# A description of the pattern of requests and utilization of nasal continuous airway pressure (nCPAP) during ground transport of children younger than 13 years of age in the Western Cape Provincial Ambulance Service, South Africa.

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# Abbreviations

| | |
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| AIDS | Acquired Immunodeficiency Syndrome |
| ALS | Advanced Life Support |
| AMS | Air Mercy Services |
| ARD | Acute Respiratory Distress |
| CAD | Computer Aided Dispatch |
| CHC | Community Health Centre |
| COPD | Chronic Obstructive Pulmonary Disease |
| CPAP | Continuous Positive Airway Pressure |
| ELBW | Extremely Low Birth Weight |
| EMS | Emergency Medical Services |
| GIT | Gastrointestinal tract |
| HFNC | High Flow Nasal Cannula |
| HIE | Hypoxic Ischaemic Encephalopathy |
| HIV | Human Immunodeficiency virus |
| LMIC | Low Middle Income countries |
| MOU | Maternity Obstetric Unit |
| NIV | Non-invasive ventilation |
| NPO2 | Nasal prong oxygen |
| PEEP | Positive end expiratory pressure |
| PICU | Paediatric Intensive care unit |
| PIP | Peak Inspiratory pressure |
| RCT | Randomised Control Trial |
| RDS | Respiratory Distress Syndrome |
| SPRINTT | Specialised Paediatric Retrieval Including Neonatal Transfer Team |
| TCC | Tygerberg Control Centre |
| TRAP | The risk assessment in paediatrics score |

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# Part A: Literature Review

## Introduction

Nasal continuous positive airway pressure (nCPAP) can be used to treat a variety of respiratory conditions that result in respiratory distress.[1] It can also be used to treat neurologic and pulmonary conditions, heart failure and cardiac related conditions in infants and children.[1] It is widely accepted as a safe method of non-invasive ventilation (NIV) when used in an optimal clinical environment such as the Intensive Care Unit (ICU).[1] However, the use of nCPAP outside of ICU settings is rising and consequently there has been an increase in the need for transferring young children, especially neonates, while on nCPAP.[1]

## Aim and Objectives of literature review

The aim of the literature review is to describe the use of nCPAP in children during medical transport before the Covid-19 pandemic.

The objectives of this literature review were to:

i. Describe the various uses of nCPAP in children as well as its modes and interfaces.
ii. Describe the reported benefits of nCPAP in general and in a transport setting.
iii. Describe transport settings where nCPAP has been successful or favoured over mechanical ventilation.
iv. Describe the reported benefits of nCPAP over mechanical ventilation in a transport setting.
v. Describe the reported cost benefit of using nCPAP in transport compared to mechanical ventilation.
vi. Describe patient safety concerns when using nCPAP in transport compared to mechanical ventilation.

## Literature search strategy

Published literature was sourced from the following online medical and scientific databases: PubMed, EMBASE, and Google Scholar. Search criteria depended on the limitations and options from the various databases but included combinations of the following search terms:

> *neonatal CPAP* OR *neonatal CPAP in transport* OR *CPAP in transport*; *pre-hospital* OR CPAP *in paediatric transport* OR *non-invasive ventilation; paediatric transport* OR *non-invasive ventilation; neonatal transport.*

Search results were further narrowed by applying the following inclusion and exclusion criteria. Inclusion criteria were: (i) articles published in English; (ii) articles published in peer reviewed journals only; and (iii) articles published in 2000 or later (i.e., January 2000 – May 2024). Articles in press (but available online) at the time of the search were also included. Abstracts and titles of studies identified by the search criteria were reviewed individually and full text articles were obtained for those considered relevant to the topic. References of included articles were also screened for potential articles that were missed by the search. No formal risk of bias assessment of articles was performed for this literature review. All articles were however screened for relevance, and applicability to the population of interest.

## Literature review findings

### Physiology

The physiological goal of CPAP is to improve lung ventilation-perfusion, and thereby oxygenation, by means of keeping the alveoli open during expiration.[2] Therefore, CPAP can only be applied to a spontaneously breathing person,[2] and allows for optimal gaseous exchange through alveolar recruitment.[3] Improved clinical parameters include an increase in functional residual capacity which improves lung volume, thereby further improving gaseous exchange with an increase in arterial oxygen pressure ($paO_2$) and a decrease in the carbon dioxide partial pressure ($paCO_2$).[3] Hypoxic pulmonary vasoconstriction and subsequent increased pulmonary vascular resistance is improved resulting in better pulmonary blood flow.[3] When clinically indicated for heart failure and pulmonary congestion, CPAP reduces preload and afterload, hence these patients see an improvement in cardiac output and pulmonary oedema.[2] Specifically in neonates where nasal CPAP (nCPAP) is most often used, it has been shown to generate more regularity in breathing patterns due to stabilization of the

chest wall.[3] Also in neonates, the inspiratory and expiratory times (I:E ratios), are increased and in the case of Respiratory Distress Syndrome (RDS), surfactant release appears to be strengthened by nCPAP.[3]

## Equipment and mechanics

An ideal CPAP delivery system must have a supply of warm humidified air or gases and must generate flow rates at least 2-3 times the child's minute ventilation.[4] Additionally, a device is needed to connect the circuit to the child's airway and there must be a way of creating positive pressure within the circuit.[4]

Generation of CPAP can be divided into two categories, namely, devices that provide continuous flow and those that have variable flow.[5] Examples of continuous flow devices include mechanical ventilators, jet ventilation and bubble CPAP.[5] Mechanical ventilators provide a continuous flow of gas and the pressure generated is regulated by an exhalation valve.[5] Jet systems allow a small jet to be produced at the nostril or in a chamber at the nasal prong interface.[5] During bubble CPAP, the expiratory portion of the CPAP device is placed in an underwater chamber which should be at a depth equal to the anticipated CPAP level. Gas then flows through the system with resultant bubbling in the chamber which causes change in the mean CPAP pressure.[5]

Variable flow devices generate CPAP in the proximal airways and, when using a variable flow device, the flow of gas determines the CPAP level. Pressure is maintained via dual injector jets directed at each nasal prong.[4] If greater respiratory flow is required, the injector jets can entrain additional flow by means of a venturi action.[4] During spontaneous expiration there is a fluidic flip which allows flow to "flip" or turn around to leave the generator chamber via the expiratory hose.[4] The basic components of variable flow include a flow driver, flow generator, circuit, humidifier, patient interface and fixation appliance.[4]

