorship programs and cost-effective CPAP (13).

A qualitative study in Malawi by Mipando et al in 2020 found problems in the division of responsibilities and disagreements on CPAP initiation between health care workers, ineffective communication between nurses and doctors (which resulted in a delay of procedure initiation), and staff shortage (18).

In Kenya, Nabwera et al 2020 found the following problems; The CPAP-patient ratio, limited space in the newborn units, electricity interferences and skilled staff turnover. However, some participants reported that training helped a lot in CPAP implementation. Effective communication between parents and Medical professionals as well as promising outcomes with CPAP use itself encouraged health care workers despite the challenges(15). However,

key informants for the Nabwera's study were only nurses; though views from other staff that involved in CPAP utilization and availability would have provided a better picture and deeper understanding of barriers and facilitators of NCPAP use.

Table 5 . Summary of the Literature review on Limitation factors and facilitators to CPAP use and accessibility.

Author/Year	Study objective	Design	Sample	Results
Maheshwari et al, in Rhode Island and Massachusetts at acute care hospitals, USA 2006	Survey of respiratory care Directors on the utilization of NIV	A regional survey	71 of the 82 hospitals	Overall usage for NIV was 20% Lower utilization rates were due to inadequate equipment, respiratory therapist training, and lack of physician knowledge.
Szymon et al, targeted members of European society and ERS national delegates 2018	To determine accessibility and limiting factors of non-invasive mechanical ventilation in the regions and worldwide.	A survey	161 responses from forty-six countries were collected.	In HIEs, NIV compensation in chronic respiratory failure management were reimbursed by insurance ($p < 0.0001$) while in LMIEs, the use of chronic NIV is not reimbursed which shows the urgency for advocacy. Financial constraints were the driving factor for NIV use.
Dewez et al, Andhra Pradesh, India 2018	Views of health workers on barriers and enablers of CPAP implementation	Qualitative study	8 FGDs made up of 51 nurses. and 8 IDIs	Barriers:-limited staff numbers, less number of equipment and consumables, poor support by health care administration, infrastructure challenges.
Kinshella et al, Sub-Saharan Africa, 2020	Facilitators and Barriers to CPAP implementation.	Qualitative study	17 studies	Understaffing and turnover affected training on CPAP use, unreliable supply, donor sustainability, leadership challenges, and motivation were the main barriers.
Mipando et al, The southern part, Malawi 2020	Enablers and Barriers of CPAP implementation.	Qualitative study	46 IDIs with Health care workers	A rigid division of responsibility and disagreements, ineffective communication between nurses and doctors, frequent rotation of nurses, staff shortage, infrastructure challenges, less availability of machines and lack of trainings.
Nabwera HM <i>et al</i> , 19 hospitals, Kenya 2020	Experiences of healthcare workers on CPAP in Kenyan newborn units.	Qualitative study	16 key informant IDIs and 15 FGDs.	Low CPAP: Patient ratio, physically limited space in the units, electricity interferences. Skilled trainings, effective communication between parents and Medical professionals,

				promising outcomes with CPAP use encouraged its implementation. However above perspectives were only from nurses amongst other staff.
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2.2 Justification and Utility

Neonatal deaths in Asia and sub-Saharan Africa remain unacceptably high contributing to about 80% of NMR globally. Although evidence has shown remarkable outcomes with CPAP use, prematurity complications mainly RDS is still high and is one of the leading causes of neonatal mortality in LMICs. In KNH, the overall NMR was 87.5% in 2018 due to prematurity complications. Therefore, RDS management has to be tackled well.

Nganga et al 2016 studied the clinical profile and audit of the management of RDS in KNH and found that 56% who were eligible for CPAP didn't receive it. However, the reasons behind this large number of missed opportunities were not addressed in this study.

To the best of our knowledge, this was the first mixed-methods study on missed opportunities for CPAP in KNH aimed to find out the proportion of missed opportunities and mitigate the barriers and facilitators of NCPAP use.

Knowing the missed opportunities and reasons associated with it will help the institution to plan for better preterm care. It will also be utilized as a tool for advocacy, allocation of resources, research, and care related to preterm births hence reducing our neonatal mortality.

2.3 Study Objectives

2.3.1 Broad objectives

To determine the proportion and reasons associated with the missed opportunity for CPAP of preterm neonates with RDS admitted in the newborn unit, Kenyatta national hospital.

2.3.2 Primary Objectives

To determine the proportion of preterm infants with RDS admitted in the newborn unit (NBU) at Kenyatta National Hospital (KNH) with a missed opportunity (within 48 hours of life) for CPAP by quantitative approach, and to determine the barriers and facilitators of CPAP utilization using a qualitative method.

CHAPTER 3 - METHODOLOGY

3.1 Study Design

A hospital-based cross-sectional study employed interactive explanatory concurrent mixed methods (qualitative and quantitative methods).

We studied overall missed opportunities for NCPAP generally with all three forms of NCPAP machines available in the unit. The quantitative approach determined the proportion of missed opportunities for CPAP in preterm neonates admitted in NBU, KNH from 28th July to 29th November 2021 while the qualitative approach explored the barriers and facilitators of CPAP utilization in the newborn unit, Kenyatta National Hospital from September to October 2021. We have used mixed methods to expand and improve the usefulness of our findings. We employed an interactive or equal status mixed approach. This approach was both explanatory because the qualitative aspect explains why we have quantitative results, and concurrent because both approaches were conducted simultaneously at some point. This mixed method approach helped us to understand the missed opportunities, barriers, and facilitators of NCPAP use in-depth and solutions to the NCPAP use barriers in our settings.

3.2 Study Site

This study was carried out at KNH, Newborn unit, Procurement department, and biomedical engineering department. KNH is a public, level 6 referral hospital in Kenya. It serves as the teaching hospital of the University of Nairobi, College of Health Sciences. KNH provides specialized tertiary health services for both adults and children in Kenya especially the most populated County of Nairobi which had a population of around 4.4 million by the 2019 census. On average, approximately 1200 neonates are admitted to NBU annually from the KNH labor ward, maternity theatre, post-delivery wards and referrals from other facilities. Newborn unit, KNH has three different types of NCPAP machines currently. Firstly, there are twelve (12) infant flow SIPAP NCPAP machines, only seven of these are functional however consumables available for infant flow SIPAP machines are only two (2). Secondly, Four (4) Pumani bubble NCPAP with their consumables, and a new type of bubble machine that was introduced at the time of this study namely Vayu bubble NCPAP machines, there are thirteen in number and only seven (7) of these are fully functional. (Appendix V)

3.3 Study Population

We included eligible preterm neonates < 37 weeks GA (based on Ballard score done by admitting clinician) with moderate respiratory distress (SAS 4-6 done by the research team)

within 48 hours of life and those who met the inclusion criteria for prophylactic CPAP (between 28-30 weeks or birth weight of 1000g -1300g). We conducted in-depth interviews with a representative sample of key informants who deal with NCPAP daily at KNH in their work mainly from the newborn unit, procurement department, and biomedical engineering department and these are neonatologists, neonatal fellows, pediatric registrars, medical officers, nurses, equipment nurse, procurement officer, and biomedical engineer.

3.4 Inclusion Criteria

Quantitative: Preterm infants (<37weeks GA), neonates (48 hours of life) who met criteria for CPAP (signs of respiratory distress, SAS 4-6) or met criteria for prophylactic CPAP (GA28-30 weeks or BW 1000g -1300g).

Qualitative: We included mostly health workers (all cadres) from KNH, NBU including neonatologists, neonatology fellow, registrars, medical officers, nurses, maintenance and equipment nursing officer, the biomedical engineer, and procurement officer from the procurement department in order to achieve a representative sample from key informants who deal with CPAP at KNH.

3.5 Exclusion criteria

Quantitative: Term neonates, infants with Silverman Anderson scored below 4 or above 6, floppy infants, apneic or gasping, infants with uncontrolled seizures, and infants with severe congenital malformations.

3.6 Study summary

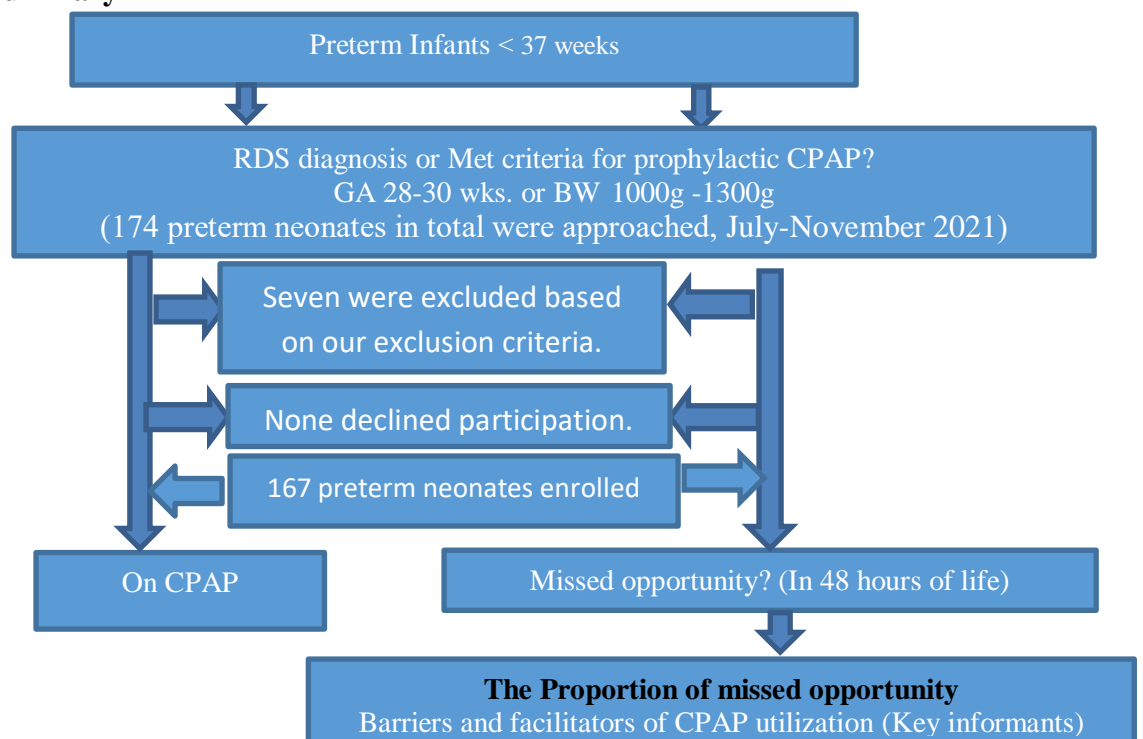


Figure 1. Study summary for quantitative study

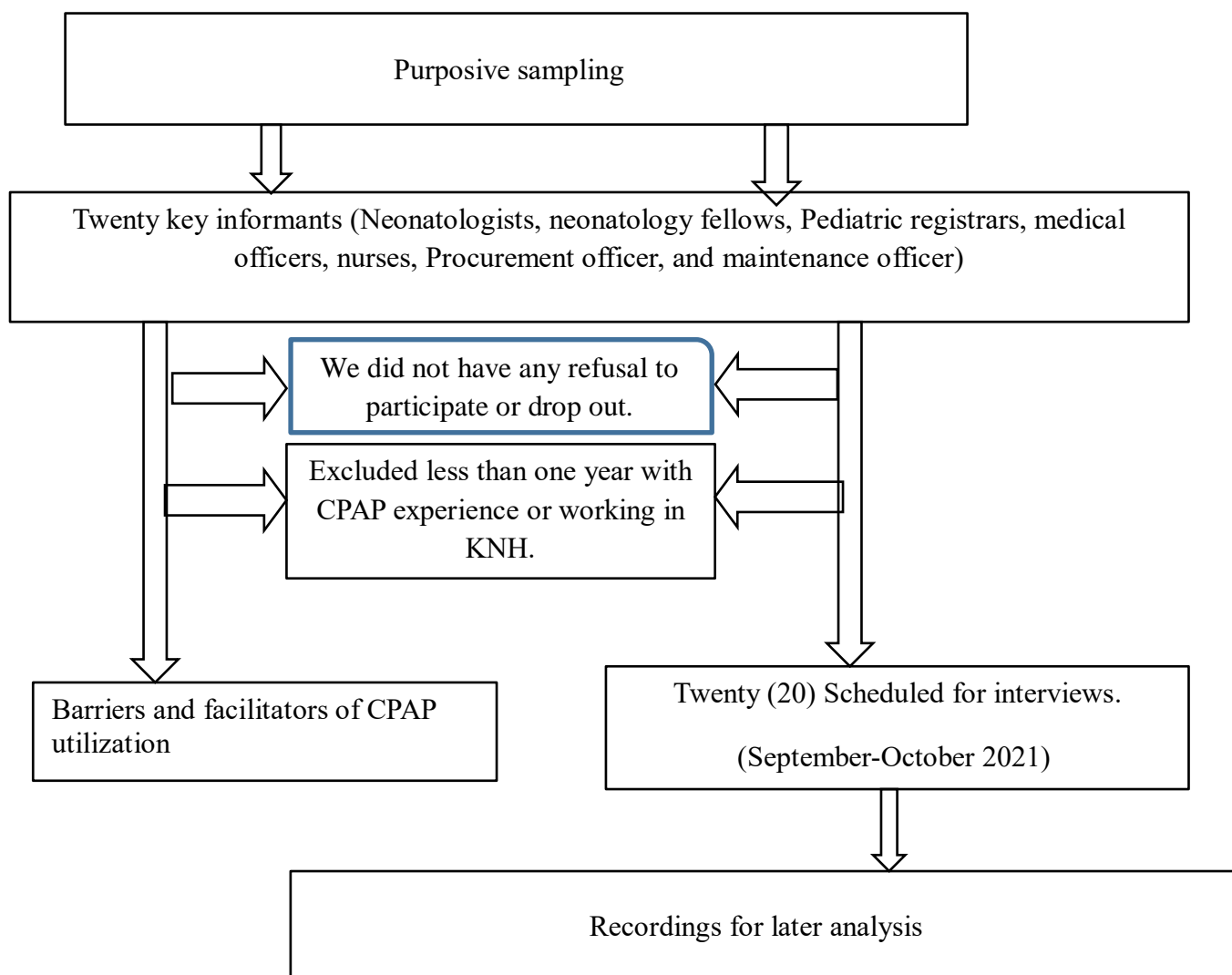


Figure 1. Study summary for qualitative study

3.7 Sample Size Determination

3.7.1 Quantitative

Quantitative: the sample size was determined by: Using a study in KNH, 56.9% did not get CPAP despite being eligible, using Fisher's Formula to get our sample size with the significance of 7.5%.

$$n = \frac{z^2 p(1-p)}{d^2} = 167$$

Estimated sample size (n) = 167 patients

z= standard normal deviate for 95% CI (1.96).

p= 56.9% (Nganga et al showed 56.9% neonates did not get CPAP (19).

d= the desired level of precision set at 7.5%.

