AUDIT ON THE USE OF CONTINUOUS POSITIVE AIRWAY PRESSURE AT KENYATTA NATIONAL HOSPITAL NEWBORN UNIT

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STUDENT'S DECLARATION

I, **Dr. Zena Ali Jeizan**, do certify that this dissertation is my original work and has not been presented for the award of a degree in any other university.

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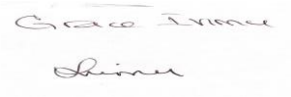
Signature:  **Date:** 24th May 2022

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ABBREVIATIONS

CPAP-	Continuous Positive Airway Pressure
CLD-	Chronic Lung Disease
FRC-	Functional Residual Capacity
FiO2-	Fraction of Inspired Oxygen
KNH-	Kenyatta National Hospital
KNH-UoN ERC-	Kenyatta National Hospital-University of Nairobi Ethics and Research Committee
LMICs-	Low- and middle-income countries
MOH-	Ministry of Health
NBU-	Newborn Unit
PEEP-	Positive End- Expiratory Pressure
RDS-	Respiratory Distress Syndrome
WOB-	Work of Breathing
WHO-	World Health Organization

OPERATIONAL DEFINITIONS

Neonate: An individual aged between 0 days to 28 days.

Clinical audit: The systematic and critical analysis of the quality of Clinical care using the ministry of health standard guidelines**.**

Guardian: A person who provides direct care to a child.

ABSTRACT

Background : CPAP is a form of positive airway pressure ventilation in which a constant level of pressure greater than atmospheric pressure is continuously applied to the upper respiratory tract and is mostly used in preterm neonates. Along with the increased survival of extremely premature newborns, better knowledge on the different kinds of respiratory diseases and advances in technology have led to new evidence in this field. The Ministry of Health Kenya has published guidelines on the use of CPAP in Basic Paediatrics Protocol (revised in 2016). This study aims to assess CPAP use in the newborn unit at Kenyatta National Hospital (KNH). This study will assess the adherence of medical staff to the guidelines and protocols of using CPAP, since adhering to guidelines brings about good outcome. Ever since the publication of these guidelines, audit on CPAP use in KNH newborn unit (NBU) has not been formally conducted. Therefore, audit on CPAP use will improve our knowledge, inform our ways of practice and, help correct errors. It will also inform development of CPAP user training that addresses the gaps in care of the preterm neonates with respiratory problems.

Objective: To audit the use of CPAP at Kenyatta National Hospital newborn unit.

Methods: This was a prospective audit study carried out over a period of three months in NBU at KNH on neonates who were put on CPAP. Neonates admitted at the NBU and were put on CPAP were enrolled into the study at admission and an audit on the use of CPAP was carried out to determine the newborns who received CPAP treatment consistent with Ministry of Health (MOH) Basic Paediatrics Protocol 2016 guidelines which is adopted by KNH NBU.

Results: The commonly documented indication for CPAP was based on the Apgar score of the neonates (100%) and Silverman-Anderson Score (SAS) score (54.2%). Complete documentation of examination findings was not done in all the 72 neonates who were put on CPAP. The examination findings not documented by clinician on admission were apnea at 21 (29.2%) and, upper chest wall retraction at 38 (52.8%). Blood culture was done in 5 (6.9%) of neonates on admission, chest Xray done on 7 (9.7%) while full hemogram and C reactive protein were done in 71 (98.6%) and 56 (77.8%) respectively. Overall documentation of CPAP use was very poor. Documentation of FiO2 was at 56 (77.8%), PEEP 48 (66.7%), PIP 17 (23.6%). There was no documentation on nasal prong size/position, head position, pressure level in all the neonates. Overall monitoring of CPAP equipment over 4 days following initiation of CPAP was poor. Pulse oximetry was done in 71 (98.6%) neonates, chest Xray was done in 24 (33.3%) neonates and BGA was least done in 18 (25%) of neonates. Documentation on weaning was done in 33 (45.8%) and it was gradual and successful in 17 (23.6%) and it

failed in 16 (22.2%). Appropriate CPAP use as per the Kenyan guidelines (Basic Paediatrics protocol 2016) in this study was at 75.2%.

Conclusion: There was poor documentation on indication of CPAP use such as SAS score which was documented in only 54.2% of the neonates who were put on CPAP. Appropriate CPAP use as per the Kenyan guidelines (Basic Paediatrics protocol 2016) in this study was at 75.2%. No recording was done on the parameters on neonate connection to the CPAP machine. There was suboptimal documentation on investigations required before CPAP connection and follow up of the neonate. Weaning was not recorded in most neonates at 54.2% and it was gradual and successful in only 23.6%.

Recommendations: There is need to have strategies to help improve documentation on indications, contraindications, investigations of the use of CPAP as well as improvement of documentation of data on CPAP set up and monitoring. There is need to provide CPAP user training on initiation, monitoring and weaning of CPAP.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background

Globally, approximately 2.9 million neonates die yearly, with developing countries contributing to the highest number of deaths. The main etiology of the deaths include: prematurity accounting for 34%, intra-partum-related conditions at 25% and infections like pneumonia at 22%.[(1)]

The major problem which is unique to these three leading causes of neonatal deaths is severe respiratory distress which is the commonest presentation(2). Respiratory distress syndrome (RDS) is the condition that causes respiratory distress in premature neonates which is primarily due to a deficit in surfactant(2). Other causes are sepsis, pulmonary hemorrhage and pneumonia. In term newborns, respiratory distress is mainly due to pneumonia, meconium aspiration syndrome, RDS and intra-partum-related hypoxia.(3) In low middle income countries(LMICs), the case fatality rate can be as high as 20% for neonatal respiratory distress.(4)

In high-income countries, CPAP or mechanical ventilation is used to deliver respiratory support to treat this condition(5). Newborns presenting with RDS can be given surfactant. However, surfactant is costly and its administration requires endotracheal intubation which makes it unsuitable in low-income settings that lack medical staff trained in endotracheal intubation(4). Mechanical ventilation needs a great level of expertise and is expensive. CPAP is simple and safe to use and recently, relatively low-priced CPAP devices have been invented, thus providing opportunity for use to be scaled up in LMICs(4).

Spontaneously breathing newborns with lung disease are put on CPAP which is a non-invasive method of applying constant expanding pressure during breathing(6). Airway instability, atelectasis and edema is managed using CPAP in newborns susceptible of developing respiratory distress(7). CPAP works in the lungs to aid in gas exchange, decrease apneic episodes, lung injury, work of breathing and to maintain functional residual capacity (FRC)(7). CPAP is mostly provided to the nostrils using a nasal mask or short bi-nasal prongs, and pressure is created using different appliances. CPAP is generally permitted, and is successful, because neonates are better or “obligatory nasal-breathers,”(8,9) neonates tongue and soft palate create a seal that sustains pressure in the lungs(7).

CPAP poses potentially fewer risks, it is easier to operate, is less expensive, training is minimal as compared to intubation and mechanical ventilation. Successful CPAP administration in premature neonates who are breathing spontaneously with RDS was first reported by Gregory et al in 1971(10). CPAP use has reduced the mortality rate of RDS from 55–35% to 20-15%(11). These developments have brought widespread and routine use of CPAP, plus scrutiny in boosting its application in neonates. Ministry of Health published the Basic Paediatrics Protocol (February 2016)(12) which covers the use of CPAP, indications and what to monitor. Training of the healthcare personnel is done through Emergency triage and assessment plus admission (ETAT+). Adherence to guidelines on the use is important so as to improve outcomes.

Audits are safety tools which are used due to their way of identifying problems and potentially dangerous situations, thus enabling prevention of adverse situations (13).

The management of neonates who receive CPAP for respiratory support emphasizes the need to adhere to the indications, contraindications and monitoring due to their increased vulnerability. In an effort to improve the quality of hospital care for the neonates who are on CPAP and to reduce the number of case fatalities the World Health Organization developed evidence based clinical guidelines on the management of neonates who are on CPAP that emphasizes on the need of monitoring. The WHO gives indications, contraindications and the things to be monitored in the care of these neonates. The guidelines have since been adopted by the Ministry of Health, Kenya and incorporated into the Basic Paediatrics Protocol 2016 [(10)]. Sufficient evidence of proper use of CPAP has shown a reduction in mortality and morbidity in these neonates.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology for CPAP use

In Kenya, the Ministry of Health recommends the use of CPAP in only level 4 or 5 hospitals. A study done by Nabwera et al who did a survey of CPAP use in newborn care in Kenya using a mixed methods approach from September 2017 to February 2018 on the use of CPAP in Kenya reported that the majority of newborn units had no formal training on its use making many staff incompetent to use it when they were on shift(14). The study by Nabwera et al also noted that CPAP was used for longer in private than public hospitals a median of 2 years was used and private hospitals used CPAP more frequently than public hospitals. This despite public hospitals having more admissions. In Public hospitals out of 29 staff only 4 could use CPAP while in Private out of 25 staff members 1 could use the CPAP machine. Nabwera et al reported that 19 neonates received CPAP in private hospitals and only 8 in public hospitals.

Rossano Rezonnico et al did a study on the impact of systemic introduction of low-cost bubble nasal CPAP in a NICU in Nicaragua from May 2006 to December 2008 a pre and post interventional study reported that after CPAP introduction mortality decreased from 40% to 23% $p< 0.0001$ and mean duration of NICU stay decreased from 17.5 to 14.6 days(15).

Jennifer Myhre et al did a retrospective chart review on effect of using low-cost bubble CPAP on premature infants with respiratory distress in Kijabe hospital and noted that survival to discharge of preterm neonates < 37 weeks who had RDS was higher after CPAP introduction in that hospital 61% to 85% p 0.007(15).