The fluidic flip, as described above, decreases the work of breathing significantly when compared to continuous flow CPAP in which the infant needs to exhale against the full ongoing flow of gas.[4] Randomised controlled trials (RCTs) have suggested that variable flow CPAP is

more advantageous than ventilator derived CPAP as it is associated with less supplementary oxygen use, decreased length of stay, decreased work of breathing and greater improvements in flow and tidal volumes.[5] In a small randomised crossover study, bubble CPAP was associated with increased work of breathing, an increased respiratory rate and thoraco-abdominal asynchrony, when compared to variable flow CPAP.[3] Variable flow has been shown to hold better uniform pressures than continuous flow, however its use is often limited due to cost and lack of availability.[4]

Patient interfaces can include a face mask, nasal mask, nasal prong, mouth piece, and helmet or head box.[2] Although full face masks can be difficult to tolerate, especially in children, they do provide a superior seal to nasal masks/prongs and there are less difficulties experienced from circuit leaks.[6] A head tent/box has been associated with less pressure sores and skin necrosis compared with tight fitting face masks.[6]

Recommended CPAP settings are variable. Starting pressures in children are currently recommended at 4-6 $cmH_2O$ whereas the starting oxygen concentration can be anywhere from 21% (i.e. room air) to 100% depending on patient needs and pathology.[7] Occasionally higher pressures of up to 8-10 $cmH_2O$ may be indicated, such as in neonates with severe RDS and stiff lungs and requiring a higher $FiO_2$.[8] The optimal CPAP pressure depends on the condition being treated, however, higher pressures should be used with caution to avoid restriction in pulmonary blood flow and overdistension of the lungs.[8]

A flow meter controls the rate at which the gas/oxygen flows and this flow rate should be adequate to prohibit carbon dioxide rebreathing.[3] Flows are usually set around 6L/min to start (5-10L on average), however if the flow is too low there may be increased work of breathing.[8] A flow of 6L/min is usually sufficient for adequate minute ventilation in most infants, however minute ventilation does not predict the flows needed in nCPAP. The continuous flow of gas through the nose and out the mouth affects how much flow is needed to maintain pressures within the pharynx.[8] In the paediatric population, specifically in neonates, it is important to warm or humidify the oxygen prior to delivery.[3]

## Indications for CPAP

CPAP is a form of non-invasive ventilation (NIV) and therefore, can only be applied to a spontaneously breathing patient and it maintains airway patency when there is airway collapse.[2] Airway collapse is seen in conditions such as obstructive sleep apnoea (OSA) which may occur because of childhood obesity, enlarged adenoids and hypotonia.[2] In neonates, CPAP can be used to treat RDS because of surfactant deficiency.[2] It is also indicated in hypoxia secondary to infection such as pneumonia and bronchiolitis, where work of breathing can be increased.[9] Positive outcomes with CPAP have also been noted in children with collapsible airways such as those with tracheomalacia.[9] Children with cardiac disease who present in congestive heart failure and associated hypoxic respiratory failure will also benefit from CPAP as it improves ventilation/perfusion (V/Q) matching and augments cardiac output.[9] CPAP can also assist with improved oxygenation prior to intubation and mechanical ventilation and conversely, after extubation when individuals may still need additional positive pressure without invasive ventilation.[9]

## Clinical benefits of CPAP

The use of CPAP has many benefits including the avoidance of invasive procedures, such as tracheal intubation, before and during transfer to reduce the risk of transporting a potentially unstable child who may decompensate on route.[1][7] Tracheal intubation poses many additional risks such as barotrauma to the lungs; airway trauma; adverse effects of sedatives, induction agents, and paralytics; an increased risk of ventilator associated pneumonia; and possible long term damage (i.e. chronic lung disease).[10]

The use of CPAP may be better tolerated in the paediatric patient in that it preserves speech and swallowing abilities.[7] When compared with invasive ventilation such as intubation, the relative ease of use and minimal need for sedating drugs during transport also makes CPAP a safer and more attractive option.[2] This is particularly important where more inexperienced and junior staff are involved in transport.

Thomas et al[11], compared CPAP and traditional mechanical ventilation in extremely low birthweight (ELBW) infants at a corrected age of 18-22 months to ascertain if there was any

difference in neurological/neurodevelopmental outcome.[11] The study sample was taken from two hospitals at the Cincinnati site of the National Institute of Child Health and Development Neonatal Research Network and included 198 babies in the CPAP group and 109 babies in the mechanical ventilation group.[11] Those on CPAP at 24 hours of life had better Bayley scores (indicating infant development) at 18-22 months corrected age compared with those in the mechanical ventilation group.[11] Conversely, the SUPPORT trial which looked at similar parameters, found no statistically significant difference between the two groups at 18-22 months of corrected age with regards to neurodevelopmental outcomes.[12]

Most of the current literature highlights short term and immediate benefits and disadvantages of CPAP, however more studies are required to investigate the long-term outcomes of CPAP and as well as CPAP versus mechanical ventilation.

## CPAP during paediatric transport

CPAP is widely used during transport of children – both intra- and interhospital transport. Many paediatric cases requiring CPAP during transport will require a blend of oxygen and medical air. Due to concerns about the harmful effects of oxygen toxicity in newborn babies and small infants, there is a move towards respiratory support using the lowest possible amount of oxygen, ideally air. Thus, it has become essential to have a source of air as well as oxygen during transport.