In the same study, forty-seven infants met the criteria for prophylactic CPAP while fifty-five had SAS 4-6, so using a stratified sampling technique we aimed to balance 2 subpopulations (76 for the prophylactic CPAP group and 91 for those who developed RDS (SAS 4-6)).

3.7.2 Qualitative

Twenty key informants were selected and projected to reach saturation based on a study by Morse et al (39) whereby no new information emerged from additional participants.

3.8 Study Period

This study was conducted on preterm infants with RDS admitted to NBU for a period of four months (July-November 2021). In-depth interviews were conducted over a two month period (September-October 2021).

3.9 Patient and participant Recruitment Procedure

3.9.1 Patient selection

The participants were selected by the principal researcher and the trained research assistant with regards to inclusion criteria (study summary flow chart), preterm infants less than 37 weeks (based on Ballard score done by admitting clinician) and within 48 hours of life, then researchers approached the parent/guardian, and explained the purpose of the study. They were allowed to ask any questions they might have for clarification which were answered satisfactorily and then participants were allowed to sign a voluntary informed consent. The consent provided details on the purpose of the study, and the study procedure. Those that signed consent voluntarily were included in the study. Covid 19 protocols were observed on personal protection throughout the study.

3.9.2 Interview of key informants

Participants were approached by the principal investigator and research assistant using purposive sampling. Twenty key informants were selected to reach saturation, 18 of them had face-to-face interviews and 2 had zoom meetings which were recorded with consent. We included health care workers working in NBU (key informants) mainly neonatologists, a fellow in neonatology, paediatric registrars, medical officers, nurses, equipment and maintenance nursing officer, biomedical engineer, and procurement officer from the procurement department in order to have representative participants to help us answer the necessary questions. Researchers then introduced themselves and explained the purpose of the study.

They were allowed to ask any questions they might have had for clarification which were answered satisfactorily and were then allowed to provide voluntary informed consent. The consent provided the details on the purpose of the study, and the study procedure. Those that consented voluntarily were included in the study. No participant refused to participate or dropped out and Covid -19 protocols were observed on personal protection throughout the study.

3.10 Data Collection

3.10.1 Quantitative data

The Parents/caregivers were asked some questions and an examination was performed on preterm infants using a standard study closed-ended questionnaire (Appendix I) to collect socio-demographic and clinical data relevant to the study.

The medical data was maintained in a locked cabinet at the discretion of the researcher alone until the collection of data finished. A computer with a password was only accessible by the research team. The researcher ensured that no interruption of service due to the collection of the data and the current service where the patient or participant was.

3.10.2 In-Depth Interview

The data were collected using open guided interviews by the principal investigator and research assistant who were all practicing health care workers and had used NCPAP machines in training and work. Both were females and had received training in conducting in-depth interviews. No other person was present during the interview sessions apart from the research team and key informants. These were audio recorded by handheld tape recorder in addition to the field notes taken during interviews and noted when data was saturated. Eighteen interviews were conducted in a private space (or office within KNH) and two key informant interviews were conducted via zoom due to work-related challenges. The sessions were recorded with consent and it took approximately 20 minutes for each participant. The interview guide was pilot tested and interviews were conducted in English and all researchers were fluent in that particular language, Key informants were informed that if they wished to express their views in Swahili, they would be given chance to do so. However, they were all comfortable and expressed their views in English. We did not return transcripts to the participants or repeat interviews.

Stage 1: Scene setting: The research team welcomed the participant; the PI formally started the interview by introducing herself, stating the research topic, the purpose of the study, and written

consent were attained. The PI then explained to the participants that she/he was invited to give his/her own opinions and that there were no right or wrong answers. The PI requested the participant for the session to be recorded by the research assistant. The recordings were kept confidential by using only participants' initials and were only used for study purposes.

Stage 2: Opening topic: The Principal investigator engaged the participant by introducing the topic and inquiring about the participant's perceptions of barriers and facilitators of CPAP utilization.

Stage 3: Discussion: The participant was involved in a detailed discussion of his/her experiences and views on missed opportunities for CPAP. Also, he/she was asked about the factors that may have contributed to the above experiences (barriers to CPAP utilization) and lessons learned from those who do get CPAP (facilitators).

Stage 4: Ending the discussion: The PI ended the discussion by thanking the participant for participating and reassuring him/her that the information given would be kept confidential.

MEASURES TO MINIMIZE THE RISK OF COVID-19 EXPOSURE DURING MY STUDY

In the course of our study, we took the following infection prevention and control measures to minimize the risk of COVID-19 exposure to the study participants, research assistant, and myself as follows:

The principal investigator and research assistant: Reference was made to MOH recommendations regarding the use of appropriate Personal Protective Equipment (PPE) and infection prevention and control guidelines when conducting the face-to-face interviews and during data collection: N95 masks were worn at all times, surgical gloves were used and disposed of appropriately as per IPC guidelines. Alcohol-based hand sanitizers and hand washing were used before and after contact with the participants. A physical distance of a minimum of 1.5 meters was maintained between us and the participants. We had been trained on the appropriate cleaning and infection control procedures necessary to mitigate COVID-19 spread at our study site.

Study participants: Alcohol-based hand sanitizers were availed to them. They were advised to maintain a social distance of at least 1.5 meters during the sessions.

3.11 Data management and Analysis

3.11.1 Quantitative Data Analysis

Questionnaires and data were kept in a lockable cabinet only accessible to the principal investigator and statistician. The data from the questionnaire were exported and cleaned in Excel, coded, and analyzed using STATA. Descriptive analysis were performed to determine proportions in all variables. These were summarized into frequency tables and charts. The Proportion of missed opportunity was computed by the number of infants who missed the chance to CPAP with the total number of eligible preterm infants as a denominator and was converted to a percentage (%) at a 95% confidence interval.

3.11.2 Qualitative Data Analysis

A hybrid approach to data analysis was employed: deductive based on our conceptual framework developed from the literature review; and an inductive approach, for which we were open to new themes that emerged during data collection. Audio recordings from IDIs were transcribed verbatim by the independent transcriber (anthropologist and a population studies researcher) with a lot of experience in transcribing as well as a trained research assistant and principal researcher as a tie-breaker. NVIVO software version 12 was utilized for data management. This transcription happened in a maximum period of one week after the recordings and analysis were conducted -guided by the thematic approach. The findings were aggregated, coded progressively, and line-by-line read to identify central themes. The central themes were revised to identify sub-themes, reports abstracted to findings, and these findings were presented in the form of direct quotations from the responses of participants.

Study tools were filed and locked in cabinets for safe storage. Digital databases were developed using Microsoft Access with password-protected to limit access from unauthorized users. Before analysis and or dissemination, data were de-identified for confidentiality.

3.12 Ethical Consideration

Approval to conduct the study was sought from the UON paediatrics and child health department and the KNH/UON Ethical Review Committee and granted under P206/03/2021. Justice to participants and respect for their autonomy according to the Belmont Principles were respected throughout the study period.

Participants were explained to fully understand the purpose, benefits, and risks involved in the study together with the study procedures. They were given a chance to ask any questions they might have had and then voluntarily chose whether or not to participate. Those who agreed

were given an informed consent form to sign. Participants enrolled were guaranteed the observance of confidentiality and were allowed to drop out at any time during the study period. Those who declined participation were not denied treatment or the care they deserve and were reassured.

Personal identification such as names of participants was not captured on data collection tools except only on consent forms, which were only accessible by investigators and weren't shared with third parties and only serial study numbers were used to identify study participants. Interviews were scheduled in a private area of KNH. After use, files were locked in cupboards and databases were password protected.

Data from this study provided information to improve the overall care and survival of preterm infants in our settings. Each participant had a fair chance of selection for the study and caution was taken not to cause any physical or psychological harm to subjects during our study.

Study participants did not incur any extra financial costs and the principal investigator did not benefit in monetary terms from this study. Special consideration was made to patients being given the health care to avoid disrupting ongoing services.

3.13 Dissemination of the Study findings

The study findings were presented first to the UON Paediatric registrars and the KNH/UON paediatric consultants during the results presentation, and a copy will be handed to the Newborn unit and KNH research department. After completion of the manuscript, it will be sent to an academic journal for approval of publication to reach a broader public and for further dissemination, discussion, and policy interventions as well.

CHAPTER 4. RESULTS

4.1 Quantitative results

A total of one sixty-seven preterm neonates were analyzed. Seventy-six of them met the criteria for prophylactic CPAP and 91 had Silverman Anderson Score (SAS) between four and six. Eighty-eight (52.7%) were male and seventy-nine (47.3%) were female. The majority of them were between 28-32 GA weeks at 63(37.7%).

Table 6: Characteristics of the Preterm infants with RDS.

		Frequency (<i>n</i> =167)	Percent	Mean (SD)
Sex	Male	88	52.7	
	Female	79	47.3	
Birth weight	Median (IQR)			1391.4 (468.4)
	1300.0 (1050.0 – 1700.0)			
	ELBW (\leq 1000)	33	19.8	850.9 (112.6)
	VLBW (1001 – 1500)	82	49.1	1233.0 (140.0)
	LBW (1501 – 2500)	51	30.5	1970.2 (280.5)
	>2500	1	0.6	2510 (-)
Gestation age	Median(IQR)			30.0 (28.0 – 34.0)
	<28 weeks	24	14.4	26.2 (0.7)
	28 to <32 weeks	63	37.7	29.1 (0.9)
	32 to <34 weeks	32	19.2	32.9 (0.3)
	34 to <37 weeks	48	28.7	34.8 (0.8)
Mode of delivery	SVD	86	51.5	
	CS	81	48.5	
Gestation	Single	146	87.4	
	Twin	17	10.2	
	Triplet	4	2.4	

Figure 3 and Table 7 below show the Silverman Anderson score of the neonates enrolled. The SAS of 4 was the commonest at 57 (34.1%) and least being those who had SAS of 6 at 47 (28.1%).

Table 7: Silverman Anderson Score

		Frequency (<i>n</i> =167)	Percent
SAS	0 – 3	22	13.2
	4	57	34.1
	5	41	24.6
	6	47	28.1

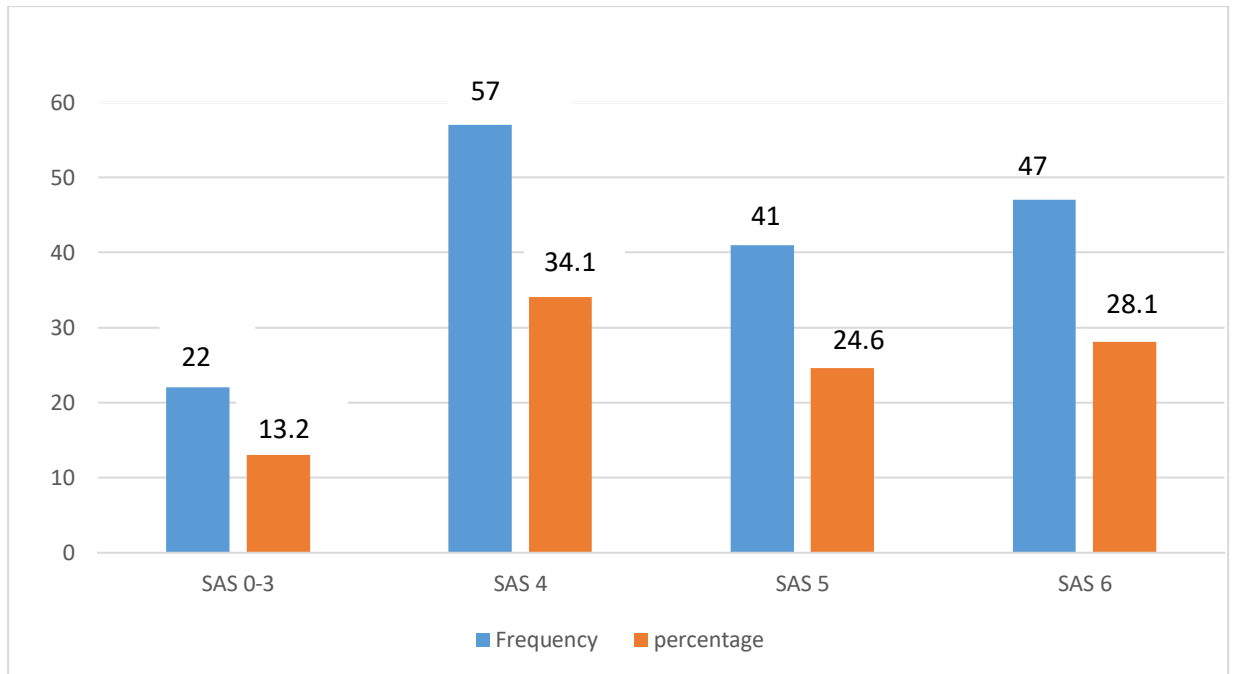


Figure 2. Silverman Anderson Score

Table 8 and figure 4 shows all neonates enrolled. The proportion of missed opportunity for CPAP was found to be 33.5% [95% CI 59.0% - 73.2%] (*n*=56). The majority of them got NCPAP at 66.5 % [95% CI 59.0% - 73.2%] (*n*=111).