A study done by Catreen F Mousa et al on the audit of CPAP in a NICU in Assiut University Children Hospital from June 2015 to January 2017 in 69 neonates reported that: outcome of CPAP use was good as improvement was noted in 58.3% cases and failed in 41.7% of cases, she also reported that using CPAP in neonates with respiratory distress in the hospital partially followed the guidelines recommended(16). An audit on the adherence to the European consensus guidelines done in UK by Tanney et al in 2011 noted that 75% of the neonates were managed as per the guidelines of CPAP use(17).

A study done in KNH in 2017 on the clinical profile and audit of initial management of RDS in preterms showed that 52% of the neonates required CPAP but only 43.1% received it (18).

A study done in Spain by Elena Bergon- Sedin et al in 2015 on auditing of monitoring and respiratory support equipment in a level 3 neonatal intensive unit using the Welsh guidelines of CPAP use noted that appropriate overall use of CPAP throughout the year was 25.93% (13).

Dewez et al in 2020 who was looking at availability and use of CPAP in India noted that clinical guidelines were available and used in 31% of the hospitals studied and the guidelines was mostly followed in the public hospitals than private hospitals(19).

2.2 Indications and contraindications of CPAP use

CPAP is mostly given to premature neonates with RDS though it can also treat neonates with disorders such as, transient tachypnea of the newborn(5), meconium aspiration syndrome (8,9),primary pulmonary hypertension(9), pulmonary hemorrhage(7), patent ductus arteriosus(10)and pulmonary edema(11). CPAP enhances pulmonary capacity succeeding repair of inborn cardiac peculiarity surgically(20–22), paralysis of hemidiaphragm, and in neonates following diaphragmatic hernia repair surgically(23). CPAP is used in dealing with neonates with infections such as, inborn pneumonia(24)or respiratory syncytial virus, bronchiolitis(25,26). It is effective for dealing with central and obstructive apneas and acquired or inborn lesions of the airway. It is contraindicated in neonates with upper airway anomalies (such as, choanal atresia, tracheoesophageal fistula, cleft palate), recurrent apneic episodes, diaphragmatic hernia that is unrepaired and those with profound cardiac instability.

2.3 Physiologic effects of CPAP use

CPAP is a positive pressure device; application of pleural pressure changes through breathing efforts of the neonates is important since alveolar ventilation during apnea cannot be sustained effectively by CPAP. Preserved distending pressure in spontaneously breathing neonates improves cardiac output, enhances aeration of lung units, alveolar get well recruited and stabilized by increasing venous return(20–22). CPAP mimics “grunting,” which is routinely expressed in neonates with low end-expiratory volume and whose lung compliance is low(10). Grunting is abolished by CPAP through the compensatory volume- preserving braking maneuver(23). To limit exhalation of gases so as to conserve end- expiratory lung volume, neonates develop tachypnea to decrease expiratory time. Reduction in tachypnea, increase in FRC and PaO2(24), reduction in intrapulmonary shunting(25), improvement in lung compliance(10) and floppy neonates chest wall stabilization is all done by CPAP(26).

Ventilatory response to CO2 during CPAP is not related to the reduction in the rate of breathing (27) as to the stretch receptor initiation (Hering-Breuer reflex) (28), alveolar dead space decrease(10), ventilation-perfusion ratio improvement(23,29–31), increase in ventilation distribution(24)and increase in end- expiratory lung volume and expiratory time (23).

Thoraco-abdominal asynchrony (32) and labored breathing(33) is decreased by CPAP. Neonates with congenital or acquired airway lesions that are prone to collapse (like, tracheomalacia) can be supported by CPAP. CPAP relieves obstruction and improves the function of the airway by making the airway stiffer and increasing its diameter so as to decrease the collapsing pressure transmurally and to minimize closure of the airway prematurely(34,35). CPAP can decrease the severity and incidence of obstructive and central apneic episodes in neonates. The risk of pharyngeal or laryngeal obstruction in obstructive apnea is decreased when using CPAP since the upper airway is splint open when using CPAP(36,37). Risk of severe central apnea is decreased by improving FRC hence, oxygenation with fewer incidences of gas exchange deterioration.

The effect of terminating CPAP in neonates, in an analysis done by *Kurtz et al* showed that such neonates on CPAP had brief central apneas, fewer obstructive apneas, apnea-associated desaturations were less severe, respiratory rates were lower and that they had normal quiet breathing for longer periods as compared to neonates breathing without CPAP(38).

2.4 Nasal CPAP Systems

The CPAP system works to conserve consistent pressure at the nasal airway opening and to control gas flow during breathing in and out. The CPAP system has 4 intermediate components: patient circuit, nasal interface, pressure-generation apparatus and heated/humidified blended gas source. Limiting and monitoring the airway pressures is done by the CPAP system(39). CPAP systems generate high level of gas flow hence, the humidifier should deliver gas that is at 37°C and is 100% saturated. CPAP is provided to the nasal airway opening by nasal interfaces.

Currently, the most commonly used interfaces are nasal masks or bi-nasal prongs. The one with the least amount of resistance to gas flow, less invasive is provided by prongs thus causes resistive work of breathing(40). For mobilization and oral feeding bi- nasal prongs are the most suitable(41). In premature neonates supported with CPAP, rate of re-intubation was found to be minimal in those using short bi- nasal prongs than those using single naso-pharyngeal prongs and this was reported in a recent meta-analysis(42).

The devices that generate positive airway pressure are either of continuous or variable flow depending on their gas flow character. The infant flow driver (IFD) CPAP is a variable flow device while the bubble CPAP is of continuous flow. A generator with a unique fluidic fluid mechanism and dedicated flow driver is present in an IFD which adjusts the gas flow throughout the respiratory cycle. The fluidic activity of the IFD provides more stable pressure

delivery, maintains FRC and aids spontaneous breathing. It is associated with decreased WOB and it decreases thoraco-abdominal asynchrony.

2.5 Clinical Management

Throughout the course of respiratory support with CPAP requirement levels are likely to differ. When adequate gas exchange and lung inflation occurs without over-distending the lung parenchyma optimal CPAP level is presumed to have occurred(43). Neonates response to CPAP is determined using chest radiographs and blood gases (44).Chest X-ray is indicated immediately after initiating the neonate on CPAP to assess for lung inflation and evaluate the etiology of respiratory distress. A lung expansion of 6 anterior or 8 posterior intercostal space is considered appropriate. Chest X-ray is required when there is a discrepancy between the CPAP pressure and FiO2 requirements and when a neonate on CPAP has a sudden unexplained deterioration(2,44).

Determination of gas exchange in neonates supported by CPAP is reliably offered by pulse oximetry and transcutaneous monitoring of CO2. Complications caused by hyperoxia should be avoided by titrating the FiO2 immediately upon confirmation of blood gas values and pulse oximetry reading and this occurs with lung recruitment(44). Neonates receiving CPAP, should have proper airway management so as to improve outcomes and reduce complications, since neonates on CPAP are supported for longer periods of time.

A neonate is considered to have adequacy of CPAP settings and does not require any change in FiO2 or CPAP pressure if he is hemodynamically stable and is comfortable· Additionally, the neonate has no recessions and is not grunting. Saturations by pulse oximetry are between 90%and 95%· Blood gas done shows a pH of between 7.35 to 7.45, PaO2 of between 60 to 80 mmHg and PaCO2 of between 40 and 60 mmHg· Monitoring of the CPAP system includes recording the CPAP pressure, FiO2 and flow rate [35]. Weaning of CPAP is done when the disease process for which CPAP is initiated is improving and the neonate is well settled. This is done by reducing FiO2 and CPAP pressure. The FiO2 is reduced in steps of 5% and then the CPAP pressure in steps of 1cm of H2O. When the CPAP pressure is 5cm and FiO2 <30% and the disease process has improved, the neonate should be removed from CPAP. After removing the neonate from CPAP, the nose should be cleared of any secretions and a frequent change in position is advised. Assessment for appropriate delivery of all components of CPAP is required before labeling CPAP failure.

Supportive care to a neonate put on CPAP entails ongoing assessment of the neonate, CPAP machine, nasal interface and ensuring early and aggressive enteral feeding. Assessment should

be ongoing, systematic, thorough and meticulous. Vitals signs need to be assessed every 2 hours and complete assessment of neonate, nasal interface and CPAP system should be done at every shift· Infant monitoring should include vital signs, assessment of all the organ systems. Respiratory monitoring should include assessment of respiratory rate, recessions, chest movements, breath sounds and assessment of Silverman Anderson score is required· Neonates need to be supported in the nesting position·

All neonates on CPAP should be fed provided there is no obvious contraindication such as necrotizing enterocolitis (NEC) or hemodynamic instability. To prevent CPAP belly, an orogastric tube should be inserted immediately after initiating CPAP and it should be above the level of stomach and kept open after an hour of feeding. Feeding a neonate who is on CPAP with an orogastric tube and prevention of CPAP belly has shown to improve the overall success of CPAP. Laboratory tests like full hemogram, c-reactive protein, Blood cultures need to be done initially before placing the neonate on CPAP in order to determine the cause of respiratory distress in the neonate.

Proper prong size selection is required, to avoid one that is too small but it should fit the entire nares without the external nares being blanched. An Appropriate size avoids prong displacement, excessive air leaks and increasing the imposed work of breathing(45). The nasal airway should be evaluated for skin breakdown when the neonate is suctioned. Specific guidelines for selecting the proper prong size and hat are given by manufacturers. The straps which should connect to the nasal interface should be adjusted to apply minimal tension on the nasal anatomy of the neonate and the hat should be tight. Nasal interface displacement, loss of system pressure and nasal injury could result from prongs that are moving excessively due to lack of stabilization(2).

2.6 Complications of Using CPAP Incorrectly

Nasal airway injury, air leak and equipment failure are the most common complications related to CPAP use. Mucus plugging can block the prongs or the prongs can be pushed in too far into the nasal mucosa causing deterioration and increased WOB due to reduced end–expiatory lung volume(45,46). The nasal septum may be traumatized and may be irritated (47,48)from lack of proper placement or misalignment of the prongs(49).