Whilst oxygen cylinders are easily available for transport in most places, medical air cylinders are more problematic. These are not available in the Western Cape (WC) of South Africa in a configuration that would reliably permit delivery of CPAP for anything but very short journeys. Even ensuring an adequate number of oxygen cylinders can be problematic, especially if the patient requires high concentrations of inspired oxygen or there is a long duration of travel.[2] This is primarily due to the lack of space in an EMS vehicle for multiple cylinders. The newer generation of transport ventilators, such as the Hamilton T1 ventilator, have built-in air turbines that entrain room air.[13]

Literature on the safety and efficacy of CPAP in children outside of ICU settings is limited, and this is especially the case with respect to CPAP use during transport of children.[14] A systematic review found that CPAP is a potentially safe mode of ventilation during transfer of children with respiratory distress between the ages of 0-18 years.[15] This review found that intubation and escalation of care during transport were only required in 0.4% of cases and an in-transport adverse event rate of 1-4% was reported.[15] Specifically, a study of 207 neonates and infants in Australia reported that these children were safely transported during interhospital ground transfer for conditions that included bronchiolitis, chronic lung disease and congenital heart disease.[16] A smaller study of 25 children with pulmonary and neurologic complications, also indicated that CPAP was safe.[7] These children were more likely to be transported from a tertiary paediatric high care or ICU to a step-down facility for maintenance care, thus demonstrating the need for CPAP use in interhospital transfer in the reverse direction of the referral pathway.[7] CPAP could therefore, become an important tool in children who are chronically ill, that require multiple transfers between primary and acute care and inpatient and outpatient management.[2]

In a 2018 case series in rural Canada, the safety and benefits of nCPAP use in neonatal and paediatric air transfers were assessed, specifically in long distance travel from a remote setting to an urban centre, with the hope of improving patient outcomes and avoiding intubation.[10] The most common paediatric transfers were for premature infants, respiratory distress syndrome and bronchiolitis.[10] Until the region acquired a Hamilton-T1 ventilator, their only method for respiratory support in flight was intubation and mechanical ventilation, however, it is acknowledged that this was not a favourable choice due to the possible complications that could occur on route and the advanced skill needed by the transporting personnel.[10] The cases where nCPAP was used in transfer highlighted improvement in outcome parameters such as arterial blood gas readings and no further clinical decompensation. Without the use of nCPAP, the above cases would have been intubated and ventilated for transport with flight times varying between 3 and 6 hours depending on weather conditions.[10]

Fleming et al[17], conducted a retrospective audit looking at data from the Neonatal Emergency Transport Service (NETS) in Victoria, Australia.[17] The aim of the study was to take a closer look at the ventilatory management of neonates with moderate to severe bronchiolitis requiring

transfer, with specific focus on CPAP use.[17] Over a period of 4.5 years (2003-2007), NETS transported 192 babies diagnosed with bronchiolitis, of these, 54 were commenced on CPAP by the referring facilities, with 51 continuing CPAP on route (86% of CPAP cases transferred by road) to the accepting facilities with an average distance of 62km away.[17] The study showed a statistically significant (p = <0.01) improvement in oxygenation from the start of CPAP to the end of the retrieval.[17] Additionally, no patients deteriorated on route, nor required invasive mechanical ventilation and no adverse events were reported.[17]

Manso et al[18], set out to assess the safety and effectiveness of CPAP in infants transported for acute respiratory failure and how this would delineate their future clinical course after arrival at the PICU.[18] The cohort study ran over a 10 year period (2006 – 2015) and only included patients from two first tier facilities that were transferred to two PICU's of the designated tertiary facilities.[18] The distances travelled were not extensive (<85km) and only children with respiratory distress less than one year of age were included.[18] Over the 10 year period, a total of 110 patients were transported (CPAP n= 71; Oxygen therapy n= 39), with bronchiolitis accounting for 81.8% of the referrals and need to transport (likely due to the age selection of the patient group).[18] None of the cases required an escalation in care whilst on route nor mechanical ventilation.[18] The outcome the study concluded a reduction in the Wood-Downes score in the CPAP group (β = −1.08; 95% CI −1.76 to −0.40; p = 0.002) and heart rate (β = −19.64; 95% CI: −28.46 to −10.81; p < 0.001).[18] Those who received CPAP were also noted to have a shorter PICU stay.[18]

Holbird et al[19], looked at clinical outcomes during paediatric patient interfacility transport, using a retrospective chart review of a provincial paediatric transport register to investigate mortality, intubation rates, and effect on length of stay.[19] Like the South African setting, there was no established protocol for starting CPAP at the referring hospital and this was largely dependent on advice from the receiving healthcare facility. A total of 120 children aged 30 days to <17 years and who were subsequently admitted to the PICU were included in the study.[19] The researchers used the Risk Assessment in Paediatrics (TRAP) score, an objective assessment tool in which higher scores are associated with a PICU admission for more than 24 hours.[19] There was an improvement in TRAP scores in those who received CPAP in transport.[19] Although bronchiolitis and asthma accounted for nearly 60% of cases, and these

often require a short duration of positive pressure for lung recruitment and could have been responsible for these rapid improvements, the study concluded that CPAP is safe and does not increase the need for intubations.[19]

In summary, there is clear evidence that CPAP is safe in transport, with most studies from high-income settings considering distance of travel; personnel skill; improved clinical parameters without the need to escalate care to mechanical ventilation; and impact on PICU stays. Whilst other ventilatory mechanisms are often mentioned or reported in the studies as part of the overview, there still appears to be a lack of information regarding an empirical comparison of outcome for mechanical ventilation and CPAP. In addition, whilst most clinicians/researchers have acknowledged that mechanical ventilation is less favourable, the data remains focused on the CPAP component only. More studies in the paediatric population are needed comparing CPAP with mechanical ventilation specifically, and CPAP with other ventilatory forms such as high flow nasal cannula (HFNC). This became an interesting topic during the Covid-19 pandemic across the adult population (not the focus of this study).

## Adult transport CPAP literature

Although no paediatric studies were found during the literature search that directly compare mechanical ventilation with CPAP during transport, there is evidence from adult transport literature on the benefits of CPAP in this setting. This study was conducted/data collected prior to the Covid 19 pandemic where CPAP and HFNC became key management strategies in adults. Since the start of the pandemic a lot more literature and a growing body of evidence has become available around this topic. Covid 19 will not be covered in the adult literature since the focus is on paediatrics and this body of evidence in paediatric transport remains largely unchanged despite the pandemic.

A systematic review by Pandor et al,[20] in the United Kingdom (UK) prehospital setting looked at 10 studies (eight of which were RCTs) that compared standard prehospital care and CPAP in adults.[20] The review aimed to establish cost effectiveness as well as clinical benefit for use of CPAP in the prehospital setting. The study found that the use of CPAP, although more expensive, reduced the risk of overall mortality (OR 0.41; 95% CI) as well as the need for

intubation (OR 0.32; 95% CI) was comparable to standard care.[20] It was noted that the long-term cost effectiveness was not certain.[20]

A cross over, observational, non-blinded study by Warner[21] in an adult population (n=89) with acute respiratory distress (ARD) in the United States of America (USA) showed great benefit in using CPAP in the pre-hospital setting.[21] Initial data before the implementation of CPAP showed that 7.9% of patients with ARD was intubated within 48 hours and the average length of the ICU stay was 8 days.[21] After the implementation of CPAP on the road, no patients were intubated and ICU admissions decreased as well as length of stay to 4.3 days.[21] More research is needed in the paediatric population to determine whether such results could be comparable.