Table 8: All preterm neonates enrolled

		Frequency (<i>n</i> =167)	Percent	95% CI
CPAP management	Yes	111	66.5	59.0% -
				73.2%
Missed CPAP	No	56	33.5	26.8% -
				41.0%
Total		167	100	

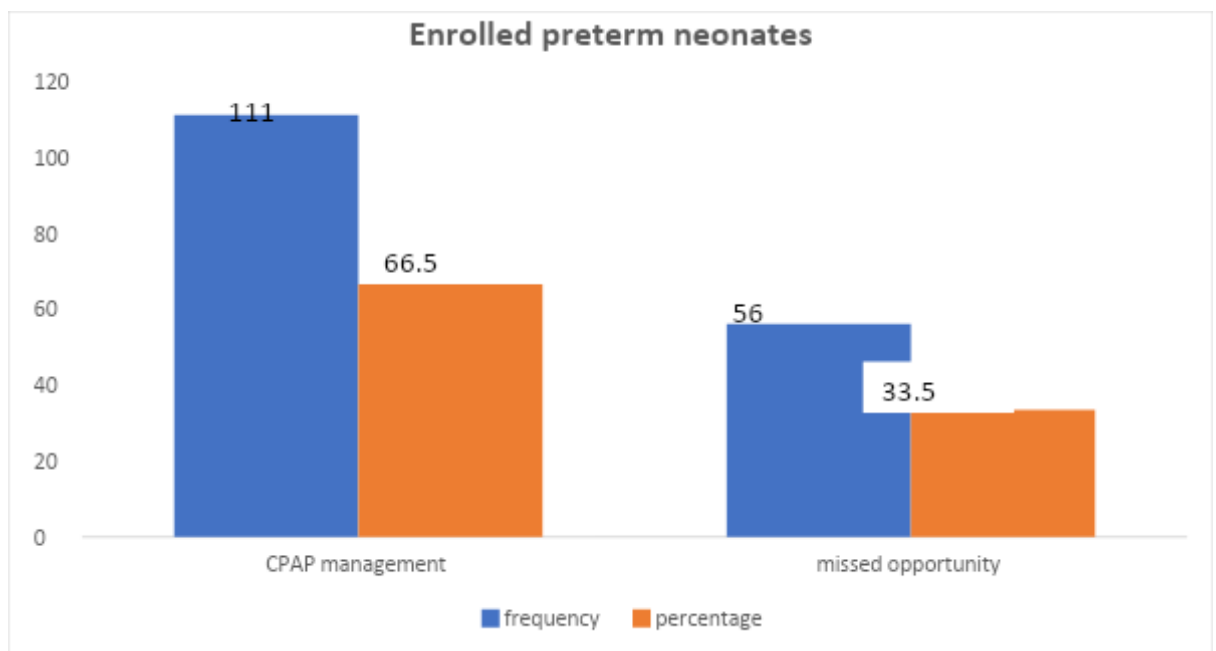


Figure 3. All enrolled preterm neonates

Table 9 and 10 shows two subpopulations, the prophylactic CPAP group and those who had Silverman Anderson Score 4-6 that we aimed to enroll using stratified sampling technique. Thirty-four (44.7%) [95% CI 34.1% - 55.9%] in the prophylactic group missed opportunity for CPAP compared to (24.2%) [95% 16.5% - 33.9%] n=22 in SAS group.

Table 9: Prophylactic CPAP group ((1000-1300g or 28-32 weeks)

		Frequency (<i>n</i> =76)	Percent	95% CI
CPAP management	Yes	42	55.3	44.1% - 65.9%
	No	34	44.7	34.1% - 55.9%
Total		76	100	

Table 10: SAS group (4-6) (exclusion of those in the prophylactic group).

		Frequency (<i>n</i> =91)	Percent	95% CI
CPAP management	Yes	69	75.8	66.1% - 83.5%
	No	22	24.2	16.5% - 33.9%
Total		91	100	

4.2 Qualitative results

We conducted 20 key informant interviews among health care workers working in NBU; mainly neonatologists, fellows in neonatology, paediatric registrars, medical officers, nurses, equipment and maintenance nursing officer, a biomedical engineer from biomedical engineering, and a procurement officer from the procurement department. The majority were females at 55% and nurses at 45% among other cadres. Average years of experience was 4 years in their respective departments and the average age was 38.9 years with the oldest being 56 years old and the youngest 27 years of age.

Table 11: Demographic characteristics of the key informant interviews.

Demographic characteristics	Number (n)	Percentage (%)
Neonatologists	2	10
Neonatology fellows	1	5
Paediatric registrars	3	15
Medical officers	2	10
Nurses	9	45
Maintenance engineers	1	5
Procurement officers	1	5
Equipment nurse	1	5
Women	11	55
	Median(IQR)	
Age in years	38.9 (29-40)	
Years of experience in the respective departments	4(3-10)	
Years of experience with CPAP usage	3(2-5)	

Benefits of CPAP

CPAP use was reported to be beneficial, reduces mortality, especially in preterm neonates, and helps to move away from invasive ventilation as a global recommendation. NCPAP doesn't have technical challenges compared to invasive mechanical ventilation and it can be initiated and monitored by any trained health care worker and informed caretaker respectively.

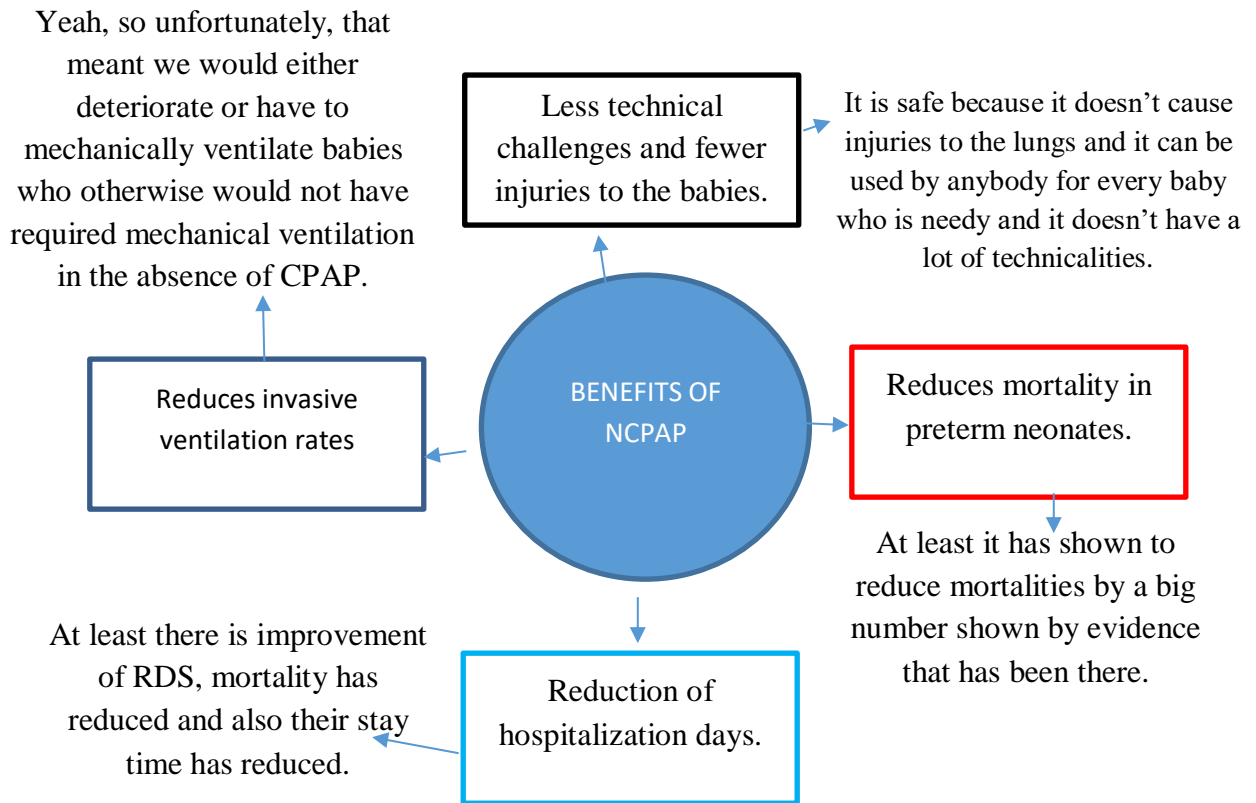


Figure 4. Major themes and direct quotations on benefits of NCPAP use.

Overall NCPAP use was reported to have good outcomes by key informants’ experience, especially in preterm neonates with RDS as long as it is started on admission compared to those who miss NCPAP use.

“You see the outcome has been good when you attend different babies with RDS. We have seen babies recover due to that and on the other side those who miss NCPAP rarely survive, so when used the outcome is good and when not used outcome is not good so I can say NCPAP is actually very necessary. ” **Nurse, NM-02**

“At least there is an improvement of RDS with NCPAP use, mortality has reduced and also their stay time has reduced. **Medical officer-DF01.**

“At least it has been shown to reduce mortalities by a big number shown by evidence that has been there especially in RDS where it allows for good standard pressures and good oxygenation and eliminates RDS mainly”. **Neonatologist-DM-03.**

“My opinion about CPAP usage especially in the preterm babies, who are born and have RDS, we start them on CPAP and usually there is good outcome and reduction of mortality when you start CPAP early or when you give them CPAP early. “**Paediatric Registrar-DF 02**

Key informants highlighted that; the importance of NCPAP use not only reduces mortality numbers but also helps in invasive mechanical ventilation reduction. This was in agreement with global evidence advocating NCPAP use since this has shown to save lives and have fewer complications.

“Since NCPAP came, we have actually seen them helping us in managing these preterm neonates. So I would say it is beneficial because we also get fewer of them needing mechanical ventilation especially when it is captured early. “**Nurse-NF 04**

“Yeah, so unfortunately, that meant we would either deteriorate or have to mechanically ventilate babies who otherwise would not have required mechanical ventilation in the absence of CPAP or two when that is not available, then we have to observe mortalities which would have been averted if CPAP was available so NCPAP is very beneficial in reduction of mechanical ventilation and mortalities. “ **Nurse, M03**

“It is beneficial because globally is the recommended treatment for RDS and the global trend is to move away from invasive mechanical ventilation. So, even western babies who have RDS are being started on CPAP first. So, it is very beneficial in the management of babies who have RDS.” **Neonatology Fellow, DF01**

NCPAP use shortens the duration of hospitalization stay and this was highlighted because RDS does improve with CPAP use since it helps lungs to have good pressures, improves oxygenation, and eliminates RDS compared to those who miss CPAP opportunity and mostly deteriorates to needing invasive respiratory support or results in mortality.

“We have noticed once NCPAP is started immediately when baby is brought , the condition improves drastically and they don’t stay for longer than 3 days even the second day so it helps those babies” **Medical officer-F01.**

“NCPAP works really well with preterm infants with severe RDS, once it is started on admission, these babies do very well. By end of second or third day, the baby is able to come out of the machine and in the next five days or so, the baby is discharged after investigations and evaluation so it saves lives especially preterm neonates”. **Nurse, NM-01**

NCPAP use was mentioned to be safe since it is a non-invasive form of respiratory support and it can be started or initiated by any trained health worker, and everyone can be able to monitor

the babies on NCPAP including caretakers as long as he/she has basic information on what to monitor.

“Okay, it has good outcomes and it is safe because it doesn’t cause injuries to the lungs and it also helps in opening of the alveolar and what can we say? If it is initiated earlier, it is where I was saying it has good outcomes. “**Nurse, F01.**

“The benefits of using CPAP is because it can be used by anybody for every baby who is needy and it doesn’t have a lot of technicalities and it can be monitored by all even the caretaker; the mother, they can understand the language that is used and the way it works.” **Nurse, F03.**

Barriers or reasons associated with missed opportunities for CPAP

Although all the participants highlighted that CPAP is beneficial as indicated in the quotes above, there were challenges associated with CPAP use.

Several barriers were mentioned to CPAP use namely; (1) the inadequate number of NCPAP machines. (2) Inadequate and inappropriate size of NCPAP accessories especially for extremely preterm neonates. (3) Inadequate training among users leads to a lack of confidence and competency to start CPAP. (4) Lack of mentorship on CPAP usage. (5) Lack of enough infrastructure to facilitate its use as well as insufficient utilities like oxygen points. (6) Staff shortage especially for monitoring and cleaning CPAP equipment after use.

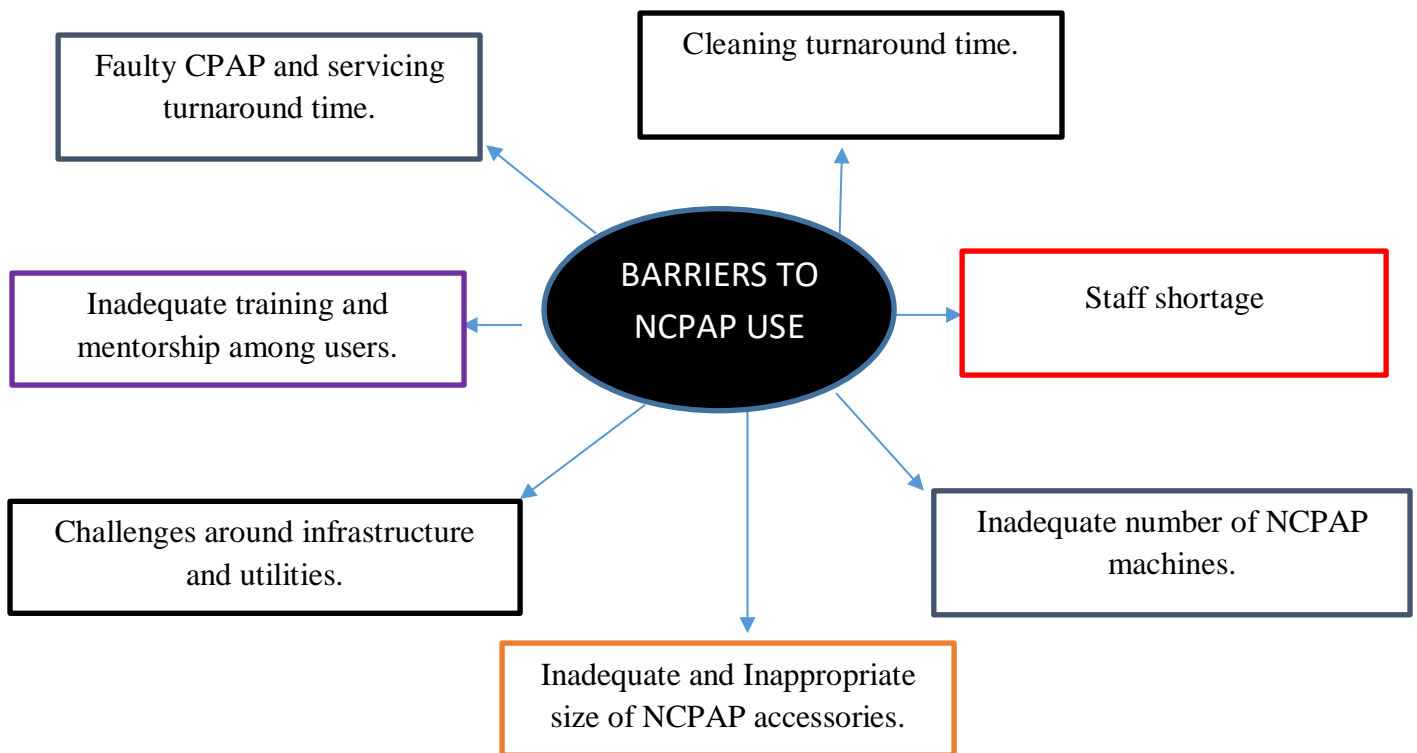


Figure 5. Major themes on barriers to NCPAP use.

Inadequate number of NCPAP machines

This was highlighted as the major barrier to CPAP use, the inadequate number of CPAP machines because the unit is a referral hospital and thus receives many preterm neonates in need of NCPAP machines and so the numbers in need might outweigh the available machines (13 fully functional NCPAP machines). When the babies are many and the CPAP machines are few, the SAS, age, and condition of the baby are used to determine which baby to start on CPAP using clinical judgment, and thus it is given to the baby who will benefit most.