Nasal mask use can cause nasal septum breakdown and erosion can occur even after short periods of being on CPAP due to necrosis at the columella (50). Nasal prongs can cause nasal widening and snubbing if CPAP is used for many days. Mucosal damage can result from inadequate humidification in the humidifying chamber(51). Head and neck irritation of the

skin from can result from improperly fixed head hats. When a neonate is complicating while on CPAP equipment, failure and dysfunction should always be considered as a potential source of the problem(2).

Air leak can also occur when high CPAP level is not accurately used. Pneumothorax(46,48,52), pneumomediastinum, pneumatocele(53–57) and vascular air embolism(58) has been reported with this treatment(59). CPAP has been reported to cause raised intracranial pressure (60) reduced urine output and reduced glomerular filtration rate (61). Abdominal distension due to swallowing of air occurs in neonates receiving this treatment, orogastric tube is used to relieve the distension(62).

2.7 Outcome

Globally, neonatal mortality attributable to complications of prematurity is at 28.6% and RDS is the condition that is mostly associated in preterm neonates (63). More than 50% of babies born at 31 weeks of gestation will develop RDS. Neonatal pneumonia and neonatal sepsis is associated with more than 80% of respiratory distress(63). Respiratory distress treatment using CPAP is recommended by WHO (12). *Jennifer et al* in Kijabe showed that early diagnosis and correct treatment have shown to have good outcomes(64). A study done by *Catreen F Mousa et al* on audit of CPAP in a NICU in Assiut University Children Hospital from June 2015 to January 2017 in 69 neonates reported that: outcome of CPAP use was good as improvement was noted in 58.3% cases and failed in 41.7% of cases. She also reported that using CPAP in neonates with respiratory distress in the hospital partially followed the guidelines recommended. An audit on adherence of the European consensus guidelines done in UK by *Tanney et al* noted that 75% of the neonates were managed as per the guidelines of CPAP use(17).

2.8 Strategic Importance and Experience at KNH

- KNH is a big training institution hence adherence to guidelines and proper documentation of findings impacts heavily on students and their practice later country wide.
- KNH is a very busy hospital with heavy workload. It has a lot of complicated cases since it’s the National referral and teaching hospital.
- There are constraints due to the limited number of CPAP machines.

2.9 Problem Statement

Approximately 2.6 million neonatal deaths occur yearly worldwide. The majority of neonatal deaths occur because of prematurity, intrapartum related conditions, and infections. The case fatality rate is as high as 20% in low resource settings and acute respiratory distress is common to these causes of death. Globally, neonatal mortality attributable to complications of prematurity is at 28.6% and RDS is the single most common condition in preterm infants. More than 50% of babies born at 31 weeks gestation will develop RDS. Neonatal pneumonia, most cases of neonatal sepsis are associated with more than 80% of respiratory distress. Survival in western countries has improved through the administration of surfactant, mechanical ventilation use or conventional CPAP.

Treatment options of RDS in low-resource settings such as Kenya is extremely limited since neither surfactant nor ventilation nor machine- generated CPAP is widely available or affordable and is technically complex. CPAP is safer than mechanical ventilation due to its lower incidence of chronic lung disease and it can be administered easily by trained nurses. It reduces up-referrals and hospital stay. The first choice for ventilatory support in tertiary centers has been increasingly CPAP due to its advantages over mechanical ventilation.

Reduction in ventilation and neonatal intensive care unit admissions as well as decrease in poor outcomes associated with prolonged ventilation could result in reduced costs of neonatal care with the successful use of CPAP. The use of CPAP for the management of preterm neonates with respiratory distress is recommended by World Health Organization (WHO). This study aims to assess the use of CPAP and the adherence to the recommended Ministry of Health guidelines.

2.10 Study Justification and Utility

At KNH, the Ministry of Health Basic Pediatrics Protocol of 2016 formed from the WHO guidelines where CPAP use was introduced have been incorporated in the hospital Standard Operating Procedures (SOPs). More than 85% members of staff have undergone training on Emergency Triage Assessment and treatment plus admission (ETAT+) in which CPAP use forms a critical component of training and they use the Ministry of Health Basic Protocol 2016 as the guideline(12).

The extent to which use based on the Ministry of Health protocol was practiced in this hospital was unknown. No study had been carried out to assess the use of CPAP at KNH and how it compares to the Ministry of Health protocol. Therefore, it was important to systemically evaluate the use of CPAP and determine areas which require improvement so as to improve our

knowledge, inform our ways of practice and to help correct errors. This study has provided baseline data for further studies carried out in the future in our region. Additionally, this will help guide our clinicians in implementing the guidelines so as to improve patient care.

Audit in a hospital setting will be extremely valuable as it evaluates real-time clinical practice and provides immediate feedback to the staff in the unit which in turn improves the quality of care(13). Moreover, this method, which is applied by clinical staff only requires simple training and involves a low cost of implementation. This study will serve as an advocacy tool by highlighting challenges and experiences.

2.11 Study Question and Objectives

2.11.1 Study Question

To what extent does CPAP use at Kenyatta National Hospital Newborn Unit follow the MOH basic pediatrics protocol guidelines?

2.11.2 Objectives

2.11.2.1 Broad Objective

To assess the adherence of medical staff to the guidelines and protocols for using CPAP in the newborn unit at Kenyatta National Hospital.

2.11.2.2 Specific Objectives

- To describe the current practices of CPAP use at Kenyatta National Hospital Newborn unit.
- To determine the proportion of neonates in Kenyatta National Hospital Newborn unit that are appropriately managed according to the Ministry of Health CPAP guidelines.

3.0 CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study Design

This was a prospective audit of care on neonates who were put on CPAP at KNH newborn unit. The method of data collection was prospective. Neonates admitted at the NBU and were put on CPAP were enrolled into the study at admission and an audit on the use of CPAP was assessed and the proportion of newborns who received CPAP treatment consistent with Ministry of Health (MOH) Basic Paediatrics Protocol 2016 guidelines which is adopted by KNH NBU was determined. Informed consent was obtained from each parent enrolled in the study. Data were abstracted from files (admission records) of neonates who met the inclusion criteria after review by the admitting doctor. Information regarding patient's demographic data, neonatal history, clinical signs examined, laboratory and radiological investigations requested, CPAP use (initiated settings, monitoring of neonate and CPAP equipment interface) was abstracted from files using a structured questionnaire. Review of the files was done daily to check if CPAP settings were changed, neonate was removed from CPAP, died, weaned from CPAP or changed to another method of respiratory support and neonate monitoring based on clinical condition of the neonate. Data on weaning neonate off from CPAP was also collected.

3.2 Study Period

This study was carried out over a period of 3 months from January to April 2021.

3.3 Study Site

The study site was the NBU of Kenyatta National Hospital. Kenyatta National Hospital, the largest teaching and referral hospital located in Upper hill, 4 kilometers from the central business district in the capital city of Kenya. Approximately 20-30% of patients are referrals from other facilities. All the sick neonates born in KNH are admitted to NBU. NBU admits neonates who are born elsewhere within the first 24 hours of life and also handles transfers from other hospitals even if the neonate is more than 24 hours old. KNH NBU admits on average 250 neonates per month, the ones admitted due to respiratory distress who may need CPAP or other forms of respiratory support account for approximately 40-50 neonates per month. This unit comprises of an admission area, neonatal intensive care unit, high dependency unit, rooms with incubators and cots for care of the preterm babies stratified by birthweight, an isolation room and a room for stable babies awaiting discharge. All neonates admitted at the unit are received by the nurse at the admission area and a pediatric resident who is also present for the purpose of taking a history, carrying out a clinical examination and initiating

management of these newborns. Part of the management team in this unit are consultant pediatricians and neonatologists who carry out daily ward rounds at the admission area before the newborns can be transferred out to other rooms for continuum of care.

3.4 Study Population

The study population was all consecutively admitted neonates who were put on CPAP in the newborn unit at KNH during the study period.

3.4.1 Inclusion Criteria

- All neonates who were put on CPAP.
- Neonate whose parents/guardian had given informed written consent for inclusion into the study.

3.4.2 Exclusion Criteria

- Neonates of age more than or equal to 28 days of age.
- Neonates who had respiratory distress receiving other methods of respiratory support rather than CPAP.

3.5 Sample Size Calculation

The sample size was estimated using the Fischer's Formulae:

$$n = \frac{Z^2\, p\,(1-p)}{d\,2}$$

$$n = \frac{1.96^2 \times 0.75\,(1-0.75)}{(0.1)^2} = 72$$

n = **72**

Given an estimated prevalence (p) of 75% adherence based on the study by Tanney et al in the UK and a level of precision of 10%.

n = estimated sample size

Z = standard normal deviate for 95% Confidence level (set at 1.96)

p =From an audit on adherence of the European consensus guidelines done in UK by Tanney et al noted that 75% of the neonates were managed as per the guidelines of CPAP use

d = precision set at 10%

N= estimated target population

3.6 Study Tools

A standardized questionnaire was used to collect data from enrolled participants.

The questionnaire included:

- Demographic data of the neonate (age, birth weight, sex, gestational age).
- An assessment on documentation of clinical signs examined, laboratory and radiological investigations requested, CPAP initiated settings, neonate examination and CPAP interface.
- Daily assessment of the CPAP settings based on the clinical condition of the neonate. This done till the neonate was discharged from CPAP or died.

The questionnaire was pretested in the newborn unit in KNH among neonates who were on CPAP.

3.7 Study Personnel

a) The principal investigator- oversaw collection of data together with the two research assistants. All data collected were entered into the computer daily until the neonate was discharged from CPAP or died.

b) Research assistants- were two clinical officers who were trained on collection of data. They were informed about the purpose of the study.