## Paediatric transfers in South Africa

In the South African (SA) setting, the ability to safely transfer paediatric patients to secondary and tertiary institutions is crucial as many sick children present to peripheral clinics and hospitals, where the level of care is not sufficient to provide high-care or paediatric intensive care. In the Western Cape (WC) province of SA these transfers are performed by the Western Cape Government Emergency Medical Services (EMS), with unstable or critically ill children being transferred largely by the Specialised Paediatric Retrieval Including Neonatal Transfer team (SPRINTT). In this context, CPAP may be commenced as a new medical therapy or an intervention that needs to be continued on route to the more appropriate level of care.

Vincent-Lambert and Wade (2018)[22] previously explored the experiences of healthcare providers in the interfacility transport of paediatric patients in the public sector in Johannesburg.[22] A major challenge identified were time delays for the ambulance to arrive, with high acuity or critical patients waiting hours for transport.[22] Lack of appropriate skills for paediatric transport and non-functional equipment was also highlighted in this study with emphasis placed on ventilators and intubation needs.[22]

Hatherill et al[23], performed a one-year prospective audit of adverse events and clinical outcome in the transport of critically ill children from other centres to a tertiary university affiliated paediatric intensive care unit (PICU) in the Western Cape.[23] Although a small study

of 202 children, 82% of cases were transported by EMS personnel without physician support and 76% by ground transport.[23] The median age of children transported was in the infant group – 2.8 months.[23] Collective adverse events were documented in 72 % of cases (36% technical; 27% clinical and 9% critical), with referrals from non-academic hospitals having the highest incidence of technical, clinical and critical adverse events.[23] The study noted a particular concern around the recognition and need for ventilatory support at the referral level and the need for dedicated paediatric retrieval teams for the transfer of patients.[23]

Most African health systems operate using a tiered referral system and transporting patients between these facilities can be expensive, time consuming and a burden to an already overstretched healthcare work force.[24] The use of CPAP also has many challenges, particularly in a low resource setting, this includes a considerable reliance on importing CPAP devices, which could be expensive and a limitation in itself if no cheaper locally manufactured options are available.[25] Additionally, some transportation services and facilities may not have an air/oxygen supply available 24/7 and no access to back up mechanical ventilation equipment/devices should the patient deteriorate.[25]

Community Health Centres (CHC) and day clinics are situated across the Western Cape province (urban and rural) and serve as the entry point to receive care.[24] CHCs and clinics are usually staffed with general practitioners or medical officers and nurses of varying experience, with some specialised clinics such as maternity and obstetric units which manage low risk pregnancies.[24] At this level the focus of treatment is primary healthcare and emergencies can be managed, but with limited capacity and resources. The aim is usually to stabilize and refer the patient to the next level in the tiered system.[24] Most CHCs do not have laboratories or radiology on site and do not have the capacity for overnight ward admissions.[24] Given the varying degrees of medical training and staff skillset at these facilities; training staff in the correct use of CPAP and identifying early clinical indicators for deterioration of failed CPAP attempts is crucial to gain the benefits of its use in the appropriate clinical context. A bubble CPAP study done in Malawi on children between 1 month and 59 months admitted to a resource constrained hospital with pneumonia, showed adverse outcomes such as skin breakdown at the nares, pneumothorax, aspiration and death.[26] The bubble CPAP was administered in a non-

ICU setting with little to no physician oversight; and demonstrates the potential consequences if not used appropriately, with the correct resources and staff training.

The next level of care is a district hospital, staffed mostly by medical officers, nurses and some specialised services such as physiotherapy.[27] Some district hospitals will have specialists to support staff e.g. internal medicine consultants, whilst others will have specialists visit the facility to do outreach and teaching. Most district hospitals will have basic laboratory and radiology services such as x-rays and ultrasound.[27] Ward admissions are possible at this level with limited high care capability. There is no dedicated ICU and usually no CT scanners or MRI, therefore most do not offer after hours emergency trauma and orthopaedic surgery.[27]

Regional hospitals and tertiary centres are very closely linked, with a full array of services and specialized care available (including paediatric and neonatal services). Both are affiliated with a university and run academic programmes for further education and training.[27] The difference between the two includes size, bed capacity, number of specialists and super specialized care e.g. neonatal care of birthweights <800g; the latter only managed at tertiary level.[27] Each tier is guided by a clinical protocol in terms what their medical disciplines can manage at that specific level and when it is appropriate to refer. The tiers are also separated by area or zone and each CHC, district, regional and tertiary centre will up refer or down refer to the facilities allocated to their zone or catchment area.[24]

## EMS qualifications

In South Africa, EMS personnel need to be so called Advanced Life Support (ALS) qualified (in this study context and time period meaning either *Ambulaans Nood Tegnikus (*ANT) or *Emergency Care Practitioner* (ECP) registered with the Health Professions council of South Africa to undertake neonatal or paediatric retrievals requiring CPAP or mechanical ventilation.[28] ALS providers could have a range of undergraduate training, from vocational training certificate courses[29], a two-year postgraduate diploma (independently administers drugs and able to carry out advanced skills)[30] or a 4 year university degree (includes diagnostic execution and critical care invasive procedures)[30]. Despite these discrepancies, most providers working on SPRINTT have a great deal of experience, clinical exposure and real time learning

in managing critically ill neonates. South Africa has since recognized the need for matched theoretical knowledge with skill and practical experience and as of 2020, critical retrievals including neonatal and paediatric remain reserved for degreed paramedics (ECP) only[28]. Much work is needed to build a workforce to meet the current goals and regulations for optimized service delivery. As with physicians, the country may face a shortage of qualified degreed paramedics[29].