“We have a very big number of premature neonates who have RDS which is most common cause of death in our unit, so premature babies who come here are more than machines that are available. Some babies do lose that opportunity but the key here is just lack of enough NCPAP machines.” **Neonatologist DM-01**

“I have encountered that experience several times, several times, it is an everyday encounter, no CPAP. Actually when you plan as a doctor for CPAP, you just write for CPAP when available because it is not available at that given time, yeah.” **Paediatric Registrar, DF01**

“Yes, a lot because we don’t have enough, they have even added but they are still less, they are not enough.” **Nurse NF01**

“I have encountered and experienced the challenge of not having enough CPAP machines, so you find I have admitted or even in the rooms the newborns am reviewing they need CPAP and you find the machines are not enough so you find the numbers are outweighing the available machines”. **Neonatologist, DM01**

“In this unit for the period I have been here, the biggest problem has been availability, the numbers outweigh the demand, so most of the time, if you look at the standard recommendations, there are babies who should have CPAP started in the delivery room, that doesn’t happen here and here most of the time, when you need CPAP, it takes a little bit of time before it is began. So, we do it but with a certain degree of delay due to availability but with the incoming of the new type of CPAP, now we are hoping that the numbers will improve and be able to start CPAP timely. “ **Neonatology fellow, DF01**

Faulty CPAP and servicing turnaround time.

It was noted throughout interviews that some NCPAP machines might be faulty and need outsourced services. Their servicing is usually prolonged or take some time to be repaired and even those that are repaired locally by KNH engineers might require external spare parts that need to be requested through procurement/supplier chain. This process takes long and some machines might not be in use for some time.

“There are machines that require outsourced services, we ask for this service and the procurement process; the servicing might take long. So, sometimes you find the down time is too long that you find a number of machines are down, yeah, so that is one. In the same breath, there are those machines that we service ourselves but we still require parts, the same thing will happen. We will request for parts but it may take longer than expected and it is not necessarily a problem with the procurement but it can also be the supplier; you tell them bring this then the supplier tells you that there is no what. So, again in KNH that is the challenge we might get. “ **Biomedical engineer, M01.**

“All the machines are on service contract that’s for sure they require a lot of money, there are so many machines in the hospital that are on servicing contract, the challenge might be follow up and probably even the supplier may take the advantage come and say am fixing this maybe there is that”. **Procurement officer, M01.**

“Yes there are no enough CPAP machines available or they are faulty or in use but nowadays at least we have Pumani CPAPs which are also helping us but still there is shortage” **Nurse F03.**

“It is because our population is very high , it is a referral facility and we get more patients than our supplies so some do miss because we don’t have enough machines or not functioning, we cannot get it repaired as fast as we need to be so I think that is a big challenge”. **Nurse-NF03**

Cleaning turnaround time.

It was noted that machines may be available but they are dirty or have been in use and need cleaning and disinfecting after use. It was noted during interviews that; there is only one nurse in charge of equipment and part of his/her responsibilities is to clean and disinfect machines after use so that they can be available for the next use. However, over the weekend days or night duties the nurse in a particular room who needs to put the baby on NCPAP machine or any other equipment, has to spare time and clean and disinfect the equipment to be able to use it. This might take some time due to a shortage of staff and this, in turn, delays the start of CPAP for babies who need it.

“There is one person who does cleanings of equipment's and it's not only CPAP only. So waiting time may be prolonged.” **Nurse, F01**

“It depends, there are days they are there and days they are not, so it depends on how many babies have been admitted with RDS, so if they have all been occupied then that becomes a problem, on the weekends, some CPAPs have not been cleaned or there is usually no one to clean them. So the nurse who is in a certain room, if you need CPAP, you need to clean CPAP, you see and it is very tedious because they are also doing other things.” **Medical officer, F01**

“You find this baby wants CPAP but you don’t get the CPAP so you decide maintaining this baby on the ventilation machine for some time, okay mostly that is what I get or sometimes on admission the baby need to be started on CPAP but it’s not available maybe the one that is available is faulty or there are no tubing’s or they are there but they are dirty, you see you cannot put dirty tubing on a baby those are some of the issue I have encountered.” **Nurse, F07**

Inappropriate size of NCPAP accessories.

It was noted during interviews that consumables, mostly nasal prongs contribute to the missed opportunity for NCPAP. This is because KNH receives extremely preterm neonates that may not be able to use the same size of nasal prongs with the late preterm or a term neonate.

“The shortage is huge, it’s huge in terms of more so like nasal prongs, and they are huge like I said if you have extreme preterm or you have the extreme low birth weight, you are likely not to get the correct nasal prongs, you will not be able to give the correct pressures. So, the machines will not be able to function appropriately, yes, and even the other consumables like CPAP tubing, some of those tubing, they become a challenge you may find some machines don’t have the tubings. ”**Paediatric Registrar, M01**

“The consumables mostly the nasal prongs for these small babies are the biggest problem especially right small nasal prong sizes for these babies who are less than a kilogram then also securing the prongs like the Pumani CPAP you need a cap even the newer vayu CPAP you need a cap, like the hats for Pumani with time they become stretched out.” **Medical officer, F01**

“Lack of the correct size of nasal prongs, so you find a very small preterm of about 800g or 1kg who is using a nasal prong of a five years old child which doesn’t fit and keeps coming out.” **Neonatologist, DM01**

“For example, Pumwani CPAP are good for bigger babies not for the preterm neonates, because of the tubing that are very heavy, we find them very heavy, it is like they pull on the baby but you see for the other CPAPs, the taller ones, those ones are good because you find you can use even for the very tiny ones and then I know we were told that the small prongs were brought but the tubing are too heavy, we actually use them because they are the ones available.” **Nurse, F04**

“Another thing they might be there but sometimes we get extreme preterm neonates; they are the ones with very low birth weight, so you find that even the smallest size of prongs doesn’t fit the nostrils so you find that it is difficult delivering the pressure and oxygen, due to the fact that prongs keeps moving out. Such babies tend to miss out the benefits of that CPAP. ”**Nurse, F05**

“We use the head gears that are worn out so you end up using the strap heads, you stretch so much. The preterm babies will require very small head gears, big babies or term babies will require big head gears but you find you have a head gear which is not fitting to the patient. ”**Nurse, M01**

“So, those are the challenges we are getting so sometimes we get very small babies who cannot fit with the smallest size of the nasal prongs for example Pumani CPAP so it gives us more difficulties. “**Nurse, M03**

Inadequate NCPAP accessories

Despite the size of consumables that might be a challenge for initiation and monitoring of NCPAP use, consumables were also highlighted as not adequate. Moreover, some may get lost or punctured and no longer be able to deliver the pressure or oxygen needed. Therefore, consumables supply was said to be inconsistent since this is based on the general paediatric department budget.

“For ICU or intensive care unit set up, it should be independent to be able to have its own budget, its own procurement and all that. So, we don’t have all that. So, all these are based on the general pediatrics department what they require so the consumables are limited on what we need and we may get them on and off, we have always run out of supplies.” **Neonatologist, DM03**

“There is shortage of CPAP machines, people even lose the bonnets, people don’t even know what a machine is, how to maintain it, because even on the floor you get some of the parts of the machines have been removed and left on the floor. “**Nurse, F01**

“The most concerning is the CPAP accessories, like now you can be the one setting CPAP but there are some things missing like the head gears or maybe we have even used them for so many times until now it can’t hold well so you need to get strappings and put which sometimes the baby sweats and it comes off or other accessories are not available as well.” **Nurse, F07**

“CPAP consumables are available but sometimes we have a problem of getting correct size nasal prongs or some are thrown accidentally, other tubing’s get punctured and then they no longer deliver the oxygen so it takes times for us to get the supplies from the stores or the supply chain because they have to make the orders which may take time. “**Nurse, M03**

“Lack of proper sizes for nasal prongs and head gears especially for preterm babies, the only thing is that they don’t really correspond with the size because sometimes we really have the extreme preterm infants so getting those prongs is a problem. “ **Medical Officer, F01**

Inadequate training and mentorship among users.

Lack of training and mentorship among the users' leads to a lack of confidence and competency to start CPAP among the HCWs. It was noted that knowing how the machine works is very crucial in starting CPAP timely and monitoring a patient on NCPAP, especially with new machines. However, it was highlighted that the majority of staff were trained on how to use NCPAP which made a difference with regards to competency and confidence in using and starting NCPAP compared to previous years where some of the health care workers had to learn from their co-workers. Despite the training that helped in this regard, not all staff got that chance to be trained due to duty responsibilities or off duty rota challenges during the time of the study.

“Well, if you ask me the old CPAPs when I came here, we had to learn the hard way such that I would personally copy from another person, I was not given that training and I think it is required especially if you have new machines.” **Nurse, F06**

“Another challenge currently is the new bubble CPAP, everyone is not conversant on how to use it so people become reluctant on using it, if you have one two or three people they will tell you they don't know how to connect this CPAP and it's there then baby misses CPAP and you just leave. “**Nurse, F07**

“The other one is competency, if someone is not competent and confident about using it, they pass it over to the next shift person. So, you will write in the file, start CPAP but they will keep moving around hoping their shift can end and someone else can come and put it. “ **Neonatology fellow, DF01**

“We don't have people who are role models or people who lead other people or do mentorship, we don't have adequate mentorship for the nurses. So because of lack of mentorship some tend to think that these machines don't work and they tend to put them aside so they will not use them, so mentorship is very important. “ **Neonatologist, DM01**

“The second problem is familiarity of the system, I know you might ask them and they have protocols on how to use it but you find that, from our point of view; from the engineering point of view, you find that the competency is not that good. The user is sometimes not understanding the system or not adhering to strict things that you need to do like leakages and such. “**Biomed, M01.** “The challenge of using CPAP is just the technical or the knowledge of using this CPAP.” **Medical officer, F01**

“The new challenge is getting the patients early, the second challenge is monitoring more so among health workers. Most of them don’t know how to monitor, even the aspect of how to increase or even how to wean off is a challenge.” **Neonatologist, DM01**

Challenges around infrastructure and utilities

Lack of appropriate infrastructure to facilitate CPAP usage was highlighted by key informants, due to limited space where to put CPAP machines, some NCPAP machines specifically Vayu bubble CPAP need resuscitaires to be put on which might not be available or not enough. Sometimes babies might need CPAP and they are sharing one incubator which becomes tricky due to insufficient incubators. For Pumani CPAP machines, it was noted that these types of NCPAP need space which might be tricky in a room that has many admissions or patients.

“The challenges around the infrastructure, I will be specific. For Pumani, you need space because the machine is big and sometimes with the crowding we have in this unit, it becomes a challenge, with Vayu CPAP you need a resuscitaires to hook up that machine, so, you cannot use in a regular cot, it needs to be put somewhere. It is all about the space, you must have something to hook it in and hold it in place. So that means if you need to put that baby on CPAP, you must have a warmer where you can put it. So the challenge is sometimes not all babies on CPAP have warmers and sometimes babies share one warmer and you can hook up one machine per warmer.”

Neonatology fellow, DF01

“So, there are times that we have to use the same source for two babies. We also have a challenge with the resuscitaires, if we are to give CPAP to babies who are less than 1kg maybe and this is a baby who should be in an incubator but it is not easy to give the baby most times because again we don’t have enough of those incubators mostly they share. So, we end up putting a baby on a resuscitaire where most times they may not get the heat, the warmth that they need, like you cannot control it when they are not in an incubator. So, there is a challenge with those small ones, who are the most to be considered.” **Nurse, F03.**

“The other thing is even a bed, you may be told the baby is in incubator and putting CPAP in an incubator where babies are sharing an incubator is a challenge.” **Nurse, M03**

“Again, the space we need for the CPAPs, actually space in terms of beds where we need to put the babies on CPAP. When the baby is on the cot, the use is not very good, we need the resuscitaires to put the baby and you find the resuscitaires are also not enough. Because our babies

are also very many, you find the babies are sharing which is a challenge to start CPAP.” **Nurse, F04**

Staff mentioned inadequate oxygen outlet points to connect to CPAP machine or a socket, hence unable to initiate NCPAP machine. Oxygen was also mentioned to be low, sometimes especially during Covid-19 pandemic and lack of generator in the unit to back up in case of power challenges.

“We have a challenge with the supply of oxygen point because mostly you find that they are limited in a room, where you are supposed to plug the CPAP.” **Nurse, F03.**

“Lack of enough utilities for example oxygen points and the space, yeah this is a very big problem, normally you will find our oxygen points, they are few oxygen points so if a baby comes in and they are from another facility then they are supposed to go to the isolation and the isolation has very few oxygen points. So, you find there are already babies there on mechanical ventilator or NCPAP machine. Yeah, so getting oxygen point is also an issue especially for babies who come from outside and we don’t want to mix them with our babies.” **Medical officer, F01**

“Another challenge on CPAP usage is number of oxygen ports; the oxygen ports that we have, they are not many, they are limited in number so if we have more ports it means we will have more babies who will be put on CPAP machines. “ **Neonatologist, DM03**

“Sometimes even lack of sockets because these machines require power so you find you may be in a room where there is no or few sockets and so the nurse will tell you that we are not able to connect in this room because we don’t have more or extra socket in this room so that we can be able to start CPAP. “ **Neonatologist, DM01**

“When power goes off in NBU there is no backup generator, the medical team start bagging and so yes the next thing is mortality.” **Neonatologist, DM01** “You find the other challenge with the consumables and oxygen, I mean honestly you find you are at work, you are told oxygen is low excuse Covid-19, so oxygen remains low, the machines cannot deliver remember these machines they need to have all these. So, when there is no oxygen as I have said before becomes a challenge.” **Medical officer, DF01**

“The most concerning challenge actually is the ports; the oxygen outlet ports because they are not enough.” **Nurse, F04**

“So, you see there are other babies who are on oxygen and if we don’t have those many ports for the oxygen, so you get a challenge you want to put this baby on CPAP but you can’t because you don’t have a port hole where to put this thing, so you end up not just using bubble CPAP because it needs an oxygen point, still it’s a challenge because if the other babies are maybe on nasal prongs and they are using those oxygen ports, you can’t remove them.” **Nurse, F07.**

Staff shortage

Challenges around human resources were highlighted especially for monitoring the neonates and cleaning the CPAP machines after use. It was mentioned that the unit has one equipment nurse and so when he is not on duty like on weekends or at night, in case of CPAP machine need, the nurse has to clean it herself/himself in addition to other duty responsibilities. There may be resuscitation that is ongoing and this might lead to delay of CPAP initiation or missed opportunity for it. It was highlighted that the new bubble NCPAP machines that were brought into the units (Vayu and Pumani), do require extra nursing care by frequent checking if nasal prongs are in/out or checking the water levels to mention a few. Doing that with staff shortage becomes a challenge hence some patients may not be getting the right pressure and the oxygen required.