3.8 Study Outcome

- Expected primary outcome was either good or poor adherence to the Ministry of Health Basic Paediatrics Protocol (2016) and it included the following composite indicators of CPAP use among neonates aged 0-28 days being admitted to KNH NBU.
    - Indication for starting CPAP.
    - CPAP settings initiated and monitoring of progress of neonate and change in CPAP settings.
    - Laboratory/ radiological investigations done.
    - Weaning off CPAP.

Table 1:summary of indicators of study outcome

Indicator	**Parameter**	
Indication for CPAP	-Birthweight - > 1000g -SAS Score >/= 4 -APGAR Score >/=4 at 5minutes	
CPAP Settings	Equipment	-FiO2 -PEEP -PIP *All should be captured
	Baby	-Nasal prong size or position -Head position -Water level in pressure generating bottle -Gas tube placement -Vitals- temp, HR, RR, Pulse Oximetry (All 3 hourly) *All should be captured
Laboratory /Radiology	-FHG -CRP -RBS -BGA -Blood Culture -Chest xray	*All should be done at least once during the period on CPAP treatment or was done on admission
Weaning	-Adherence– gradual or failed -No adherence	

3.9 Study Procedure

3.9.1 Screening

The principal investigator and the two research assistants reviewed the records of all neonates admitted daily in order to identify those that were eligible for the study. Neonates who met the inclusion criteria were enrolled into the study.

3.9.2 Sampling

Consecutive sampling was done until the sample size was achieved. A written consent was acquired from the parent/guardian after explaining the purpose of the study, its benefits and risks in English or Kiswahili. Once the patients were enrolled into the study, demographic data were noted down in the questionnaire. This included study identity number, age, sex, gestational age, birth weight. Files (admission records) were audited for documentation of clinical signs examined, laboratory and radiological investigations requested, indication for CPAP use, CPAP settings initiation by using the assessment tool. All the information was noted down on the questionnaire. The daily record of the neonate was reviewed to include the duration of CPAP use, change of settings, if CPAP was continued or changed to another form of respiratory support, or until neonate death or discharge from CPAP.

3.9.3 Confidentiality and Privacy

All patient information was handled with strict confidentiality. The data were stored in password protected files on a computer. Patients were identified by unique study number their names did not appear on the data collected.

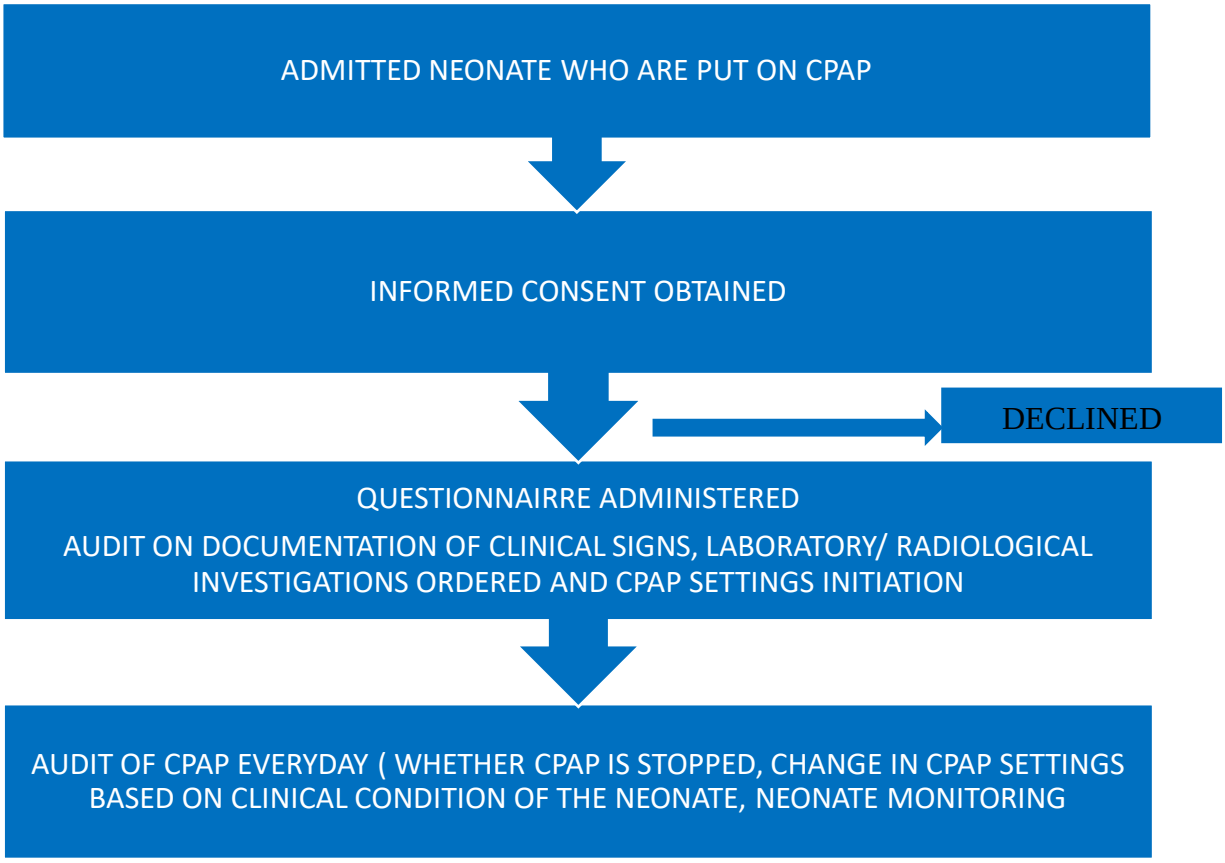
3.9.4 Safety of Medical Records

Patient records were not to moved out of NBU, relevant data were abstracted and entered into questionnaires which were stored in lockable cabinets. All electronic versions of the data were protected by passwords with restricted access.

3.9.5 Non-Interruption of Services

Data were collected after daily ward round after treatment was given to prevent interruption of work.

3.10 Study Flowchart



3.11 Data Collection, Management and Analysis

3.11.1 Data Collection

After identification of eligible participants, data were collected ,using a questionnaire as described in the study tool from identified neonates whose parent/ guardian gave informed written consent.

3.11.2 Data Management

Data were checked for completeness, accuracy and consistency. Collected data were entered in MS-EXCEL computer storage program daily until upon discharge from CPAP or death of the study participant. Data verification was done manually by proof reading. The data were stored in confidentiality preventing inappropriate use of data by use of passwords. Only the principal investigator and research assistants had access to the data. Data were protected throughout the data cycle from creation to destruction and prevented from unauthorized sharing.

3.11.3 Data Analysis

Data analysis was done using STATA software package. Continuous variables were summarized using medians (ranges) and means (standard deviation). Categorical variables were provided as frequency distributions using graphs or tables. I recorded the number of neonates whose CPAP use complied with the Kenyan national recommendations. The data collected on the audit of CPAP use was contrasted with the recommended Kenyan national guidelines. The proportion of correct CPAP use was determined by a 95% confidence interval.

3.12 Ethical Consideration

a) Permission was obtained from KNH Ethics and Research Committee to carry out the study (Appendix VII). Copies of the protocol and the consent form were given to the above-named committee for written approval prior to commencing the study.

b) A full explanation of the study was given to the parents/ guardians and written consent in English or Kiswahili signed by the parent/ guardian was obtained to participate in the study.

c) All patient information was handled with strict confidentiality. The data were stored in confidentiality preventing inappropriate use of data by use of passwords. Only the principal investigator and research assistants had access to the data.

d) Each patient was identified by a unique study number.

e) During auditing, if any life-threatening condition was identified it was communicated to the ward clinician and resuscitation and emergency care was done if indicated.

f) The overall study findings were availed to the specialists and staff, thereby contributing to the improvement of care delivered to this subset of neonates. The study findings were also presented to the University of Nairobi (UON) Department of Paediatrics and Child Health Academic Staff and Students in fulfillment of the requirements of the MMed Program.

3.13 Control of Bias and Errors

a) Measurement bias- the questionnaire was pretested to reduce bias, ensuring the questions were sensitive enough. Training the research assistants on the data collection procedure will also reduce bias.

b) Selection bias- only those neonates who met the inclusion criteria were included in the study. KNH is a tertiary hospital and the majority of the patients are referred due to their illness severity.

c) Information bias- was reduced by assessing the responses given in the questionnaire daily during data entry to ensure validity of data collected.

d) Recall bias- only relevant recorded data were obtained from the documents.

4.0 CHAPTER FOUR: RESULTS

4.1 Socio-demographic Characteristics of Study Population

A total of 72 neonates aged 0 to 28 days admitted were enrolled in the study. The greatest proportion of neonates were preterm 64(88.9%). Most neonates 53(73.6%) had a weight of more than 1000g. Out of the total neonates 43(59.7%) were male and 29(40.3%) were female.

Table 2: Recorded neonate demographic information

Gestational age	**Frequency**	**Percent**
Range, *median (IQR)*	32 (30-34)	
Preterm (less than 37 weeks)	64	88.9
Full term (more than or equal to 37 weeks)	8	11.1
Birth weight		
Mean +-SD	1039 ± 500	
Less than 1000g	19	26.4
More than 1000g	53	73.6
Gender		
Male	43	59.7
Female	29	40.3

4.2 Documentation on Neonate History

There was no difference in the mode of delivery of neonates as SVD and cesearean sections were each at 36(50%). Neonates with documented diagnosis of fetal hypoxia were 32(44.4) while 40(55.6%) did not have fetal hypoxia. Neonates weaned from mechanical ventilation were 7(9.7%) while 65(90.3%) were not weaned from the ventilator.