## Risks and contra-indications to CPAP

Despite its many benefits, CPAP can have some drawbacks such as gastric distention and reflux which may lead to aspiration in younger children and those with known gastrointestinal disorders.[7][15] Air leaks, including pneumothorax, pneumomediastinum and pneumocephalus,[4] have been associated with CPAP use, however in a RCT looking at prophylactic CPAP versus oxygen alone, no difference in the incidence of air leakage was found.[8] There are currently no results available from RCTs comparing air leaks between CPAP and mechanical ventilation.[8]

Other potential limitations include an inability to physically tolerate CPAP, which is particularly problematic in children; the need to repeatedly clear the airways due to secretions or reposition the device; and clinical deterioration whilst on route that may result in intubation and escalation of care.[7][15] Positioning and fixing the nCPAP interface can be difficult at times and nasal trauma including excoriation and scarring can occur if not monitored or if pressure points are not protected.[8] Although it is important to select the largest prongs that will comfortably fit the child in order to maintain pressure and minimize leaks, prongs that are too large can also damage the nasal septum and cause septal erosion.[8]

Absolute contra-indications for nCPAP use include maxilla-facial trauma or recent maxillofacial surgery, GIT bleeding, haemoptysis, cardiac arrest and complete upper airway obstruction such as severe epiglottitis or foreign body.[2]

## Conclusion

There is still much to be learnt about the indications and appropriateness regarding the use of CPAP and the lack of knowledge and training in CPAP use among doctors, paramedics and nurses remains a huge barrier.[25] International literature explored the benefits, ease of use and cost effectiveness of CPAP in an already well established high income healthcare systems and retrieval networks. There is also a gap noted in the direct comparison and outcome of mechanical ventilation vs CPAP in the paediatric population. There is a vast array of further study opportunity in this field, including the need for focus on primary transport vs interfacility transport; mode of transport and impact of distance/time travelled. The key message to date is that CPAP is safe and serves as a good starting point for the other studies to follow. The study that follows below contributes to the needed body of evidence of how a paediatric retrieval system providing ventilatory support would fit into South Africa's and specifically the Western Cape's tiered healthcare system.

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# Part B: Manuscript in article format

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# Utilization of Nasal Continuous Positive Airway Pressure (nCPAP) During Paediatric Ground Transport in the Western Cape, South Africa

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## Abstract

**Background:** Nasal continuous airway pressure (nCPAP) is used to treat respiratory conditions resulting in respiratory distress. It is a widely accepted method of non-invasive ventilation in children in optimal environments such as the Intensive Care Unit (ICU). It's use outside of ICU settings is increasing, with a consequent increased demand for transfer of children, especially neonates, on nCPAP.

**Methods:** Retrospective data from the Western Cape public sector Emergency Medical Services electronic records (April-June 2019) for cases where a transfer on nCPAP was requested or administered are described. Data described includes patient demographics, facility data, mode of ventilation during transport, and disease profiles.

**Results:** A total of 325 cases were included in the study, of which 289 CPAP requests were made; 226 (78.2%) of these cases were CPAP. It was utilized most in neonates <24 hours old and infants in the 1–3-month age group. Respiratory conditions were the most common reason for needing CPAP (n=181; 76.1%), with pneumonia being documented in 46.4%, and unspecified respiratory distress in 42.5% of cases. Of the 226 CPAP requested and given cases, CPAP was started by the facility in 133 cases (58.8%), with 74.4% of these being district hospitals.

**Conclusion:** nCPAP is the most used form of ventilatory support in children under 13 years during ground interfacility transfers for respiratory conditions. More studies are needed to investigate safety, suitability, and ease of use of CPAP for staff of varying skill sets and whether this makes a difference to outcome.

# Introduction

In 2018, South Africa recorded 10.7 neonatal deaths per 1000 live births[1], and one in three children dying under the age of five years were in the neonatal period.[1] A lack of timeous critical care transport services has been cited as one of the top ten preventable causes.[1]

Nasal continuous positive airway pressure (nCPAP) can be used to treat a variety of respiratory conditions that result in respiratory distress[2], as well as neurologic and pulmonary conditions, heart failure and cardiac related conditions in infants and children.[3] It is widely accepted as a safe method of non-invasive ventilation (NIV) when used in an optimal clinical environment such as the Intensive Care Unit (ICU).[2] However, the use of nCPAP outside of ICU settings is rising and consequently there has been an increase in the need for transferring young children, especially neonates, while on nCPAP.[2][4][5]

Kamath et al (2011)[6] identified the important role continuous positive airway pressure (CPAP) might play in low resource settings like South Africa. Many facilities in these settings are not equipped with appropriate resources to provide mechanical ventilation nor CPAP which results in the inability to initiate an intervention timeously when a child requires it, and over referral of children to already overburdened secondary and tertiary centres, when they may improve clinically with 24-48 hours of CPAP and avoid the need for referral.[6] This is important in the South African context where many maternal and obstetric units and primary health care facilities do not have overnight admitting capabilities, therefore referral is prudent, but initiation of CPAP with continuation during transport could be beneficial in terms of patient outcome.[6] Many primary health care facilities are not staffed by doctors, however, with adequate training and education, CPAP can be effectively applied by nurses and other healthcare workers while awaiting, and in preparation for, transport which has been shown to improve neonatal survival.[6] Previously Holbird et al (2020)[7] described clinical outcomes during paediatric patient interfacility transport in a setting similar to South Africa, and reported improvements in The Risk Assessment in Paediatrics (TRAP) scores in those children who received CPAP during transport.[7] The study concluded that CPAP is safe and does not increase the need for intubations.[7]

In South Africa, the ability to safely transfer paediatric patients to secondary and tertiary institutions is crucial as many sick children present to the community health clinics and district

hospitals, where the level of care is not sufficient to provide high-care or paediatric intensive care. South Africa, and Sub-Saharan Africa in general, has a shortage of specialized paediatric retrieval services, including neonatal services.[1] These services are mostly concentrated in the private sector and the few public sector specialised retrieval services are limited to urban areas. In the Western Cape province of South Africa many such transfers are performed by the Western Cape Government Emergency Medical Services (EMS), with unstable or critically ill children being transferred by the Specialised Paediatric Retrieval Including Neonatal Transfer team (SPRINTT). Here, nCPAP may be commenced as a new medical therapy or an intervention that needs to be continued on route to higher levels of care.[3] The current study aims to describe the pattern of requests and use of nCPAP during transfer of children under the age of 13 years by the public sector SPRINTT service in the Western Cape. Understanding this pattern can inform how a specialised paediatric retrieval system providing ventilatory support can support quality patient care in tiered healthcare systems.