“In this unit we have staff shortage, so most of the time it is one or two people in the room and as we said CPAP is a form of respiratory support and respiratory support requires monitoring vital signs and functionalities especially for bubble CPAP, you want to make sure your prongs are in, checking water levels are okay. So, we have instances where, you actually walk in the room and the nasal prongs are in the air. So, we have those instances where the baby is on CPAP but actually the interface is not in place and that is mainly contributed by the patient nurse ratio. You can find one nurse nursing fifteen babies; will they have enough time to check out on everybody very often as required?” **Neonatology fellow, DF01**

“These machines in between use they have to be cleaned and we only have one equipment nurse, at most with a student who work Monday to Friday, weekend and night there is no equipment nurse. So we may have shortage of staff to do equipment cleaning and this delays CPAP initiation or a baby misses the opportunity to be put on CPAP.” **Neonatology fellow, DF01**

“And also, you find even the nurses are not really adequate to monitor these children when they are on CPAP, in terms of decreasing the FIO2 even when you want to wean off the machine it becomes a challenge.” **Neonatologist, DM01**

“So the required skills is lacking because am only one person who handles the machine day in and out and when am away there may be requirement of those who have the clear understanding of how the machine operate and how to prepare them so that’s is another big challenge so we don’t have adequate staffing to take care of the preparation and maintenance of CPAP machines.”

Nurse, M03

“Yes another thing is others miss because of the work load, I am alone, I cannot move back, front, south, east west. Lack of human resource and machines, we need more resources and human resource.”

Nurse, NFO1

The partnership between health care workers and caregivers on CPAP usage.

There were mixed feelings regarding the partnership between health workers and caregivers. The majority of the participants cited that there was a need to improve the partnership between health care workers and caregivers. The reason is that mothers/caregivers are not part of this process of initiating CPAP. Some would be shocked to find their babies on CPAP and when the nasal prongs were off, they didn't know how to put them back or inform nurses. The most important reason highlighted for the poor partnership was staff shortage hence lack of time to explain to the caregivers about CPAP initiation and monitoring.

“I would say here it is not as good as expected, there is no much of partnership because most of the times you find the baby is on CPAP but the mother is not even aware and they will come asking that they never get any person to explain to them why the baby is on CPAP, yes and when he is being weaned off, they may still not be informed of the same. So, the partnership is poor. Yes the reason is because of staff shortage hence lack of time to explain to caregivers why the baby is started on CPAP.”

Neonatologist, DM03

“It doesn’t exist, the caregivers don’t really know what CPAP is all about. Communication is very key but I don’t think we have that kind of family centered care at the unit for the mothers or caregivers to be able to know these machines like CPAP and all that. It still lacks and I think it is something we should think about.”

Neonatologist, DM01

“So the partnership with caregivers in New Born Unit, Kenyatta National Hospital, the numbers there, the partnership I would still say is below 50% because out of ten mothers, how many mothers know their babies are on CPAP, how many mothers understand what their babies are suffering from and why they are on CPAP I bet you can find almost 80% don’t know, they can’t really explain to you what the baby is on that and even the condition their baby is suffering from

and I would not even blame the health care workers due to staff shortage we have currently.’’

Paediatric Registrar, DF02

‘‘There is a discrepancy because we tend to be overwhelmed with the number of patients we have to take care of and the caretakers who are also supposed to be trained on how to use or to understand how a CPAP works because for example, if in a room you have for example, seven babies on CPAP but there are also other babies who are not on CPAP, they may be even more critical than those ones and the others may even be having a resuscitation, so you have to work between informing the mothers about the CPAP and resuscitation. So, you find the caregivers are not so much involved because of lack of time to reaching them.’’ **Nurse, F03**

However, some participants disagreed with poor partnership and mentioned that they involved the mothers/caregivers by talking to them about CPAP initiation and they would later assist in the care of the babies and CPAP monitoring especially when nasal prongs are out.

‘‘So, in this unit, what I have seen most of the time is when a baby requires CPAP we start. We don’t most of the time wait for the mother to consent but later on we will explain to them that your baby had respiratory distress and therefore we started. If they are there, we seek verbally consent. If they are not there, most of the time we start and then just inform them that their baby had respiratory distress and therefore the baby was started on CPAP. So, far I haven’t seen instances where a mother clashes on with the health care providers because the baby is on CPAP and generally giving them instructions. So, there is that communication in terms of how to feed the baby on CPAP and sometimes it will be them reporting a complication like having pressure on the nostrils. Mostly we tell them if you notice any problem, report back.’’ **Neonatology Fellow, DF01**

‘‘Okay, the partnership is important because I have to explain to the mother about the CPAP and what it does and I find it good because when you explain to the mother or caregiver what you are doing, they are usually supportive so that even when the baby takes the nasal prongs out, the mother will return them because she knows why they have been put. So, that partnership is important.’’ **Nurse, F04**

‘‘Well when it comes to CPAP use, well these mothers, the health worker normally explains to them that your baby has been put on CPAP because of this and this, they are given the reasons and maybe you tell them if you see this the prongs maybe they have come out, you report so that

we put them back because of the challenge I told you that we don't have the correct head gears and nasal prongs so we work together as a team to monitor babies on CPAP.” **Nurse, F07**

“I have never encountered that because before I start using the CPAP, I usually explain to the mother the benefits of it, why CPAP and how the child will benefit. I have not encountered any difficulty with any parent.” **Paediatric Registrar, M01**. “I think there is good partnership, they help each other out, when you need help, they are ready to assist, like we assist each other, yeah.” **Medical Officer, F01**

Facilitators of NCPAP use

Since Kenyatta national hospital is a referral facility that receives babies from different peripheral facilities and varied conditions of babies, this has led to CPAP availability and provision in addition to global evidence of CPAP efficacy. CPAP training mostly by NEST also was highlighted as a factor that facilitated NCPAP use and competency among the users.

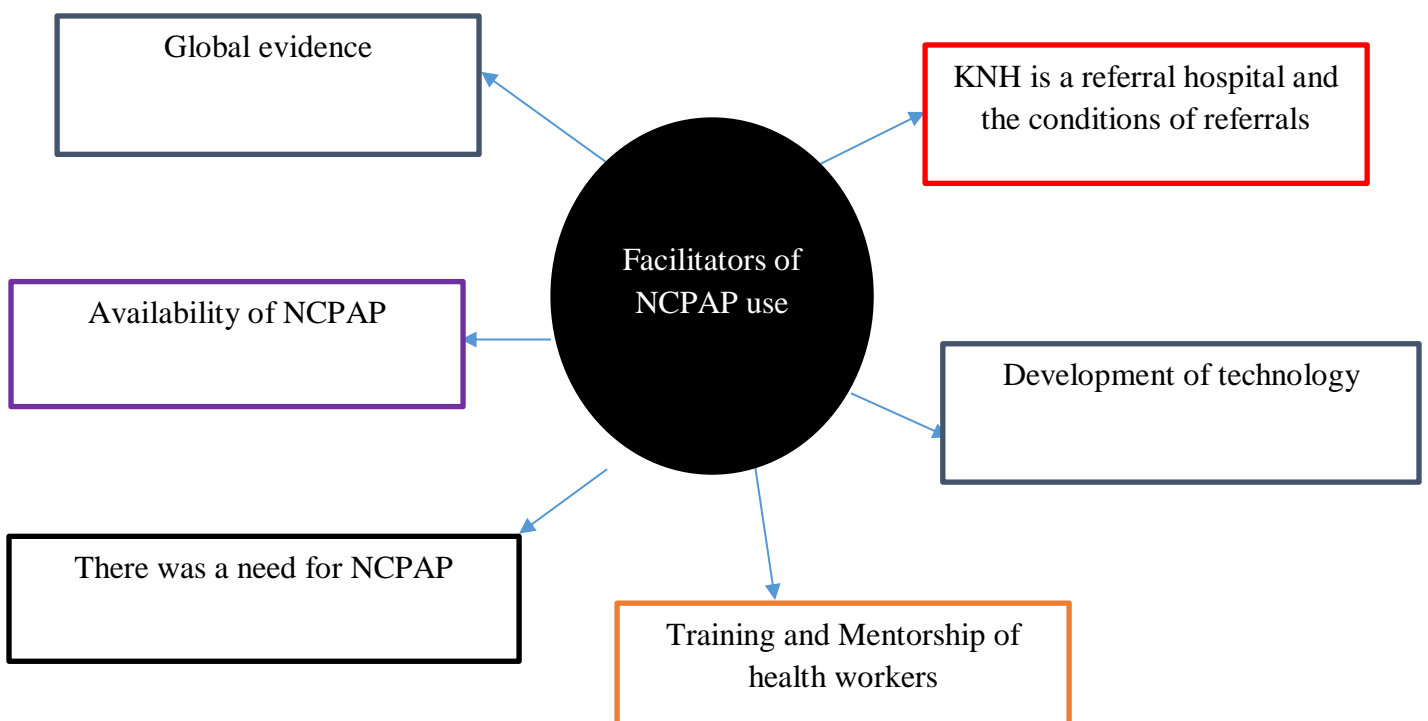


Figure 6. Major themes on facilitators of NCPAP use.

Availability of CPAP

KNH was mentioned as one of the facilities in Kenya that do have NCPAP machines in place and so this has facilitated NCPAP training and its use.

“So, you find we are the one of the hospitals that have CPAP.” Nurse, F01, “I think continuous medical education mostly and some donors I hear some donors has donated the CPAP machines, although I haven’t seen them yet.” **Nurse, F06**

Training of health workers

Training which equips health workers with the knowledge of the importance of CPAP and skills to use it was highlighted as an important factor that facilitated NCPAP use by increasing competency and confidence hence successful initiation, monitoring, and weaning off NCPAP machines. It was also noted that especially paediatric registrars that do rotate in the unit have orientation packages including NCPAP training in their first weeks of reporting to the unit.

“So, what has facilitated mainly is after the NEST training because you realize that previously, competency was a problem, having the necessary knowledge and skills. So, after the NEST training; the uptake has improved.” **Medical officer, DF01**

“I think the biggest challenge is people are familiarizing themselves because their mode of operation is different from the previous types of machines we have had. So, the principle is the same but the application of the machine is different. So, there has been a learning curve which is ongoing on CPAP training.” **Nurse, M03**

“And also, the expansion in terms of people undergoing a lot of CPAP use trainings, the skill also has been spread. So, people being trained and skilled and then availability of the CPAP but definitely the demand was high because the mortality was high.” **Neonatologist, DM01**

“And for the doctors’ side, we now have an induction program which now includes respiratory support that includes the CPAP, mechanical ventilation a factor to use as new doctors rotating in the unit have to undertake within the first two to three weeks of coming to the unit (this is ongoing).” **Nurse, M03**

Mentorship among the health care providers.

Mentorship which promotes CPAP use especially when new machines are being introduced in the unit was highlighted to prevent delay in CPAP initiation and prevent a negative approach toward new NCPAP machines in the unit.

“The other thing is establishing a mentorship program within the unit. So, two nurses have been selected to spearhead CPAP roll out so that those who are struggling can be mentored even with the new CPAP machines that were just brought, there is continuous training because we realized the lack of confidence and issues about operating the machine, was contributing to the delay of NCPAP initiation so training people and having a mentorship in the unit so that there is continuous helping out those who have issues.” **Neonatology fellow, DF01**

“So, that acceptance of change is also an issue, so that is why we put the mentorship program so that people don’t have negative attitude towards a certain machine before they even try it, because for a long time there were using the old machines and they were used to them and especially because that older machines, the nasal interface is very nice, once you put it and it is clipped. These new ones they keep slipping off more frequently especially the Pumani, securing the nasal prongs is still a problem. The bubble CPAP you have to keep checking water and adding which the other CPAP machine doesn’t have. These addition roles of these machines make some people shy away from them.” **Neonatology fellow, DF01**

Global evidence

The Staff thought that global evidence in terms of NCPAP efficacy and reduction in mortalities associated with missed opportunities for NCPAP did facilitate its use in KNH newborn unit.

“Okay, there is global evidence to less push for ventilating babies, CPAP has been shown to be beneficial and with that kind of information, with that kind of data worldwide and also within Africa, the move is now towards CPAP and advocate for that. So basically education around it.”

Neonatologist, DM01

“I think that some of the factors that facilitated NCPAP availability are the high mortality that are associated with the missed opportunities for NCPAP in our preterm neonates.”

Neonatologist, DM03

There was a need for CPAP machines

A need for NCPAP was there because the unit receives mostly preterm babies, it was noted that before NCPAP implementation, RDS was mainly being managed by giving oxygen therapy and that could lead to mortalities, hence NCPAP implementation and scale-up.

“There was need for it because we get many especially premature babies, who are the most beneficiaries of CPAP and this facilitated the hospital to see the need because we were losing many babies and we don’t have enough mechanical ventilation for all our babies. So, the CPAP has helped a lot.” **Nurse, F03**

“The factors that facilitated I would say was the need for them and also the hospital saw the need to bring them for us to use after seeing many of the preterm neonates at times we would lose them because we didn’t have an option because we were just using the oxygen with the non-rebreathe masks, the nasal prongs but we would find that they were not very good with those babies who had a lot of work of breathing and then the ventilators were also very few. So, that was actually what made it necessary for us to have the CPAPs.” **Nurse, F04**

KNH is a referral hospital and the conditions of referrals

Kenyatta national hospital is a national referral hospital that does receive babies from peripheral facilities, either public or private hospitals as well as KNH labor ward and theater. This labor ward receives high-risk deliveries including premature deliveries among other obstetric emergencies. The majority of admissions do need advanced care or respiratory support, and this has facilitated NCPAP use in the unit due to the condition of admissions on daily basis.

“The factors I would say, first of all the condition of the babies that we receive every day and based on the diagnosis and the severity of the respiratory distress, I will put in both respiratory distress for the term babies and respiratory distress syndrome for the preterm neonates that will be one key factor.” **Nurse, F05**

“We admit babies from all over the country; may be from private clinics, public hospitals, they may be from our KNH labor and theater as well, so they all refer all babies here and that is what led to us having the CPAP machines here because it is now basically the population of babies born in the whole country.” **Nurse, M01**

“One of the things you get those babies who sometimes need ventilation machine and we don’t have a ventilation machine so we end up using CPAP at least to deliver some pressures so that

was one of the factors since the CPAP is just like a vent, the picture I see is noninvasive. Another factor is less invasive ventilation, once you have a CPAP and also give surfactant, you can start the acute babies on CPAP for like a day; twenty four hours they usually get better and if they don't get well is when you go for a ventilation so those are some of the factors.” **Nurse, F07**

Development of technology

Technology has facilitated NCPAP use, for example, oxygen delivery and electricity that do support successful NCPAP initiation.