Table 3: Recorded Data about Neonate History

	No.	%
Mode of delivery		
SVD	36	50.0
CS	36	50.0
Diagnosis of fetal hypoxia documented in the notes		
Yes	32	44.4
No	40	55.6
History of weaning from mechanical ventilation		
Yes	7	9.7
No	65	90.3

4.3 Audit on Documentation for Indication of CPAP Use

The commonly documented indication of CPAP use was based on the Apgar score of the neonates (documented in 100%) and SAS score (documented in 54.2%) and weight>1000g in 73.6%.

Table 4: Indication for CPAP use

	Adherence		**No adherence**	
	No.	%	No.	%
Apgar score *n (%)*	72	100.0	0	0.0
SAS score *n (%)*	39	54.2	33	45.8

4.4 Audit on Documentation of Examination Findings

The examination findings least documented by clinician on admission were apnea at 21 (29.2%), upper chest wall retraction at 38 (52.8%). Signs of respiratory distress were recorded in >70%. Systemic examination was done in most neonates with chest examination done in 72 (100%) of the neonates.

Table 5: Recorded data about examination by admitting doctor in studied cases

Examination	**Adherence**		**No adherence**	
	No.	**%**	**No.**	**%**
Pulse rate (Resting) (b/m) *n (%)*	69	95.8	3	4.2
Xiphoid retraction *n (%)*	68	94.4	4	5.6
Respiratory rate (c/m) *n (%)*	67	93.1	5	6.9
Oxygen saturation *n (%)*	67	93.1	5	6.9
Nasal flaring *n (%)*	67	93.1	5	6.9
Lower chest wall retraction *n (%)*	61	84.7	11	15.3
Temperature (Core) (c) *n (%)*	45	72.5	27	37.5
Grunting *n (%)*	51	70.8	21	29.2
Upper chest wall retraction *n (%)*	38	52.8	34	47.2
Apnea *n (%)*	21	29.2	51	70.8
	Normal		**Abnormal**	
Chest exam *n (%)*	72	100.0		
Abdominal exam *n (%)*	71	98.6	1	1.4
Cardiac exam *n (%)*	70	97.2	2	2.8

4.5 Assessment of Investigations Done at Admission (Pre-Connection)

Blood culture was done in 5 (6.9%) of neonates on admission, chest xray done in 7 (9.7%) while full hemogram and C reactive protein were done in 71 (98.6%) and 56 (77.8%) respectively.

Table 6: Recorded data about investigations (pre connection)

	Adherence		No adherence	
	No.	**%**	**No**	**%**
Full hemogram *n (%)*	71	98.6	1	1.4
C reactive protein *n (%)*	56	77.8	16	22.2
Blood Sugar *n (%)*	45	62.5	27	37.5
Blood gas analysis *n (%)*	15	20.8	57	79.2
Chest Xray n *(%)*	7	9.7	65	90.3
Blood culture *n (%)*	5	6.9	67	93.1

4.6 Audit on Documentation of CPAP Equipment Monitoring During Use

According to Kenyan guidelines Basic Paediatric Protocol 2016 monitoring of the equipment during use should be done. Overall documentation of equipment use was very poor. Documentation of FiO2 was at 56 (77.8%), PEEP 48 (66.7%), PIP 41 (56.9%). There was no documentation on nasal prong size/position, head position, water level in the pressure generating bottle in all the neonates.

Table 7: Monitoring of CPAP equipment during use

	Adherence	**No adherence**
FiO2 *n (%)*	56 (77.8)	16 (22.2)
PEEP *n (%)*	48 (66.7)	24 (33.3)
PIP *n (%)*	41 (56.9)	31 (43.1)
Nasal prong size/position *n (%)*		72 (100.0)
Head position *n (%)*		72 (100.0)
Water level in the pressure generating bottle *n (%)*		72 (100.0)
Gas tubing correctly placed *n (%)*		72 (100.0)

4.7 Audit on CPAP monitoring over 4 days

Overall monitoring of CPAP equipment over 4 days was poor.

At 24 hours- For 49 (68.1%) neonates' equipment was monitored.

At 48hours- For 40 (65.6%) neonates' equipment was monitored.

At 72 hours- For 37 (68.5%) neonates' equipment was monitored.

At 96 hours- For 17(31.5%) neonates' equipment was monitored.

Table 8: Overall monitoring of CPAP equipment

		At 24 hours n=72 No. %	At 48 hours n=61 No. %	At 72 hours n=54 No. %	At 96 hours n=42 No. %
Documentation of progress	Yes	72 100	61 100	54 100	42 100
	No				
Condition of the neonate	Still on CPAP	61 84.7	54 88.5	42 77.8	23 54.8
	Removed from CPAP		1 1.7	9 16.6	11 26.1
	Dead	11 15.3	6 9.8	3 5.6	8 19.1
Neonate monitoring vitals-3hourly	Yes	71 98.6	61 100	54 100	42 100
	N/A	1 1.4			
CPAP adjustment monitoring (FiO2, PEEP)	Yes	49 68.1	40 65.6	37 68.5	30 71.4
	No	23 31.9	21 34.4	17 31.5	12 28.6

4.8 Audit on Documentation on Investigations for Follow Up

Pulse oximetry was done in almost all 71 (98.6%) neonates, chest xray was done in 24 (33.3%) neonates and BGA was least done in 18 (25%) of neonates.

Table 9: Recorded information on investigations for follow up

	Adherence	**No adherence**	**No Info**
Pulse oximeter *n (%)*	71 (98.6)		1 (1.4)
CXR *n (%)*	24 (33.3)	29 (40.3)	19 (26.4)
BGA *n (%)*	18 (25.0)	39(54.2)	15 (20.8)4)

4.9 Audit on Documentation of Weaning

Documentation on weaning was done in 33 (45.8%) it was gradual and successful in 17 (23.6%) and it failed in 16 (22.2%).

Table 10: Audit on weaning from CPAP

	Adherence	**No adherence**
Weaning *n (%)*	33 (45.8)	39 (54.2)
If weaned	**Frequency**	**Percent**
Gradual and successful	17	23.6
Failed	16	22.2
N/A	39	54.2

Appropriate CPAP use in KNH NBU as per the Kenyan guidelines (Basic Paediatrics protocol 2016) in this study was at **75.2%.**

5.0 CHAPTER FIVE: DISCUSSION

This study was carried out to audit the use of CPAP against recommended Kenyan guidelines in NBU at KNH a national referral hospital in Kenya. This was the first audit study done in this unit on CPAP use after CPAP machines were introduced in the unit.

Complete documentation of examination findings was not done in all the 72 neonates who were put on CPAP. Indication of CPAP use, like SAS score, CPAP equipment monitoring like FiO2 was also documented poorly. Christopher et al in Wales also noted poor documentation of findings in patient records FiO2(65). This may be because documentation was not done in a structured neonatal admission record. It was presumed that examination findings like apnea and upper chest wall retraction were only documented if they were present, it may be because documentation was not structured in the admission records.

A study done by Dewez JE et al in 2020 on CPAP use in India also showed poor documentation of respiratory distress which was practiced in only half the hospitals that were studied(19). An audit done by Catreen F Mousa et al in Egypt also noted a big defect in recording of patient findings in the patient record(16). This was also noted in an audit study done by Nabwera et al which also noted a deficit in documentation of patient features(14).

From our study monitoring of equipment was noted to be poor despite the availability of equipment, this was also seen in the study in India by Dewez et al 2020 who noted basic equipment of monitoring was available but the monitoring was limited(19). This may be attributed to the limited number of workforce who are required to do the monitoring.

In our study weaning from CPAP was gradualand successful in 23.6% of cases by using the guidelines. This is lower compared to the study done by Catreen et al in Egypt where in their case weaning from CPAP was gradual and successful in 58.3% of cases by using the guidelines. In our study failure of weaning from CPAP occurred in 22.2% of cases. Our results agreed with that represented by Maiya et al., 2009(66) who found that failure in weaning was in 20%. This failure of weaning could be attributed to failure in the CPAP system which resulted in sudden disconnection of CPAP to connect the patient to mechanical ventilation or death. This failure could also be related to low gestational age (28wks or less) and low birth weight especially from 750 grams to 1250 grams.

Other studies supporting weaning as gradual such as Todd et al., 2012(67) study stated that weaning should be done when neonates were clinically stable on CPAP 4-6cm with FiO2 <25% for at least 12 hoursand that method (Taken 'OFF' CPAP with theview to stay 'OFF' completely) significantly shortened CPAP weaning time, CPAP duration, oxygen duration,

BPD and length of admission.

In our study appropriate CPAP use as per the Kenyan guidelines (Basic Paediatrics Protocol-2016) was at 75.2% and was agreeable to the study done by Tanney et al in the UK at 75% based on adherence of the European consensus guidelines (17). This study was also supported by Catreen et al, 2018 done in Egypt who noted standard guidelines of CPAP use in the Assuit University hospital partially followed the reference guidelines and they used the American association respiratory care and Queensland clinical guidelines which was the adapted protocol of using CPAP(16). Higher adherence to standard guidelines, contrary to our study was by Chritopher et al 2020 in Wales who did a full audit cycle of quality of improvement on management of RDS before and after introduction of the guidelines in 2015 and 2018 respectively, on CPAP use and they noted an improvement on adherence to CPAP use from 93% to 98%(65). A study done by Dewez JE, Nangia S et al 2020 in India which looked at the availability and use of CPAP for neonatal care in public facilities in line with standards guidelines noted a lower adherence compared to our study at 31% in the public health facilities studied.(19). Complete adherence to guidelines was shown to increase CPAP success with a reduction in need of mechanical ventilation.

5.1 Study Strengths

a) The findings of this study will provide valuable information for improving use of CPAP in neonates.

b) The audit will guide uptake and implementation of the recommended standard guidelines.