## Methods

A retrospective chart review of data from the Western Cape Government EMS SPRINTT electronic records for the period 1 April to 30 June 2019 was performed. Ethical approval was obtained from the University of Cape Town Human Research Ethics Committee (860/2019), as well as Western Cape Government: Health and Wellness (WC_202002_001). SPRINTT serves the metropolitan municipality of Cape Town, and the West Coast, Winelands and other rural districts of the Western Cape, up to 300km from Cape Town. If a paediatric patient requires transfer whilst on nCPAP, the referring facility will, following consultation with a paediatrician at the accepting facility, contact the central control centre to dispatch the SPRINTT. Aeromedical Services (fixed & rotor wing retrievals) provides a service to more distant locations but is restricted by weather and availability of suitable landing locations.[8]

This study included all children under the age of 13 years transported in the Cape Town Metropole and greater Western Cape area by Western Cape EMS, during the study period, who either had a request for nCPAP during transport by the treating clinician or who received nCPAP during transfer, for any clinical condition. Only data on interfacility transport was included, and primary calls were excluded. Cases where no correlating Electronic Patient Care

Records (ePCR) records were found were also excluded. Cases transferred by rotor wing and fixed wing transport were excluded.

Cases were identified by an automated search of the Computer Aided Dispatch (CAD) system for all variants of the spelling of the acronym 'CPAP'. This algorithm was piloted and adjusted following manual verification. The CAD database was searched for all CPAP requests for the study period. The following data points were extracted: incident type; patient demographics; diagnostic category; nCPAP recorded as being requested or not at initial call; geographical location of referring and receiving units; and response times of each call. Incorrectly identified calls and duplicate entries identified by the algorithm were excluded.

The CAD reference number was used to identify the corresponding ePCR. Data was extracted for each case including, mode of ventilation during transport (none, nasal prong oxygen, high flow nasal cannula (HFNC), nCPAP or mechanical ventilation), ventilation settings (e.g. nCPAP pressure, if intubated - Peak Inspiratory Pressure (PIP) and Peak End Expiratory Pressure (PEEP) & $FiO_2$), vital signs at start and end of transport (heart rate, respiratory rate, oxygen saturations) and any adverse outcomes mentioned in the ePCR during transport. Cases were categorised as: CPAP requested and given; CPAP requested and not given; CPAP not requested and given; CPAP not requested and not given.

Analysis was performed using Microsoft Excel and standard descriptive statistics were performed. All data was deidentified prior to analysis.

## Results

A total of 375 cases were identified from the CAD using the CPAP search algorithm. After these cases were cross referenced with ePCR, 325 cases were included in the study (Figure 1).

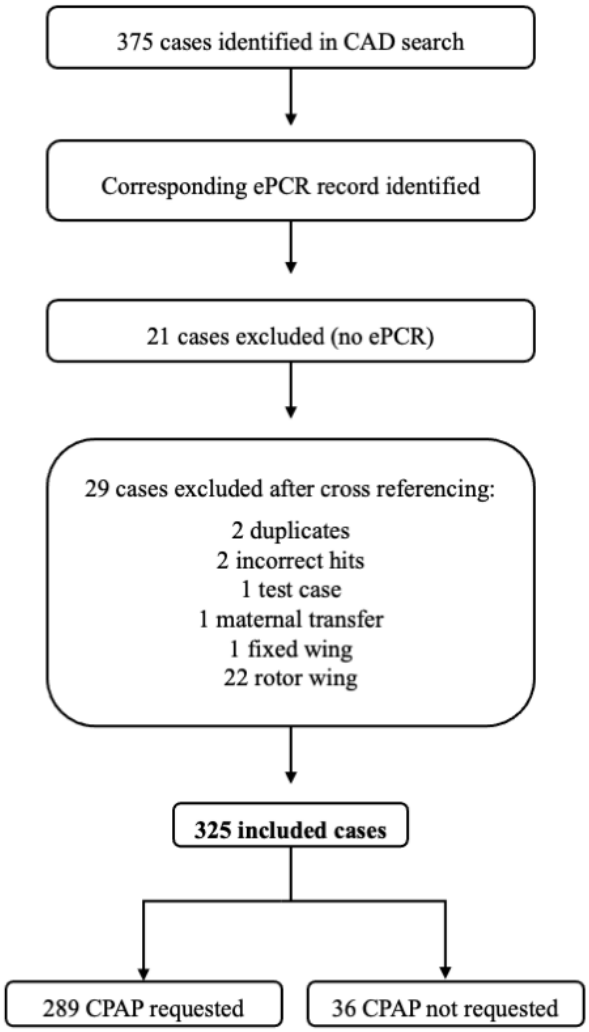


**Figure 1: Study sampling and exclusion process**

*CAD: Computer Aided Dispatch; CPAP: Continuous positive Airway Pressure; ePCR: Electronic Patient Care Record*

A total of 289 (88.9% of included cases) CPAP requests were made and in 226 (78.2%) of these cases CPAP was given. Of the 58 cases (20.1%) where CPAP was requested but not given, other forms of oxygen/ventilatory support were utilized. These included Nasal Prong Oxygen ($NPO_2$) (72%), mechanical ventilation (9%), Bag-Valve-mask (BVM) (2%), room air (3%), Neopuff (2%), Adrenalin neb (2%), Face Mask Oxygen ($FMO_2$) (3%), non-rebreather

mask (2%), high flow oxygen (2%) and none recorded (3%). Of the 238 cases where CPAP was given during EMS transfer, it had been requested in 226 (94.9%) of cases. CPAP was initiated by SPRINTT in 74 cases (31.1%); by the referring facility in 138 (57.9%) cases; and initiation was unclear from the documentation in 26 (10.9%) cases. In seven cases, it was not clear from the clinical notes whether CPAP was given or not.

Of the 238 cases where CPAP was given (requested and not requested), 138 (57.9%) were male (in three cases sex was not recorded). The age groups where CPAP was utilized the most was in neonates <1 day old (n=58, 24.4%), and infants in the 1–3-month age group (n=67, 28.1%) (Figure 2). Respiratory conditions accounted for the most common reason requiring CPAP (n=181; 76.1%), with pneumonia being documented in 84 cases (46.4%), respiratory distress without a specific diagnosis in 77 cases (42.5%), and the remaining 11% of cases being for bronchiolitis, lower respiratory tract infection (LRTI) and apnoea/hypoxia. Other diagnostic categories included cardiac, sepsis, gastrointestinal tract (GIT) conditions (acute gastroenteritis and necrotizing enterocolitis), neurology (Hypoxic Ischaemic Encephalopathy (HIE), seizure, intra-cranial haemorrhage) and other undefined conditions.