“Development of technology and availability of utilities such as electricity has also played an important role in scaling up of CPAP use.” **Nurse F04**

When asked if the MOH or a sponsor wants to offer this unit CPAP support, what type of support would you ask for? This was asked to try and understand the solutions to the mentioned challenges on NCPAP use and below are themes that arose on solutions to barriers on NCPAP use.

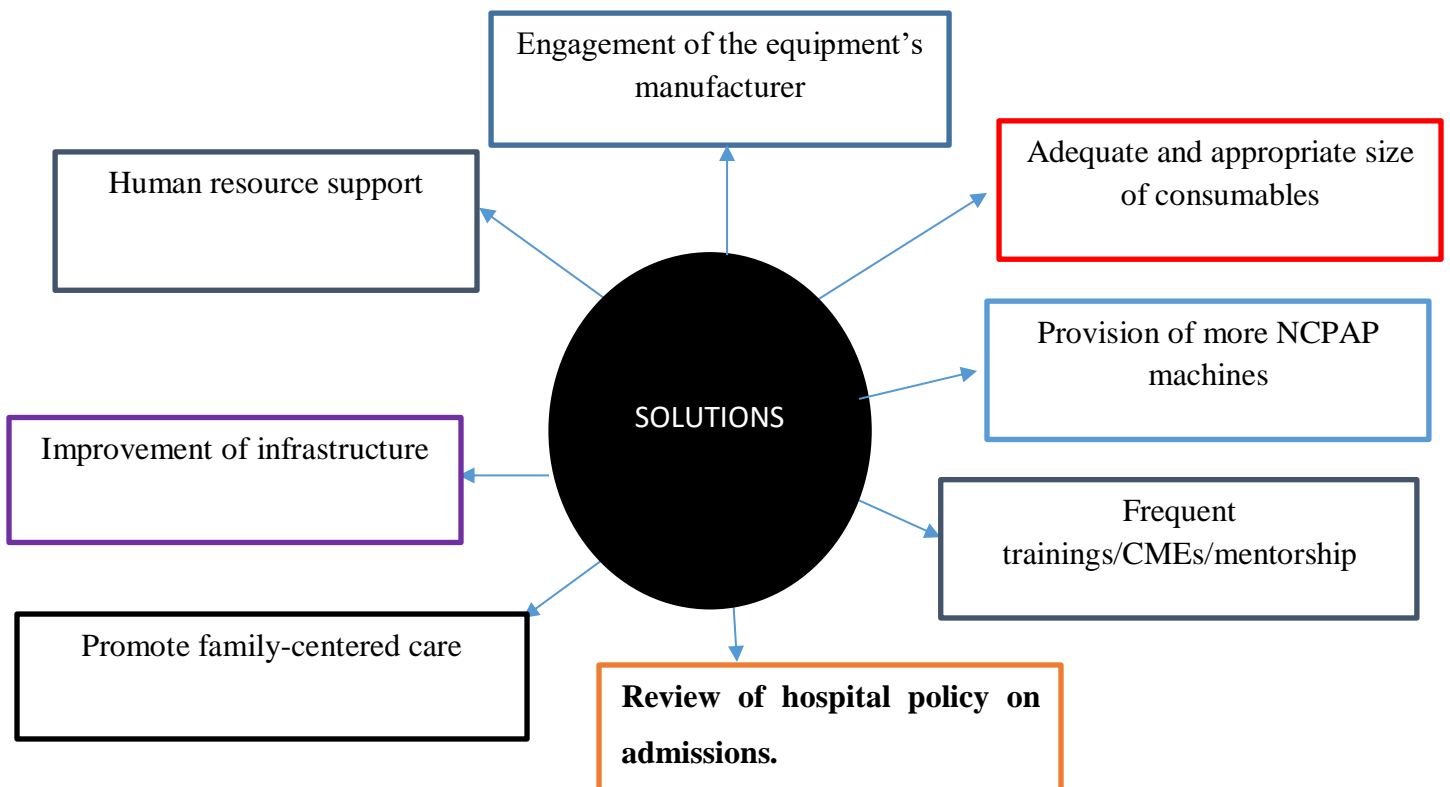


Figure 7. Major themes on solutions to barriers of NCPAP use.

Provision of More NCPAP machines.

Although Pumani and Vayu NCPAP machines were brought and were new at the time of this study, it was highlighted that getting more CPAP machines would help to treat more preterm neonates in need and to help in case other machines are down or faulty or others are waiting to be cleaned and disinfected. Participants also highlighted the importance of maintenance of already available machines to prevent prolonged downtime of machines.

“For now, looking at the numbers of children dying from RDS, the support for us would be to get more CPAP machines, CPAP machines that probably will not use piped oxygen but the key is just getting key functional CPAP machines, if we could get that number up probably we would get to save more babies.” **Neonatologist, DM01**

“First and foremost, is the number of equipment we would like to get more, the reason is that the space will be good because we believe we can serve more babies but I am most interested in having bigger number of equipments so that even when there is down time of an equipment, I have backup.” **Biomed, M01**

“There is a lot, number one is to increase the space because we have so many babies who need CPAP which is unavailable most of the time. We increase the space and also increase the number of oxygen ports, you increase the number of CPAP machines and the maintenance of those CPAP machines because now we have so many CPAPs which are broken down. So, maintenance of them is also important. Yeah.” **Medical officer, DF01**

“Probably we should have one particular room with CPAP machines and with that they will need to add more resuscitairs where you know, they don’t have to be moved every other time.” **Nurse, F05**

“To get more old CPAP machines because I find it more efficient because it alarms when there is an error so it alerts in advance so it alerts you and the numbers we have with nurses ratio, I think we need the alerts, this makes monitoring easy.” **Nurse, F06**

Human resource support

Key informants highlighted that getting more NCPAP machines goes hand in hand with human resource support to address staff shortage in the unit and thus optimize the use of CPAP and monitoring since this is a mode of respiratory support that needs monitoring like other respiratory support. This was noted that; these machines need frequent nursing care such as checking

whether nasal prongs are in or adequate water levels to make sure that satisfactory pressure and oxygenation are being delivered. Staff shortage concerning cleaning and disinfection of these machines for the next use was also highlighted.

“The biggest support I would ask for is to have sufficient staff members because the use of CPAP is very laboring and intensive on the monitoring side so every time a child is on CPAP then it does take up a lot of nursing care, if it is to be done properly. If we are to give proper CPAP that is the biggest thing I would ask for. I would ask of sufficient number of skilled staffs to provide the care as per the guidelines.” **Nurse, M03**

“So, the thing is even if you bring in more CPAP machines, there has to be an increase in number of staffs who will be able to monitor the CPAPs because it is dangerous to leave a baby on CPAP and walk away without proper monitoring that can lead to medical complications or CPAP failure.” **Neonatologist, DM03**

“So, if we can get more people to be able to decontaminate and even clean those machines, then there would be a good turnaround time for these machines and more babies would be able to access these machines.” **Neonatologist, DM01**

“So that if we don’t have adequate nurses, if we don’t have adequate personnel, we will put these children on oxygen and we will be having oxygen toxicity because there are no adequate people to monitor so the machines may be going the other way round and causing complications. So we need numbers, yeah.” **Neonatologist, DM03**

Frequent training/CMEs and mentorship

Training of staff including biomedical engineering staff was mentioned to increase staff confidence and competency in CPAP use hence successful initiation of CPAP monitoring and knowing what to do when machines are down. So frequent NCPAP training and mentorship were mentioned to be important especially when new machines are introduced in the unit.

“the skills they have is through experience but if we can get a formal training, that can help, you know now the skills the biomedical engineers have is due to where they work but if we can get training that is training all the biomedical engineers in the hospital then that can be good because especially for hospital coverage, when we are not there and our colleagues are covering the NBU, so that is normally a challenge.” **Biomedical engineer, M01**

“Yeah, definitely continuing with capacity building, capacity building is very key, we keep giving feedback so you find after the training we monitor and evaluate, then we give feedback on the use of CPAP and people once they get the feedback will improve on that and we have the continued monitoring I think that is what will help us.” **Neonatologist, DM03**

“Our support is continuous CMEs and even teachings about the use of CPAP so that everybody should be equipped with knowledge on how to nurse such a patient or start CPAP.” **Nurse, F02**

“Sometimes us staff, you may find that one may have knowledge on one type of NCPAP and then when the other CPAP is introduced, for example there is one that was introduced last week, not many knew how to go about it. It may seem simple but you know sometimes we can’t just assume on such parameters so you find that there needs to be frequent updating of the facility staff on how to use the equipment.” **Nurse, F05**

“So, I think it will be more of addition of more equipments and also having someone on the ground who will always be updating or training the staff on the use and the benefits of NCPAP. Since we keep rotating in the rooms, at least no one misses out on the CPAP use or on how to use and care.” **Nurse, F05**

“Mostly I would say communication is the first thing, and very important at least to have people who are informed about every kind of machine that is being brought and especially since at the end of the day we are all aiming at helping a patient that has come. “**Nurse, F05**

“ Support in the sense that at least they have someone who will always be briefing us on the different types because you will find that for calibrations, there are different types or ways of doing it, depending on the machine and also always having audits on CPAP usage and the outcomes of the patient, are they benefitting or are there those that have better performance than others because you will find like for example, the Pumani where we get the preterm neonates who don’t really like benefit so much because of the size of the nasal prongs. So the audits are so important to know the challenges, maintenance of the machines and their performance as well as trainings for those who may have missed out on updates of new machines that have just arrived.” **Nurse, F05**

“Specialization such that a room with CPAP and have skilled HCW allocated in that room, I am thinking, now even if we have these machines, they would have made the unit in such a way that we only have a room with a machine with people familiar with the machine. I think it can make the people work better because sometimes even when you put a CPAP in B1, it is just left there

as I told you because of the number of patients I am supposed to be instilling saline in the CPAP or in the nostrils because the dry air sometimes we are giving it affects the nerves so it even worsens the condition of the baby. So, they should consider such things, if we have a CPAP, let it be a CPAP with people who understand what a CPAP is and how to manage it and who were trained. **‘Nurse, F01**

‘‘Have champions to promote CPAP use, the support of mentorship we have, I would ask the sponsor to provide a CPAP champion in the unit, someone who will spearhead and guide practically and on the ground on the use of CPAP machines and the challenges people are facing providing solutions, empowering people on the ground that is what I would suggest a champion on the ground, a CPAP champion in NBU.’’ **Neonatologist, DM01**

Provision of adequate and appropriate size of consumables

Throughout the interviews, it was noted that not only providing adequate NCPAP accessories but also considering the appropriate size of consumables to help all preterm infants including extremely low birth weight preterm neonates of which nasal prongs among other accessories don't fit in most of the cases.

‘‘And then another thing would be for the manufacturers, okay we appreciate that they are targeting most preterm neonates but as I said the nasal prongs, some may be big and you see that is the smallest size that is available but you see for the smallest prongs, they are not fitting. So mostly we do force them fit those preterm neonates. **Nurse, F05.** The correct gears maybe the head gears, we need the provision of the right tubing.’’ **Nurse, M01**

‘‘So I believe the prongs may be made a bit soft, so that they can actually be comfortable to the nasal space because the current ones when deep in the nose can actually easily injure the membrane so actually I have noticed that. So probably we can look for soft nasal prongs and that can make things better and also interface if we can improve on interface as well.’’ **Nurse, M02**

Promotion of Family-centered care.

Family-centered care was mentioned to be emphasized so that caregivers are on board when NCPAP is being initiated and the monitoring process. It was also noted that informed caregivers do help in monitoring these babies in case they know what to monitor and what to expect.

“Okay, the partnership is important because I have to explain to the mother about the CPAP and what it does and I find it good because when you explain to the mother or caregiver what you are doing, they are usually supportive so that even when the baby takes the nasal prongs out, the mother will return them because she knows why they have been put. So, that partnership is important.” **Nurse, F04**

“The optimal use of what we have, we make sure that there is good family centered care so that we can have the parents on board on how we are managing the babies and then we need people to spearhead or we need mentorship on health care workers and people who will be role models to spearhead the use of CPAP in the unit.” **Neonatologist, DM01**

“I think my comment on that is engaging with the caregivers for them to understand because the appearance of a child being on a CPAP machine can be a bit scary. So, you need to explain to them benefit of the machine and what the set up means and they don’t panic on seeing the child on the CPAP machine and also engaging the caregivers to continue with other supportive care especially nutrition now that our mothers are big partners in that sense that they would provide and feed the babies every three hourly. So, maintaining that supportive care is important even as the CPAP is going on.” **Nurse, M03**

Review of hospital policy on admissions

The staff highlighted the importance of hospital policy on admissions to reduce crowding in the unit, crowding may increase NCPAP missed opportunities due to hospital-acquired infections leading to needing NCPAP machines later on and staff shortage to closely monitor those already admitted.

“one is with regards to the admission policy which we have reviewed and enforcing the admission policy to try and reduce overcrowding in the unit and then internally within the unit, we are also taking care of other issues which contribute to infants falling sick and requiring CPAP internally, so a key on those hospital acquired infections. So, we have introduced new IPC; quality improvement procedures which are ongoing and being monitored and key in engaging with partners; program partners to have new machines for instance with the NEST program and also with the Vayu CPAP team (this is ongoing).” **Nurse, M03**

Improvement of infrastructure

The participants underlined the importance of having adequate space since these machines need space and additional resuscitaires, incubators, and oxygen ports. All these need infrastructure to support them.

“Adequate space- so when I say space I mean you need space because like in Pumani you need some centimeters from the wall it has to have a space so that it can pull air so if you are just in a small room and you are having many machines and you will not be able to pull adequate air from these machine to concentrate oxygen well so we need space so that we can be able to work well in the NBU that for me is a challenge.” **Medical officer, DF01**

“So, if we can get more infrastructure in terms of availability of resuscitaires, incubators and more oxygen ports and space.” **Nurse, M07**

Engagement of the equipment’s manufacturer

Engaging manufacturers of this equipment was mentioned by the key informants to ensure continuous and timely maintenance as well as discussion around affordable consumables.

“First of all, we engage the user in fact any donation we have to engage the user on the cost of maintaining them all those things have to be taken into consideration, there are some machines that you may be given here probably the consumables that we can’t be able to afford so they have to be cost effective.” **Procurement officer, M01**

Discussion

Our study points out the proportion of the missed opportunity for NCPAP of preterm neonates admitted to NBU, Kenyatta National Hospital, and describes barriers and facilitators of NCPAP use from the key informants that deal with NCPAP use. The facilitators of NCPAP use reported were: i) the training and mentorship of health workers, ii) availability of NCPAP machines, iii) KNH being a referral hospital and conditions of referrals, iv) global evidence that NCPAP use is beneficial, v) development of technology, and vi) there was a need for NCPAP use. Barriers to NCPAP use were mainly: i) the inadequate number of NCPAP machines, ii) inadequate training and mentorship, iii) inadequate and inappropriate size of NCPAP consumables, iii) staff shortage, iv) faulty CPAP and v) long servicing turnaround time, vi) long cleaning turnaround time, vi) infrastructure challenges e.g. limited space in the unit, and vii) insufficient utilities like oxygen outlet points.