5.2 Study Limitations

i. Proper documentation was a limitation. Being an audit study, results only reflected what was documented. Due to poor documentation, may be tasks were done and not documented, thus the results might be affected. To mitigate it a general talk was given before completion of the study on proper documentation.

ii. Hawthorne effect: Staff might have switched their way of practice when they came to know about the study.

iii. Small number of CPAP machines in the newborn unit.

iv. Bias

a) Measurement bias- to reduce bias the questionnaire was pretested, ensuring the questions are sensitive enough. Training the research assistants on the procedure of data collection also reduced bias.

b) Selection bias- only those neonates who met the inclusion criteria were included in the study. KNH is a national referral hospital and a large number of the patients are referred due to their illness severity. Generalization was a problem as the NBU is a specialized unit.

c) Information bias- was reduced by assessing the responses given in the questionnaire daily during data entry to ensure validity of data collected.

d) Recall bias- only relevant recorded data were obtained from the documents.

CHAPTER 6: CONCLUSION, RECOMMENDATION, CONFLICT OF INTEREST AND STUDY DISSEMINATION PLAN

6.1 Conclusion

- There was poor documentation on indication of CPAP use like SAS score which was documented in only 54.2% of the neonates who were put on CPAP.
- Appropriate CPAP use as per the Kenyan guidelines (Basic Paediatrics protocol 2016) in this study was at 75.2%.
- No recording was done on the parameters on neonate connection to the CPAP machine.
- Investigations at admission and those required for follow up of the neonate was suboptimal.
- Weaning was not recorded in most neonates at 54.2% and it was gradual and successful in only 23.6%.
- A study in Wales by Christopher et al on a full audit cycle of a quality improvement project showed significant improvement in care after guidelines were introduced(65).

6.2 Recommendations

- Following the guidelines about indications, contraindications, and investigations of the use of CPAP.
- Recording all the data in the patient sheet as there is a big defect in recording data especially data of CPAP set up and monitoring.
- Considering addition of master sheet containing data about CPAP set up and monitoring to patient sheet to ensure recording of all these data so not to be missed.
- Clinical monitoring and regular check of CPAP systems during use must be done as per the guidelines to ensure good results.
- Ensure availability of adequate number of CPAP machines.

6.3 Conflict of Interest

There was no conflict of interest.

6.4 Study Dissemination Plan

The study findings were presented to the UoN department of Paediatrics as part of the requirements of the Masters of Medicine Program in both hard and soft copies. Hard copies of the results shall be sent to the University of Nairobi repository for storage. The findings were also shared with the office of the head of department Paediatrics in KNH with a view of dissemination of the new knowledge that has been generated to improve patient care. The findings shall also be submitted for publication in peer reviewed scientific journals.

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APPENDICES

AUDIT ON THE USE OF CPAP AT KENYATTA NATIONAL HOSPITAL NEWBORN UNIT

Appendix I: Assessment Tool

Instructions: Tick/circle appropriately as required and fill in the details or measured values where applicable.

Neonate demographic information

1. Study No**:**
2. Date of data collection:
3. Date of admission:
4. Time of admission:
5. Date of birth:
6. Sex: Male Female
7. Gestational age (weeks):
8. Postnatal age (days):
9. Birth weight (grams):
10. Admission weight (grams):
11. Date of discharge/death:
12. Apgar score: No information:
13. Mode of delivery: SVD C/S Vacuum Forceps
14. History of fetal hypoxia: Yes No
15. History of weaning from mechanical ventilation: Yes No

Indication for CPAP use

Whether the following indications were noted or not?

Weight	Present	Absent	No information
Apgar score	Present	Absent	No information
SAS Score	Present	Absent	No information

Clinical features (signs/ symptoms) requiring CPAP

Whether the following clinical features for CPAP use were noted by the clinician or not?

Temperature(*C)		No information
Pulse rate(beats/min)		No information
Respiratory rate(breaths/min)		No information
Oxygen saturation		No information
Lower chest wall retraction	Yes No	No information
Upper chest wall retraction	Yes No	No information
Xiphoid retraction	Yes No	No information
Nasal flaring	Yes No	No information
Grunting	Yes No	No information
Apnea	Yes No	No information
Chest exam Normal	Yes No	No information
Abnormal	Yes No	No information
Abdominal exam Normal	Yes No	No information
Abnormal	Yes No	No information
Cardiac exam Normal	Yes No	No information
Abnormal	Yes No	No information

Laboratory/ radiology investigations (pre connection)

Whether the following tests were ordered?

Full hemogram	Yes	No	No information
C reactive protein	Yes	No	No information
Blood gas analysis	Yes	No	No information
Blood sugar	Yes	No	No information
Blood culture	Yes	No	No information
Chest Xray	Yes	No	No information

Other Investigations (specify): 1. 2. 3.

CPAP setting at admission

FiO2	Recorded	Not recorded
PEEP	Recorded	Not recorded
PIP	Recorded	Not recorded
Nasal prong size/position	Recorded	Not recorded
Head position	Recorded	Not recorded
Humidifier water level	Recorded	Not recorded
Gas tubing placed correctly	Recorded	Not recorded

Audit at 24 and 48 hours

	At 24 hours	**At 48 hours**
Documentation of progress	1.Documented? 1) YES 2) NO Clinical condition 1) Still on CPAP 2) Removed from CPAP 3) Dead	1.Documented? 1) YES 2) NO Clinical condition 1) Still on CPAP 2) Removed from CPAP 3) Dead
CPAP settings	**Neonate monitoring** 1. Yes 2. NO **CPAP adjustment/monitoring (FiO2, PEEP)** 1. Yes 2. No	**Neonate monitoring** 1. Yes 2.NO **CPAP adjustment/monitoring (FiO2, PEEP)** 1.Yes 2. NO

Audit at 72, 96 hours, discharge from CPAP/death

Documentation of progress	1. Documented? 3) YES 4) NO Clinical condition 4) Still on CPAP 5) Removed from CPAP 6) Dead	1.Documented? 5) YES 6) NO Clinical condition 7) Still on CPAP 8) Removed from CPAP 9) Dead	
CPAP settings	Neonate monitoring 3. Yes 4. NO CPAP adjustment/monitoring (FiO2, PEEP) 1. Yes 2. NO	Neonate monitoring 5. Yes 6. NO CPAP adjustment/monitoring (FiO2, PEEP) 1. Yes 2. NO	

Audit on investigations for follow up

BGA	Yes	No	No information
CXR	Yes	No	No information
Pulse oximeter	Yes	No	No information

Audit on weaning from CPAP

Weaning	Recorded	Not recorded
Gradual and successful		
Failed		

Appendix II: Consent Document and Form

Consent document information in English

Date:

Study Title: AUDIT ON CPAP USE AT KENYATTA NATIONAL HOSPITAL NEWBORN UNIT

Investigator: Dr. Zena Ali Jeizan

Paediatric resident, University of Nairobi

P.O Box 41922-80100, Mombasa.

Mobile: 0726677444

Email: zenaali60@gmail.com

Supervisors:

Professor Grace Irimu

Professor, Department of Paediatrics and Child Health

University of Nairobi P.O Box 49872.

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Dr. Florence Murila

Senior Lecturer, Department of Paediatrics and Child Health

University of Nairobi P.O Box 49872.

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or

Kenyatta National Hospital/University of Nairobi-Ethics and Research Committee

College of Health Sciences

Telephone: (+254-020) 2726300-9, extension 44355

P. O Box 19676-00202, Nairobi.

Email: uonknh_erc@uonbi.ac.ke

Introduction

I am a postgraduate student at the University of Nairobi, pursuing studies leading to specialization in Paediatrics and Child Health. I wish to request your permission, for your baby to participate in a study that will form part of my degree work. The purpose of the consent form is to provide you with information that you will need to help you decide whether to participate in the study. Kindly read the information in this consent form carefully and ask questions or clarifications on any matter pertaining to the study. This process is termed "informed consent". The study will involve evaluation of files for documentation on CPAP use. This will be recorded and analyzed for research purposes only.

Purpose of the Study

The purpose of this study is to evaluate CPAP use in neonates. It will provide information on the current practices on CPAP use and the steps that need to be taken to improve on CPAP use. The information gathered will help in improving knowledge and correct errors on the use of CPAP.

Background

Respiratory support to manage acute respiratory distress in neonates can be provided by CPAP or mechanical ventilation. Mechanical ventilation entails endotracheal intubation, an invasive procedure requiring advanced technical skills and is expensive. CPAP has become widely used and accepted as a treatment for RDS since its first introduction in 1971 by *Gregory et al*. CPAP is a relatively simple and cheap intervention that saves lives.

Study Procedures

Neonates aged 0 to 28 days being admitted to KNH, NBU will be included in the study. Files of the enrolled participants will be evaluated for neonatal assessment, investigations requested and CPAP indication and settings after obtaining an informed written consent from the parent/ guardian. Review of the files will be done daily until upon discharge from CPAP or death. The data will be filled in the questionnaire.

Benefits

The results of this study will inform clinicians on CPAP use and how to properly use it. It will provide information on current CPAP use. The results of the research will also help clinicians know the proper use of CPAP.

Risks

There will be no harm or risks anticipated to your baby during the study. There will be no invasive procedures carried out in the study that may harm your baby. Refusal to participate in the study will not alter the treatment of your child in any way.

Right of withdrawal

The study will be fully voluntary. There will be no financial rewards to your baby for participating in this study. You are free to participate or withdraw from the study at any point you feel like without any explanations. Refusal to participate in this study will not affect the management given to your baby in any way.

Confidentiality

The information obtained about your neonate will be kept in strict confidence. No specific information regarding your neonate will be released to any person without your written permission. We will however discuss general overall findings regarding all neonates assessed but nothing specific will be discussed regarding your baby's condition. Your baby's study identity number will be used for follow up in the NBU and will not be revealed to anyone.