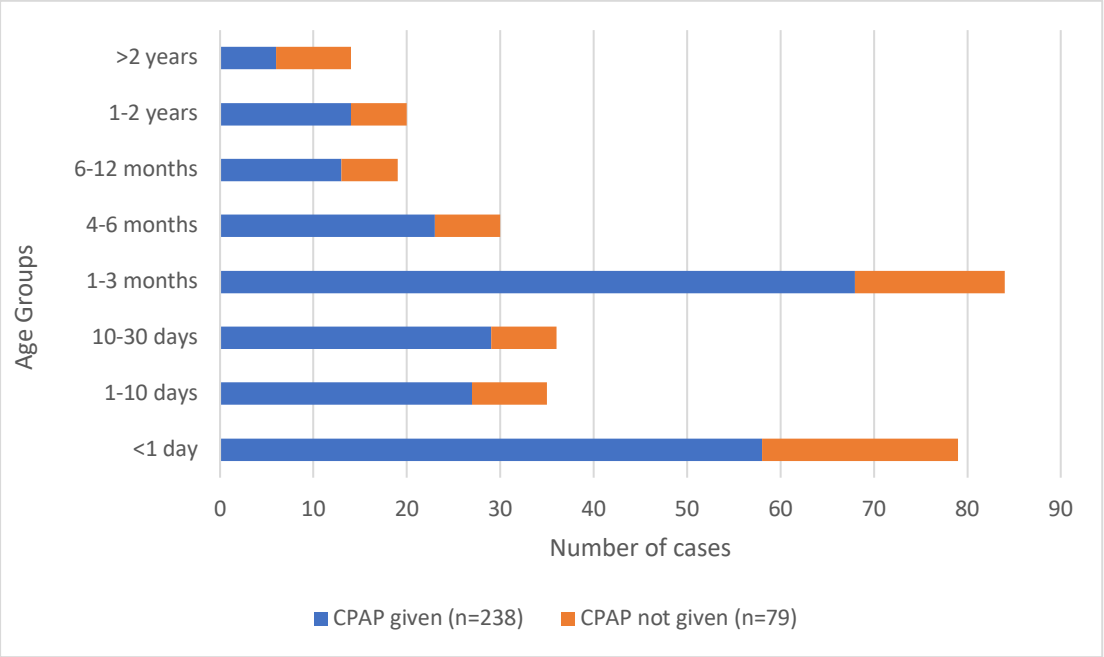


**Figure 2: The distribution of continuous positive airway pressure requests by age (n=289)**

*CPAP: Continuous Positive Airway Pressure*

Of the 226 cases where CPAP was requested and given, 133 cases were started by the referring facility (58.8%) of which 74.4% were district hospitals. Similarly, 62.7% of cases in which CPAP was initiated by SPRINTT were patients referred from district hospitals. One particularly busy district hospital accounted for 18% of all transfers where CPAP was requested and given, and nearly a third (28%) of all requests from district hospitals. The top three referring district hospitals were all within a 40km radius of the designated accepting tertiary hospital.

Community health centres (CHCs) staffed by generalists and/or nurses were the second most common group of referring facilities to have CPAP requested and given; with 12% (n = 16) of the facility initiation group being started by the referring CHC and 19% (n = 13) being started by SPRINTT. In total, 79% of CPAP requested and CPAP given cases referred from the CHC (n = 29), regardless of whether started by the facility or SPRINTT, originated from the maternity ward/unit and only 21% from the emergency centre.

**Table 1: Distribution of cases by service initiating CPAP and referring facility, where CPAP was requested and given (N=226)**

| Referring facility | CPAP initiated by*: | | |
|---|---|---|---|
| | Referring facility (n=133, 58.8%) | SPRINTT (n=67, 30%) | Total cases |
| Community Health Centre | 16 (12%) | 13 (19%) | 29 (13%) |
| Clinic | 0 | 1 (2%)) | 1 (0.4%)) |
| Maternity Hospital | 1 (0.8%) | 3 (5%) | 4 (2%) |
| District Hospital | 99 (74.4%) | 42 (62.7%) | 141 (62.4%) |
| Regional Hospital | 12 (9%) | 5 (8%) | 19 (8%) |
| Tertiary Hospital | 5 (4%) | 3 (5%) | 8 (4%) |
| Unknown | - | - | 26 (12%) |
| Total | 133 | 67 | 226 |

**In 26 cases, initiation of CPAP is not clearly documented.*

Of the total CPAP requests made (n=289), regardless of whether it was given or not, only 12 requests came from tertiary hospitals. Ten of these cases were interfacility transfers to other tertiary centres, one transfer was to a maternity hospital and only one was a downward referral to a regional hospital. Similarly, only 23 of all CPAP transfer requests were made by the two regional hospitals with 83% of those coming from one of the two. All requested transfers from the regional hospitals, regardless of whether CPAP was given or not, were taken to tertiary centres and no downward referrals were identified in this group. This upward referral pattern is similar when considering cases in which CPAP was given, regardless of whether it was requested or not (n=238). In these cases, 78% were referred to tertiary centres, 12% to regional centres, 6% to maternity hospital and 4% to district hospitals.

The SPRINTT, responded to 220 (92.4%) of the 238 cases in which CPAP was given. Other EMS response units, who were able and equipped to give CPAP, accounted for <2% of all CPAP given cases. These units would not normally respond to paediatric and neonatal CPAP cases, however, at the time the request was made, SPRINTT was unavailable, and these units were considered for dispatch. Personnel on duty at the time responding from these units were presumed competent in delivering CPAP based on their credentials that were input into the database.

No adverse events nor complications were recorded in the clinical notes for any included cases. However, in general, clinical note taking was poor. The detail of clinical notes in the ePCRs varied substantially and vital signs, chief complaint and clinical narratives were not consistently recorded in the same locations. Many providers did not document their own clinical examination findings other than the vitals. Only one case contained a narrative of a code blue and resuscitation on route but was recorded as the primary complaint and not an adverse event. It was unclear whether this was a cardiac or respiratory collapse and the reason for it.