The proportion of missed opportunities for NCPAP was 33.5% and the majority of those with missed opportunities for NCPAP were in the prophylactic group at thirty-four (44.7%). In 2008, 39 (66%) of patients who did not get a chance for the NPPV trial were intubated instead in an observational study done in Canada. (17) On the other hand, Gregory et al found in 2009 that noninvasive ventilation use was less than 50% despite being the first line. (35) A prospective study done in Malawi found the proportion of missed opportunities for NCPAP to be 28.7%. (28) Nigerian health facilities survey on accessible respiratory support showed oxygen to be the commonest available respiratory support at almost thirty-eight percent (38%) and 28% of the fifty-four facilities surveyed did not have any form of NCPAP machines.(29) This shows that we still have missed opportunities for NCPAP in the region. Nganga et al 2016 found that 56.9% of two hundred and six (206) preterm neonates that were admitted by then in the Newborn unit, KNH didn't receive NCPAP, despite being eligible (19). This shows an improvement of 23.4% reduction in NCPAP missed opportunities in the Newborn unit, KNH five years later. The contribution to this reduction could be explained by an increase in the number of NCPAP machines, staff training, paediatric registrars' orientation on NCPAP use that was recently introduced in the unit. An improvement was also seen at Nakuru county referral hospital, Kenya in CPAP scale up from two percent (2%) in 2016-2017 to seventeen percent of CPAP use in 2018 after the quality upgrading initiative. (40)

The participants mentioned that; CPAP is beneficial and helps in the reduction of neonatal mortality and the need for invasive mechanical ventilation. In India, CPAP use was perceived as an important and simple intervention that helps in the reduction of mechanical ventilation needs and neonatal mortality decrease. (38) The same findings were seen in a recent Kenyan study

where healthcare workers thought CPAP use to have positive newborn care outcomes. (15) This was comparable with results from four observational studies from a systematic review done to find out the efficacy and safety of CPAP in LMICs which showed 66% neonatal mortality reduction, and a single study showed 50% mechanical ventilation reduction. (30) A non-randomized control study from Malawi showed a twenty-seven percent (27%) improvement in survival of neonates with RDS after the introduction of NCPAP versus oxygen therapy (28). This was consistent with a prospective pre-and post-intervention study using CPAP in Nicaragua that showed mortality reduction by a half and intubation reduction by 33%. (31) A Previous observational study in Uganda showed BCPAP introduction has reduced mortality by 44% in preterm neonates less than 1500g (12). A randomized control trial done in Tanzania showed a 52% lower risk of death with the BCPAP group(21). A similar study in Kenya showed survival rates of 61% vs. 85% for Pre-BCPAP and post low cost BCPAP group respectively, in addition to that, there were fewer infants referred in the post BCPAP period 4% vs. 17% in the Pre-BCPAP group. (27)On the other hand, a systematic review in 2020 showed clinical improvement and mechanical ventilation reduction without change in mortality by BCPAP use. (41) In contrast, the BCPAP failure rate in an Indian study was higher at 42% in the RDS group compared to other CPAP indications studied including meconium aspiration syndrome. (42)

Our study key informants believed that infrastructure challenges, CPAP consumables, and inappropriate sizes of nasal prongs especially for preterm neonates hinder CPAP use. These findings are similar to a systematic review from seventeen (17) studies done in sub-Saharan Africa that showed unavailability of CPAP machines, and shortage of consumables were recurrently stated barriers to bubble CPAP implementation. (13) A related study done from 19 hospitals in Kenya found the same barriers to using CPAP to be infrastructure-related challenges, inadequate and inappropriate size of consumables mainly nasal prongs, and this happened mostly after completion of donor's implementation. (15) Another study in India showed that lack of enough equipment and consumables changed health care workers' perception of CPAP quality and effectiveness. (38)Therefore, these are challenges faced by low limited settings where mostly NCPAP machines are donated without a clear plan of a constant supply of consumables versus demand or maintenance/repair of such equipment, thus a need for young inventors of new technologies as well as training of biomedical engineers in these settings for the sustainability of this essential equipment. This will help in the demand versus supply balance. (43)

Timely maintenance of NCPAP machines and consumables was highlighted as a challenge by our study key informants, this was in alignment with a study in Ghana, which found the majority

of the donated equipment to be non-functional in a follow-up study. (44) Our study participants believed that engagement of manufacturer's equipment, provision of more CPAP machines, and adequate and appropriate size of consumables would overcome barriers to NCPAP use and this was consistent with a world health organization protocol for medical devices regulation. (45) On the other hand, a study by Patrick et al, highlighted the importance of detailed engagement of equipment donors in LMICs.(44)

In addition, our findings showed that sometimes CPAP machines and consumables might be available, however, staff shortage might delay its initiation and monitoring challenges. Health workers in Malawi recently expressed CPAP initiation and monitoring challenges they face especially when there is a shortage of cover (night duty hours), this may lead to delayed CPAP initiation and poor monitoring. (18) Overwhelming of health care workers by many patients in India was thought to lead to poor neonatal outcomes and mortalities without close monitoring. (38) This was in agreement with an observation study in Nairobi, Kenya, where nursing staff shortage led to handing over of tasks from one shift to the next whereby completion of tasks by eighty percent of the baby was only completed by about 14% of the babies assessed in this study, which in turn led to negative consequences for the neonates. (46) A systematic review in SSA did show workloads in the units with limited staff affects the quality of care and training opportunities. (13) Nevertheless, there is a need to think about world health organization recommendations on task shifting which would help in improving access to newborn health interventions in such staff shortage situations. (47)(48)

Although, perceptions about the partnership between health workers and caregivers varied; most of the key informants mentioned a need to improve the involvement of caregivers on CPAP initiation and monitoring, since they may help to report any complications or work as a team in monitoring those babies on CPAP. This was consistent with Qualitative studies in Kenya and Malawi found that the involvement of caregivers increases CPAP acceptability and makes work easier for health care workers in terms of monitoring as a result of teamwork. (15)(18) In contrast with a qualitative study in Malawi where caregivers received insufficient, unreliable, and infrequent information about CPAP which exposes gaps in information and psychological support that caregivers of infants on CPAP do receive in the hospital. (49) The gap between caregivers and health care providers' partnership was recently recognized and some protocols have been developed to help in this regard. (50)(51)(52)

Our study participants believed that global evidence of CPAP efficacy enabled its use. This was commonly mentioned in different studies. (53)(54)(55) On the other hand, the barriers to NCPAP use were alleviated by promising outcomes of CPAP in a recent Kenyan study. (15)

Our findings also underlined that; staff training facilitated NCPAP use, this is in line with findings from an observational study from a rural Ugandan neonatal ICU which showed that; training using the Silverman-Anderson respiratory severity score made it practicable to implement CPAP in newborn care safely (20). In Malawi, the competency in using CPAP increased from thirty-two percent to ninety-seven percent, and CPAP use improved by sixteen percent after the peer mentorship program(56). A similar study from AIC Kijabe Hospital Nursery, Kenya showed higher survival to discharge rates, the adequate training of staff after the introduction of CPAP which concurred with the hiring of a clinical officer likely enabled staff to initiate CPAP safely, and hence favorable outcomes. (27) A related study in Kenya on effective training of trainers after NCPAP implementation showed promising results on successful initiation of CPAP by nurses as well as competency to do so. (57) The health partnership and international experts' upkeep on training schemes have been shown to improve CPAP uptake in the newborn care units from four different hospitals in Rwanda. (58) On the other hand, insufficient training was mentioned as a barrier to NCPAP use, and hence frequent training/CMEs and mentorship was thought to play an important role in CPAP use by our study participants. Two studies in Rwanda and Ghana presented a challenge in the identification of eligible neonates after short training. (44)(59) Carns et al, recently highlighted that training and mentorship do increase CPAP uptake. (60)

Study strengths and limitations

This study ensured a fairly accurate representation of NCPAP users in Kenyatta National Hospital. We involved key informants from different health care professionals and engineers that deal with CPAP routinely in their work. This was to gain a deeper understanding of the facilitators and barriers to CPAP use. This study will improve the quality of care for preterm infants. The key limitation of this study is that the enrollment of the preterm neonates in terms of gestational age was based on Ballard's score done by the admitting clinician. Secondly, it would have been better to look at missed opportunities for Bubble versus other forms of NCPAP machines to know which type of NCPAP machines are frequently in use for a deeper understanding of the opportunities we have for improvement. Lastly, recall bias for key informants may have occurred given certain answers required recall however they were given ample time to answer questions.

Conclusion

This shows that progress has been made. There is a 23.4% reduction in NCPAP missed opportunities in the Newborn unit, KNH five years later (between 2016 and 2021). However, we still have missed opportunity for NCPAP at 33.5% [95% CI 59.0% - 73.2%] in NBU, KNH. Missed opportunity for prophylactic group and SAS group was found to be 44.7 (34.1% - 55.9%) and 24.2 (16.5% - 33.9%) respectively.

Barriers to NCPAP use were mainly related to medical products and technologies, health workforce related challenges, and service delivery.

Solutions highlighted by the key informants are: provision of more NCPAP machines, Human resource support, frequent training/CMEs/mentorship, infrastructure improvement, adequate and appropriate size of consumables, promotion of family-centered care, and engagement of the equipment's manufacturer.

Recommendations

Future CPAP scale-up should consider the provision of more NCPAP machines, human resource support, frequent training/CMEs/mentorship, infrastructure improvement, the adequate and appropriate size of consumables, and promotion of family-centered care.

This study was done when new NCPAP machines were being introduced in the unit and therefore, a similar study in the future including caregivers and focus group discussions would help in quality care improvement.

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Time frame

	2021												20	22			
Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
Proposal development	█																
ERC approval			█														
Data collection							█										
Data analysis													█	█			
Results presentation																█	
Final report																█	

Study Budget

NAME: Dr. Peace Kakibibi		REF: KNH/R&P/23K/54		
COMPONENTS	UNIT OF MEASURE	DURATION/NUMBER	COST (KSHS)	TOTAL (KSHS)
Personnel				
Research Assistant	1	34	1,500.00	51,000.00
Statistician				30,000.00
Transcribing Fees	20	1	2,000.00	40,000.00
Printing				
Consent Form	1	8	10.00	80.00
Questionnaires	1	3	10.00	30.00
Interview Guide	1	2	10.00	20.00
Final Report	1	100	10.00	1,000.00
Photocopying				
Consent Form	200	4	5.00	4,000.00
Questionnaires	200	3	5.00	3,000.00
Interview Guide	25	2	5.00	250.00
Final Report	6	100	6.00	2,600.00
Final Report Binding	6	1	500.00	3,000.00
Other Costs				
ERC Fees				2,000.00
Batteries	3	1	350.00	1,050.00
Poster Printing				3,000.00
In-depth Interviews snacks	22	1	200.00	4,400.00
Note books	2	1	100.00	200.00
Pens	5	1	50.00	250.00
Box Files	2	1	350.00	700.00
Total				146,480.00

I was privileged to receive KNH Research funding 2021-2022 for this project.

APPENDICES

Appendix I: Study Questionnaire

Missed opportunities for CPAP in preterm neonates with RDS admitted at KNH, NBU

Fill all sections

Study number: _____

Date: _____

Socio-demographic data and neonatal characteristics

Date of birth: ____ / ____ / ____

1. Child's age in hours _____ Days _____

2. Gender of child: Male Female

3. Child Birth weight _____

4. Gestation age in weeks _____

5. Mode of delivery _____

6. Type of gestation _____

Patient clinical and management data

7. Clinically indicated for CPAP: Yes No

8. indicated for Prophylactic CPAP: Yes No

9. Respiratory exam using standard tool (SAS) _____

	Upper chest movement	Lower chest retractions	Xiphoid retractions	Nares dilation	Expiratory grunt
Grade 0	Synchronized	None	None	None	None
Grade 1	Lag on inspiration	Just visible	Just visible	Just visible	Heard with stethoscope
Grade 2	Seesaw	Easily seen	Easily seen	Easily seen	Heard by ear

10. Patient management (CPAP or not): Yes No

Appendix II: The key informants' interview guide

Missed opportunities for CPAP in preterm neonates with RDS admitted at KNH, NBU

Study Number: _____

Study Site: _____

Tick: Male _____ Female _____

Moderator: _____

Notes taker: _____

Date _____

Start time: _____

End time: _____

Instructions to the facilitators: Introduce yourselves first, ensure the participants are comfortable. Ask the participants to introduce themselves using their initials and age.

Thank them for accepting to be part of the discussion, reconfirm their signed consent and reassure them of confidentiality. Ask them permission to tape-record the session and take notes.

Standard procedure for discussion.

You will do the talking mostly during the discussion. I will guide you using some questions. We will not call you by name, but by pre-allocated numbers to keep your identity confidential. There are no wrong answers, Everyone's views will be respected and are very important to this study. Whatever is said here will remain here. In the course of this discussion, we will be using a recording device and taking notes.

IDI Guide (key informants):

Your participation in this study is well appreciated, looking forward to hearing your views on missed opportunities for CPAP in the new born unit, KNH

1. Firstly we would like to know more about you, how long have you been working in KNH? How many years of experience with CPAP usage?
2. Do you think CPAP use is beneficial?
 - a) If yes kindly what are its benefits? It is possible to provide CPAP effectively in your unit? If yes what are some factors you think facilitated CPAP usage and availability?
 - b) If no, why do you think so?

3. Literature has shown that CPAP is very useful although not all infants get that chance, some do miss that opportunity?
 - a) Have you encountered this experience before in your practice?
 - b) If so what do you think are the reasons behind this?
 - c) What is the most concerning aspect of using CPAP in your unit?
4. How about those who get CPAP?
 - a) What are the reasons behind this?
5. If participants haven't provided enough information especially on the following aspects kindly do ask explicitly.

Kindly elaborate on how your unit manages/managed:

- a) Availability/shortage of CPAP machines
 - b) Availability/shortage of CPAP consumables
 - c) Facilitators/Challenges with infrastructure that may hinder CPAP usage
 - d) skilled staff shortage
 - e) Adequate/Inadequate training and knowledge for CPAP use
 - f) Effect of partnerships between healthcare workers and caregivers on CPAP usage
6. If the MOH or a sponsor wants to offer this unit CPAP support, what type of support would you ask for?
 7. Lastly, what is the most important point you said in the discussion about the use of CPAP in your unit?
 8. Is there any other comment you want to add or like us to know before we end?

Thank you so much for your time and participation!