Problems or Questions

If you ever have any queries about the study or about the use of the results you can contact the principal investigator,

If you have any queries on your rights as a research participant you can contact the Kenyatta National Hospital Ethics and Research Committee by calling 2726300, extension 44355.

Principal Investigator:

Dr. Zena Ali Jeizan
Paediatric resident, University of Nairobi
P.O Box 41922-80100, Mombasa.
Mobile: 0726677444
Email: zenaali60@gmail.com

Supervisors:

Professor Grace Irimu
Professor, Department of Paediatrics and Child Health
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Kenyatta National Hospital/University of Nairobi-Ethics and Research Committee

College of Health Sciences
Telephone: (+254-020) 2726300-9, extension 44355
P.O Box 19676-00202, Nairobi.
Email: uonknh_erc@uonbi.ac.ke

Consent Form

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

Parents/Guardian's Signature ---------- Date----------

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

Investigator's Signature---------- Date----------

Consent information document in Kiswahili

Tarehe ----------

MADA YA UTAFITI: MKAGUO WA KUTUMIA MASHINI YA KUPUMUA YA AINA YA CPAP KWA WATOTO WACHANGA KATIKA HOSPITALI YA TAIFA YA KENYATTA KATIKA WADI YA WATOTO WACHANGA.

Mtafiti Mkuu:

Dr. Zena Ali Jeizan

Mwanafunzi wa shahada kuu ya matibabu maalum ya watoto

Chuo kikuu cha Nairobi, Sanduku la posta 41922-80100, Mombasa

Simu ya mkononi: 0726677444

Barua pepe: zenaali60@gmail.com

Kiongozi:

Profesa Grace Irimu

Matibabu ya Watoto, Chuo kikuu cha Nairobi,

Sanduku la posta: 49872

Simu ya mkononi: 0722564600

Barua pepe: girimu2014@gmail.com

Dr. Florence Murila

Matibabu ya Watoto, Chuo kikuu cha Nairobi

Sanduku la posta: 49872

Simu ya mkononi: 0729430022

Barua pepe: fmurila@gmail.com

Ama

Kenyatta National Hospital/Chuo kikuu cha Nairobi Kamati ya Maadili na Utafiti

Chuo cha Sayansi cha Afya,

Simu ya ofisi (+254-020) 2726300, unganisha 44102

Sanduku la posta: 19676-00202, Nairobi

Barua pepe: uonknherc@uonbi.ac.ke

Utangulizi

Mimi ni mwanafunzi wa udhamili katika Chuo Kikuu cha Nairobi, kutafuta masomo na kusababisha utaalamu katika watoto. Ningependa kuomba ruhusa yako kushiriki kwa mtoto wako katika utafiti ambayo ni muhimu kwa kazi yangu ya shahada. Utafiti itahusisha ukaguzi

wafaili kwa kumbukumbu na maagizo ya mashini ya kusaidia Watoto kupumua ya CPAP. Hii itakuwa kumbukumbu na kuchambuliwa kwa madhumuni ya utafiti huu.

Madhumuni ya Utafiti

Madhumuni ya utafiti huu ni kukagua shughuli na maagizo ya mashini CPAP kwa Watoto wachanga dhidi ya miongozo iliyopendekezwa Kenya kati ya Watoto waliyolazwa na walioko katika wadi ya watoto wachanga katika KNH nakuamua matokeo yao kila siku. Taarifa itakayokusanywa itasaidia katika kuboresha elimu na kusahihisha makosa juu ya matumizi ya mashini ya CPAP. Itatoa taarifa juu ya usimamizi wa sasa wa mashini hiyo na hatua ambayo itaweza kuchukuliwa ili kuboresha usimamizi.

Maswala ya Msingi

Usaidizi kwa watoto kupumua unaweza kupewa kwa njia ya CPAP or mashini ya kupumua ya kuwekwa mpira njia ya kupumua. Njia ya kuwekwekwa mpira njia ya kupumua inahitaji watu waliosomea hiyo kwasababababu ina hitaji kubebea upande hiyo kwasababu ni ngumu. Mashini ya CPAP ilianza kutumiwa toka mwaka wa 1971 na *Gregory* na wenzake. Mashini ya CPAP ni njia rahisi na haihitaji pesa nyingi kutumiwa kudumisha maisha ya watoto wachanga.

Utaratibu wa Utafiti

Watoto wachanga kutoka siku ya kuzaliwa hadi siku ya ishirini na nane waliyo kwenye wadi maalum katika KNH, watukuwa kwenye utafiti. Faili ya washiriki waliojiunga zitakuwa zikikaguliwa kwa ajili ya upimaji wa utotoni, uchunguzi wa kuwekwa kwa mashini ya CPAP baada ya kupata kibali sahihi au kutiwa saini na mzazi/ anayemsimamia mtoto. Ukaguzi utafanyika kila siku. Matokeo yatajazwa katika karatasi kila siku.

Faida

Matokeo ya utafiti huu yataweza kuendeleza maarifa juu ya mashini ya CPAP. Pia kutoa taarifa juu ya usimamizi wa sasa wa mashini ya CPAP.

Hatari

Hakutakuwa na madhara au hatari yoyote kwa mtoto wako wakati wa utafiti. Hakutakuwa na taratibu vamizi kufanyika katika utafiti ambayo inaweza kumuumiza mtoto wako.

Haki ya kujiondoa

Utafiti huu utakuwa kikamilifu hiari. Hakutakuwa na tuzo ya fedha kwa mtoto wako kwa ajili ya kushiriki katika utafiti huu bila kueleza lolote. Kukataa kushiriki hakutaarithi usimamizi wa mtoto wako kwa njia yoyote.

Siri

Taarifa zitakazopatikana kwa mtoto wako zitawekwa katika ulinzi mkali. Hakuna taarifa maalum kuhusu mtoto wako itatolewa kwa mtu yeyote bila idhni yako kwa maandishi. Sisi tutajadiliana kwa ujumla matokeo ya kuhusu watoto wachanga wote lakini hakuna kitu maalum yatajadiliwa kuhusu hali ya mtoto wako. Kitambulisho maalum ya mtoto wako itatumika kwa ajili ya kufuatilia katika wadi ya watoto wachanga na sikuwa wazi kwa mtu yeyote.

Matatizo ama Maswali

Kama utakuwa na maswali yoyote kuhusu utafiti au juu ya matokeo unaweza kuwasiliana na mpelelezi mkuu, Dr. Zena Ali Jeizan kwa kupiga simu nambari 0726677444. Kama una maswali yoyote kuhusu haki yako kama mshiriki wa utafiti unaweza kuwasiliana nasi Kenyatta National Hospital, Maadili na Utafiti wa Taifa kwa kupiga 2726300, unganisha 44102.

Fomu La Kutoa Idhini Ya Kushiriki Katika Utafiti

Mtafiti Mkuu:

Dr. Zena Ali Jeizan
Mwanafunzi wa shahada kuu ya matibabu maalum ya watoto
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Barua pepe: zenaali60@gmail.com

Wasimamizi:

Profesa Grace Irimu
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Mimi---------- baada ya kupokea taarifa za kutosha kuhusu utafiti, faida na hatari NIMEKUBALI/ NIMEKATAA (weka duara kwa uliyochagua) kushiriki katika utafiti

wa mtoto wangu. Naalewa kwamba ushiriki wetu ni kwa hiari yangu na kwamba mimi niko huru kutoka wakati wowote. Nimepewa fursa ya kutosha kuuliza maswali na kutafuta ufafanuzi kuhusu somo hili na kushughulikiwa kwa kuridisha.

Sahihi ya mzazi/ mlezi---------- Tarehe----------

Mimi----------natangaza kwamba nimeelezea ya kutosha kwa mshiriki juu ya utaratibu wa utafiti, faida na hatari, na amepewa muda wake kuuliza maswali na kutafuta ufafanuzi kuhusu somo. Mimi nikamjibu maswali yote aliyotoa kwa kadri ya uwezo wangu.