Appendix III: Informed consent

Study Title: Missed opportunities for CPAP in preterm neonates with RDS admitted at KNH, NBU

Institution: Department of Paediatrics and Child Health, University of Nairobi

Principal Investigator: Dr. Peace Kakibibi Paediatric Registrar, UON

Supervisors:

1. Dr. Diana Marangu Department of Paediatrics and Child Health, University of Nairobi

2. Dr. Florence Murila Department of Paediatrics and Child Health, University of Nairobi

Ethical Approval: This study has the approval of Kenyatta National Hospital/University of Nairobi Ethical and Research Committee (KNH-UON ERC)

Informed consent has two parts:

Information sheet

Consent form

Part 1: Information sheet

Introduction

My name is Peace KAKIBIBI; I am a postgraduate student in the Department of Paediatrics and child health at the University of Nairobi. I wish to inform you about medical research to be conducted by the above-listed researchers. The purpose of having this discussion with you is to inform you of the aim of this study so that you can make an informed choice on whether to participate. Please feel free to ask any questions regarding the purpose of the study, your rights as a volunteer, and any risks or benefits accorded to you for agreeing to participate in this research. We will clarify anything you have not understood. Should our answers be satisfactory, you may decide to participate or not too. Once agreeable to participate, I will ask you to sign the consent form below once you are satisfied. Kindly read through the rest of this form to understand the general principles that apply to all medical researches. Your decision is voluntary and you have the right to withdraw anytime without any explanation.

What is this research about?

The purpose of this study is to find out how many preterm neonates with RDS miss CPAP when it was indicated and the reasons behind these plus possible lessons to be learnt from those who get it. RDS is one of the commonest diseases seen in preterm neonates because their lungs haven't adequately matured yet to allow them to independently breathe on their own therefore

there will be a need to be assisted hence the use of CPAP. This important machine is widely available in the developed world and it has shown remarkable good outcomes when used however may not be available to every preterm infant in need in our settings hence why this study needs to be done. The findings of this research will help in advocacy for our children.

Benefits

Parent/ caregiver: If any other illness is found that wasn't previously diagnosed, it will be liaised with the primary doctor and ensure appropriate management is given. The public at large will benefit in the future from information learned from this research.

Key informants: There will be no direct benefits to you, however, the results will help us to find out gaps we have for improvement towards better preterm care in the future, your future child, grandchild, or mine may benefit from this.

Any risks involved?

There will be no dangers to your health since we will not perform any procedures on you or give you any medicine, only questions will be asked. None of your rights will be infringed during this research.

Confidentiality

Parent/ caregiver: All possible efforts will be made to keep your baby's information confidential; we will not use your name or child's name in the publication of results.

Key informant: All the information obtained from you will be kept at utmost confidentiality. Your name will not be used or mentioned during the handling of the data or in any resulting publication. Serial numbers will be used instead.

Study procedure

Parent/ caregiver: If you agree to participate, a doctor will ask you for some information then examine your child and ensure his/her comfort. The child will continue normal routine management and monitoring.

Key informant: With your permission, I will ask your experiences and views on missed opportunities, reasons behind this, and also lessons to be learnt from those who do get CPAP. All information obtained will be kept confidential. This process will take about 30 minutes -1 hour of your time.

Costs

This will cost you almost 30 minutes -1 hour of your time; kindly do note that this participation is entirely voluntary and no monetary compensation for your participation.

What are your rights as a participant?

You agree to participate in this research voluntarily. You are free to withdraw from this research at any point without giving us explanations. Your refusal to participate in this research will not be held against you and it will not influence you in any way. You can ask questions that will enable you to comprehend the nature of this research.

Questions

Contacts

Should you have any questions about your rights as a research participant, feel free to get in touch with any of the following:

- 1. Principal investigator Dr. Peace Kakibibi
Tel 0797326028
- 2. Supervisors:
 - Dr. Florence Murila
Tel 0729430022
 - **Dr. Diana Marangu**
Tel 0721282815
- 3. The Chairperson, KNH-UON ERC Committee
Tel 2726300/2716450 Ext 44102

Email uonknh-erc@uonbi.ac.ke

I now request you to sign the consent form below:

CONSENT TO PARTICIPATE IN THE STUDY

I have read and have also been clarified the content on this consent form and I have fully understood, the risks and benefits have been explained to me therefore I consent to participate in the study with my child. I understand that my participation is voluntary and that I am free to withdraw from the study at any point without any loss of benefit or injustice to me. I have also understood that all efforts will be made to keep my personal and child’s identification confidential.

Name of participant.....

Date.....

Signature of participant.....

Researcher's statement

I confirm that I have explained the details of the research to the participant and that he/she has understood.

Name of researcher.....

Date.....

Signature of researcher.....

Appendix IV: Idhini ya habari

Kichwa cha Somo: Fursa zilizokosekana Kwa CPAP katika watoto wachanga wa mapema na RDS ilikubaliwa katika KNH, NBU (Missed opportunities for CPAP in preterm neonates with RDS admitted at KNH, NBU)

Taasisi: Idara ya Watoto na Afya ya Watoto, Chuo Kikuu cha Nairobi

Mchunguzi Mkuu: Daktari Peace KAKIBIBI, Msajili wa Watoto, UON
Wasimamizi:

1. Daktari Diana Marangu, Idara ya Watoto na Afya ya Watoto, Chuo Kikuu cha Nairobi
2. Daktari Florence Murila, Idara ya Watoto na Afya ya Watoto, Chuo Kikuu cha Nairobi

Idhini ya Maadili: Utafiti huu una idhini ya Hospitali ya Kitaifa ya Kenyatta / Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi (KNH-UON ERC)

Idhini ya habari ina sehemu mbili:

- Karatasi ya habari
- Fomu ya ridhaa

Sehemu ya 1: Karatasi ya habari

Utangulizi

Naitwa Peace Kakibibi; Mimi ni mwanafunzi wa uzamili katika idara ya watoto na afya ya watoto katika Chuo Kikuu cha Nairobi. Ninataka kukujulisha juu ya utafiti wa matibabu itakayofanywa na watafiti walioorodheshwa hapo juu. Kusudi la kuwa na mazungumzo haya na wewe ni kukujulisha juu ya lengo la utafiti huu ili uweze kufanya uchaguzi sahihi ikiwa utashiriki. Tafadhali jisikie huru kuuliza maswali yoyote kuhusu utafiti huu, haki zako za kujitolea na hatari yoyote au faida unayopewa kwa kukubali kushiriki katika utafiti huu. Tutafafanua chochote ambacho hujaelewa. Ikiwa majibu yetu yataridhisha, unaweza kuamua kushiriki au kutoshiriki. Mara tu utakapokubali kushiriki, nitakuuliza utie sahihi fomu ya idhini hapa chini mara tu utakaporidhika. Soma kwa fadhili fomu hii yote ili uelewe kanuni za jumla zinazotumika kwa tafiti zote za matibabu. Uamuzi wako ni wa hiari na una haki ya kujiondoa wakati wowote bila maelezo yoyote.

Je! Utafiti huu unahusu nini?

Madhumuni ya utafiti huu ni kujua ni watoto wangapi wa kuzaliwa mapema walio na shida ya kupumua (RDS) na wanakosa matibabu ya mashine ya kusaidia kupumua(CPAP) wakati

inahitajika na sababu za kukosa hayo matibabu pamoja na kujifunza kutoka kwa wale wanaopata. watoto wa kuzaliwa mapema walio na shida ya kupumua (RDS) ni moja ya ugonjwa wa kawaida unaoonekana katika watoto wachanga wa kuzaliwa mapema kwa sababu mapafu yao hayajakomaa vya kutosha kuwaruhusu kuvuta pumzi peke yao kwa hivyo watahitaji kusaidiwa na matibabu ya CPAP. Mashine hii muhimu inapatikana sana katika ulimwengu ulioendelea na imeonyesha matokeo mazuri wakati inatumiwa hata hivyo haipatikani kwa kila mtoto wa mapema anayehitaji haswa inchi ambazo hazijaendelea na ndivyo maana utafiti huu unahitaji kufanywa. Matokeo ya utafiti huu yatasaidia katika utetezi kwa watoto wetu.

Faida

Mzazi / mlezi: Ikiwa ugonjwa mwingine wowote utapatikana na haukuwa umegunduliwa hapo awali, mawasiliano na daktari wa msingi yatafanywa na kuhakikisha matibabu inayofaa atapata. Umma kwa jumla utafaidika baadaye kutoka kwa habari itakayotoka kwa utafiti huu.

Watoa habari muhimu: Hakutakuwa na faida za moja kwa moja kwako, hata hivyo matokeo yatatusaidia kujua mapungufu tuliyonayo ya kuboreshwa kuelekea utunzaji bora wa watoto waliozaliwa mapema katika siku zijazo, mtoto wako wa baadaye, wajukuu au wangu anaweza kufaidika na hii.

Hatari yoyote inayohusika?

Hakutakuwa na hatari kwa afya yako kwani hatutakufanyia lolote au kukupa dawa yoyote, ni maswali tu yataulizwa. Hakuna haki yako yoyote itakayokiukwa wakati wa utafiti huu.

Usiri

Mzazi / mlezi: Jitihada zote zinazowezekana zitafanywa kutunza habari za mtoto wako kuwa siri; hatutatumia jina lako au jina la mtoto katika kuchapisha matokeo.

Mtoa taarifa muhimu: Habari zote zilizopatikana kutoka kwako zitahifadhiwa kwa siri kabisa. Jina lako halitatumiwa au kutajwa wakati wa utunzaji wa data au katika chapisho lolote. Nambari zilizofuatana zitatumika badala yake.

Utaratibu wa kusoma

Mzazi / mlezi: Ikiwa unakubali kushiriki, daktari atakuuliza maswali kisha apime mtoto wako na ahakikishe starehe yake. Mtoto ataendelea na matibabu na uchunguzi.

Mtoa habari muhimu: Kwa idhini yako, nitauliza uzoefu wako na maoni yako juu ya fursa zilizokosekana, sababu za hii na pia masomo ya kujifunza kutoka kwa wale wanaopata NCPAP.

Taarifa zote zitakazopatikana zitahifadhiwa kwa siri. Utaratibu huu utachukua kama dakika thalathini (30) hadi lisaa limoja ya muda wako.

Gharama

Hii itachuwa wa karibu dakika thalathini (30) hadi lisaa limoja muda wako, pia kumbuka kuwa ushiriki wako ni wa hiari kabisa na hakuna fidia ya pesa kwa ushiriki wako.

Haki zako kama mshiriki ni zipi?

1. Unakubali kushiriki katika utafiti huu kwa hiari yako.
2. Uko huru kujiondoa kwenye utafiti huu wakati wowote bila kutupa ufafanuzi.
3. Kukataa kwako kushiriki katika utafiti huu hakutatumika dhidi yako na hautashawishiwa kwa njia yoyote.
4. Unaweza kuuliza maswali ambayo yatakuwezesha kuelewa wazi hali ya utafiti huu.

Maswali

Mawasiliano

Ikiwa una maswali yoyote juu ya haki zako kama mshiriki wa utafiti huu, jisikie huru kuwasiliana na yoyote afuatao:

1. Mchunguzi mkuu

Daktari Peace Kakibibi Simu 0797326028

2. Wasimamizi:

Daktari Florence Murila Simu 0729430022

Daktari Diana Marangu Simu 0721282815

3. Mwenyekiti, Kamati ya ERC ya KNH-UON

Simu 2726300/2716450 Ext 44102

Barua pepe: uonknh-erc@uonbi.ac.ke

Sasa naomba utie sahihi fomu ya idhini hapa chini:

UKUBALIANO WA KUWEKA PICHA KATIKA MAFUNZO

Nimesoma na pia nimefafanuliwa yaliyomo kwenye fomu hii ya idhini na nimeelewa kabisa, hatari na faida zimeelezwa kwangu kwa hivyo ninakubali kushiriki kwenye utafiti huu na mtoto wangu. Ninaelewa kuwa ushiriki wangu ni wa hiari na kwamba niko huru kujiondoa kwenye utafiti wakati wowote bila kupoteza faida yoyote au dhuluma kwangu. Nimeelewa pia kuwa juhudi zote zitafanywa kuweka siri kitambulisho changu cha kibinafsi na cha mtoto wangu.

Jina la mshiriki Tarehe

Sahihi ya mshiriki

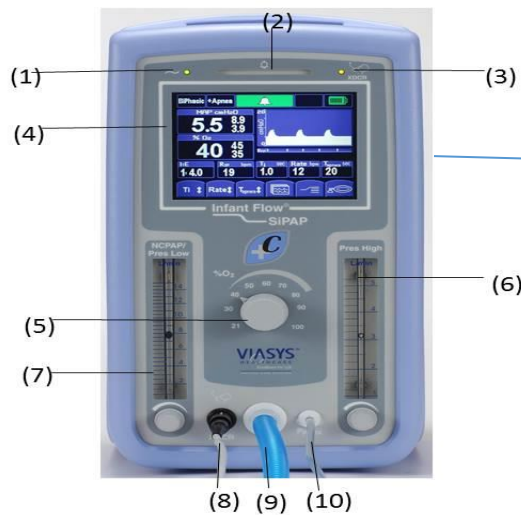
Kauli ya mtafiti

Ninathibitisha kuwa nimeelezea maelezo ya utafiti kwa mshiriki na kwamba ameelewa.

Jina la mtafiti Tarehe

Sahihi ya mtafiti

Appendix V: Types of NCPAP Machines in NBU, KNH



- 1) Power LED
- 2) Alarm Warning Bar
- 3) Transducer Interface LED
- 4) LCD Touch Screen
- 5) % O2 Control
- 6) Pres High Flow Meter
- 7) nCPAP Pres Low Flow Meter
- 8) Transducer Interface Connection
- 9) Circuit Connection Inspiratory Limb
- 10) Connection Proximal Pressure Line

Thirteen Infant flow NCPAP machines in total, only Seven (7) are functional however available consumables are only two for this type of NCPAP machines.

Four (4) Pumani bubble CPAP machines.



Thirteen (13) Vayu NCPAP machines in total, only seven of these are fully functional with their accompanied consumables.



Appendix VI: KNH-UoN ERC approval



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Ref: KNH-ERC/A/270

26th July, 2021

Dr. Peace Kakibibi
Reg. No.H58/34977/2019
Dept. of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi



Dear Dr. Kakibibi

RESEARCH PROPOSAL: MISSED OPPORTUNITY FOR CPAP IN PRETERM NEONATES WITH RDS ADMITTED AT KENYATTA NATIONAL HOSPITAL, NEW BORN UNIT (P206/03/ 2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 26th July, 2021 – 25th July, 2022.

This approval is subject to compliance with the following requirements:


- i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affect 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 KNH- UoN ERC for each batch of shipment.
- 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.

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This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Yours sincerely



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

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Paediatrics and Child Health, UoN
Supervisors: Dr. Florence Murila, Dept. of Paediatrics and Child Health, UoN
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