Sahihi ya mpelezi---------- Tarehe----------

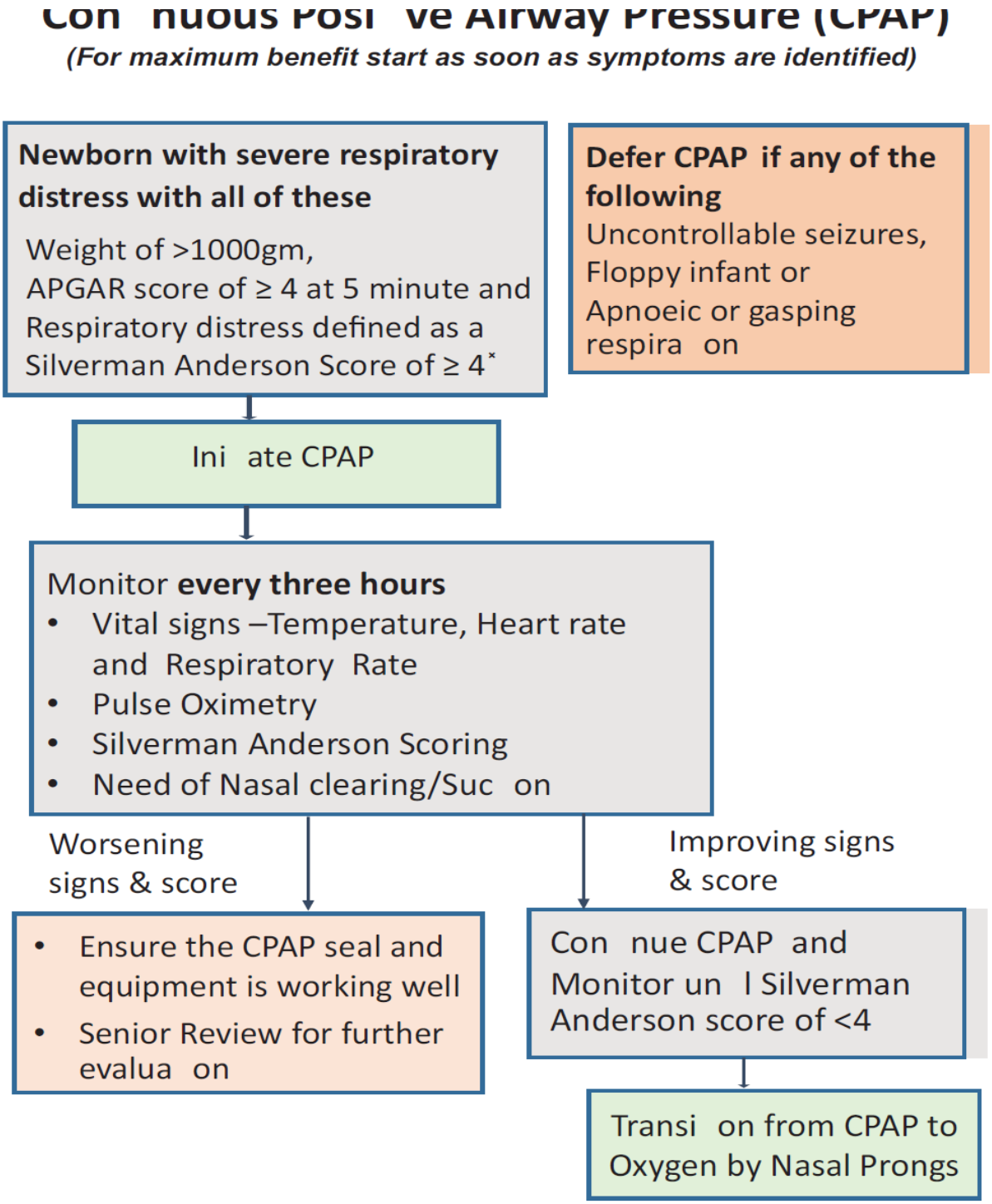
Appendix III: Study Budget

Category	Remarks	Units	Unit Cost (KShs)	Total (KShs)
Proposal Development	Printing drafts	500 pages	5	2,500
	Proposal Copies	10 copies	350	3,500
Data Collection	Stationery Packs (Pens, Paper and Study Definitions)	20	100	2000
	Research assistants	2	8000	16000
Data Analysis	Statistician	1		30,000
Thesis Write Up	Computer Services			5,000
	Printing drafts	1000 pages	5	5,000
	Printing Thesis	10 copies	500	5,000
Contingency funds				20,000
Total				**89,000**

Appendix IV: Time Frame

Number	Activity	Estimated Time
1	Proposal Development and Presentation	Jan 2020
2	Submission of proposal for ethical approval	September 2020
3	Ethical corrections, pretesting and seeking permission	October to December 2020
4	Data Collection	January to March 2020
5	Data Analysis	April 2020 – June 2021
6	Thesis writing	July to November 2021
7	Thesis submission	December 2021

Appendix V: Continuous Positive Airway Pressure (CPAP)



ADDITIONAL CARE (for babies on CPAP)

- Insert an orogastric tube for stomach decompression and feeding. *(Leave the tube open to allow gas to escape)*
- After taking a sepsis screen including blood culture start antibiotics.
- **Initiate enteral feeding by day 2-3:**
  - Give expressed breast milk by orogastric tube
  - If baby not tolerating full feed give trophic feeds
  - When oxygen is no longer needed, allow the baby to begin breastfeeding.
  - If the **baby cannot breastfed**, give expressed breast milk using a cup or tube

Observation & / Documentation:

Baby

- Hourly temperature, heart rate, respiratory rate, SpO_2
- Prongs – check patency every 1-2 hrs
- Document any changes in the infant's condition infant, position & comfort
- Abdominal distension
- Thermal environment
- Medications
- Feed/Fluid balance
- Procedures and investigations
- Parental interaction

Equipment Hourly

- FIO_2
- CPAP settings & adjust as needed
- Gas flow rate
- Water level in humidifying chamber
- Humidifier and circuit temperature

Weaning baby from CPAP

As the score reduces/baby improves gradually reduce FiO2 by 5%.

When FiO2 is <30% discontinue CPAP to nasal prongs.

Continue monitoring RDS Score to ensure baby does not require re-introduction of CPAP

Continue monitoring O saturations till baby no longer needs O2

Appendix VI: Silverman Anderson Score and its interpretation

Score	Upper chest retrac on	Lower chest retrac on	Xiphoid retrac on	Nasal flaring	Expiratory Grunt
0	Synchronised	None	None	None	None
1	Lag during inspira on	Just visible	Just visible	Minimal	Audible with Stethoscope
2	See - Saw	Marked	Marked	Marked	Audible without Stwthoscope

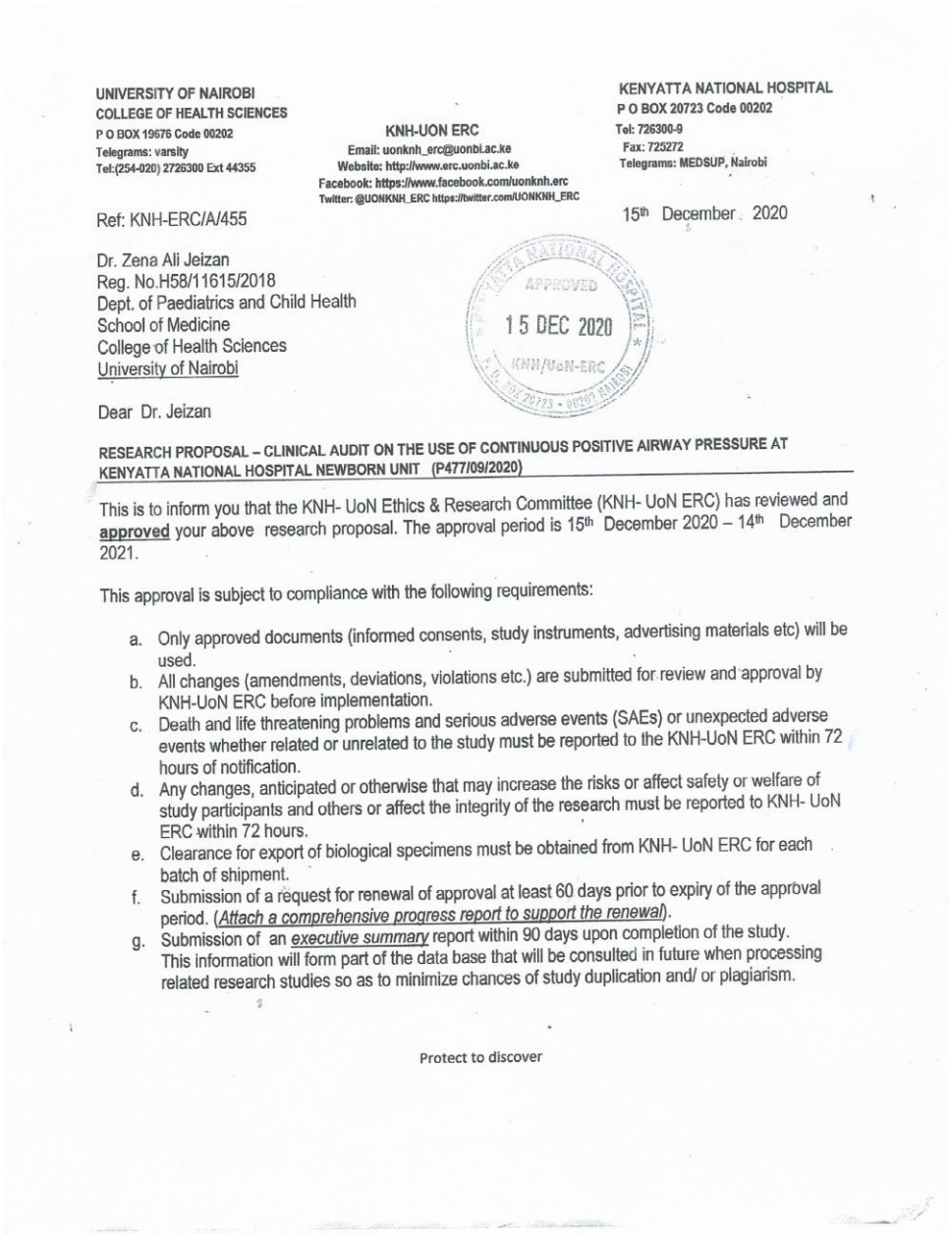
Interpretation

Score 1-3 = Mild respiratory distress –Oxygen by nasal prongs

Score 4-6 =Moderate respiratory distress - CPAP

Score > 6 = Impending respiratory failure –mechanical ventilation

Appendix VII: KNH/UoN-ERC Letter of Approval



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Ref: KNH-ERC/A/455

15th December 2020

Dr. Zena Ali Jeizan
Reg. No.H58/11615/2018
Dept. of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi

APPROVED
15 DEC 2020
KNH/UoN-ERC

Dear Dr. Jeizan

RESEARCH PROPOSAL – CLINICAL AUDIT ON THE USE OF CONTINUOUS POSITIVE AIRWAY PRESSURE AT KENYATTA NATIONAL HOSPITAL NEWBORN UNIT (P477/09/2020)

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 15th December 2020 – 14th December 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. 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.
d. 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.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. 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.

Protect to discover

Appendix VIII: Certificate of Plagiarism

Turnitin Originality Report
AUDIT ON THE USE OF CONTINUOUS POSITIVE AIRWAY PRESSURE AT KENYATTA NATIONAL HOSPITAL NEWBORN UNIT by Zena Ali Jeizan
From Pediatrics and Child Health (Master of Medicine)

- Processed on 07-Dec-2021 15:22 EAT
- ID: 1723313261
- Word Count: 9459

Similarity Index
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