## Discussion

CPAP can be initiated before transport when clinicians are secure in the knowledge that CPAP will be maintained during transport, and the literature review gives strong evidence that this is a lifesaving measure by preventing unnecessary invasive ventilation. This study shows that a

small, dedicated retrieval team can provide CPAP for paediatric transfers, even in a country like South Africa, with a largely overwhelmed EMS system servicing a quadruple burden of disease.[9] However, further studies would be required to comment on the effectiveness or efficiency of this service. This study further highlighted that CPAP was most used in the neonatal period and for upward referrals of CPAP i.e. escalation in care to the next best centre of excellence. Most cases where CPAP was requested and those which received CPAP were almost exclusively managed by the SPRINTT during transfer. In addition, a higher-than-expected amount of CPAP initiations were initiated by SPRINTT. Although anecdotal evidence has suggested many facilities await EMS arrival to start CPAP, our data has not supported this, and showed some two-thirds of CPAP was initiated by referring facilities, demonstrating a clear need for CPAP, and the ability and resources to initiate and maintain it.

This data showed CPAP being used most in neonates <1 day old and infants 1-3 months, which may be linked to specific training on CPAP in those who work frequently with neonates and are attuned to the technique. CPAP can be used in older children and for other conditions such as cardiac and chronic neurological conditions[3], however this was not evident from the data in this study. There is also a growing body of literature on the use of CPAP and HFNC in adults for chronic respiratory disease management such as chronic obstructive pulmonary disease (COPD) and after the recent covid 19 pandemic. More studies are needed in children on the use of CPAP in other medical conditions outside of the neonatal and infant period.

In keeping with results from Venter et al (2021)[1], our study showed male babies needed CPAP more often than female babies (58% vs 41%). Interestingly, the male gender is considered an independent risk factor for worse outcome and higher neonatal morbidity and mortality, particularly in preterm infants.[10] As seen in the study by Murray et al (2008)[11], CPAP in this study was primarily used for respiratory conditions, with pneumonia (46%) and unspecified respiratory distress (43%) being predominant. Given the age of more than half the children transported i.e. <3 months old, perhaps the unspecified respiratory distress was synonymous with newborn respiratory distress syndrome i.e. hyaline membrane disease (HMD) or general RDS secondary to other pulmonary pathology. Since the clinical documentation was vague, there may have been more missed pneumonia cases in the unspecified RDS group. The newborn group (<1 day old) were not further classified by level of prematurity. Similarly,

Murray et al (2008)[11], demonstrated a 61% RDS group; and 11% bronchiolitis group in a predominant infant age group.

Most CPAP requests came from district Hospitals, which is to be expected since this is the first level where specialist paediatricians oversee clinical management, and they would likely be key to identifying the need for CPAP. It was interesting to note that a particular district hospital had the greatest number of patients needing CPAP. This district hospital, like others on the same level, has a mix of doctors of varying experience, and the range of experience could account for the difference (and knowledge) around when to request CPAP, identifying who needs CPAP and starting CPAP. Similarly, hospitals starting CPAP more often could be due to their patient profile i.e. sicker patients (again not clear from the note keeping) or due to the skill of staff at the hospital and their ability to identify the need, or to available CPAP resources. These questions cannot be answered in this study, but it merely highlights a gap for future studies. At present, most institutions (often tertiary and secondary centres) in the Western Cape have individualised protocols for CPAP initiation and there is a lack of standardised provincial training guidelines that would ease the referral process from CHC's and district hospitals and mitigate the limitations of staff skill and resources. There may be a future opportunity for SPRINTT to develop a more formalised program as research in this area continues.

In many high income settings, specialized paediatric ICU trained retrieval teams exist that mostly comprise consultant paediatric or anaesthetic physicians and paediatric ICU nurses or critical care paramedics.[11][12][13] In these settings, well-established paediatric intensive care networks exist, and distance and times of transfers in some regions are generally shorter (the average distance travelled by a UK paediatric retrieval team by ground was 31km).[13] South Africa faces a shortage of doctors and specialized doctors such as paediatricians and neonatologists[1], and almost all such transfers are undertaken by EMS staff alone. In South Africa, EMS personnel deemed Advanced Life Support (ALS) providers could have a range of undergraduate training, from vocational training certificate courses[14], a two-year postgraduate diploma (independently administers drugs and able to carry out advanced skills)[15] or a 4 year university degree (includes diagnostic execution and critical care invasive procedures)[15]. South Africa has since recognized the need for matched theoretical knowledge with skill and practical experience and as of 2020, critical retrievals including neonatal and paediatric remain

reserved for degreed paramedics[16]. Much work is needed to build a workforce to meet the current goals and regulations for optimized service delivery. As with physicians, the country may face a shortage of qualified degreed paramedics[14].

SPRINTT initiated CPAP in 30% of cases that received CPAP, and although this study was not able to identify why this was the case, we suspect this includes inadequate identification of deteriorating cases by hospital staff; a lack of CPAP resources or a lack of knowledge on CPAP use. Most SPRINTT initiations (62.7%) came from district hospitals where more senior staff were present. Conversely, of the 289 CPAP requested cases, 20% were stood down by SPRINTT and they opted to administer other forms of ventilatory support such as nasal prong oxygen. Our study revealed that although most CPAP requests were made by doctors, in some cases EMS staff were left with the final assessment of the need (or lack thereof) for CPAP, demonstrating their skills, treatment decision making and experience over generalist staff.

The data collected for this study from 2019 is now some five years old, but we have no reason to believe that there have been significant changes in CPAP usage or availability in the interim given the ongoing paucity of literature and guidelines pertaining to paediatric interfacility transport. The main limitation of this study involves the accuracy and completeness of the recorded information in the clinical records databases. A possible clinical practice policy could be implemented based on these study findings whereby completeness of medical records and astute clinical governance regarding these records can encourage staff compliance. It would then be interesting to repeat this study and possibly identify if addressing the gaps in clinical record keeping, would allow for more detailed CPAP utilization findings such as more accurate diagnoses; clinical response to CPAP; deterioration on route, adverse events, comparison between the modes of ventilation and clinical outcome etc.

Since the initial CPAP request data (as collected for ongoing SPRINTT data collection improvement and clinical quality control) was hand searched, there is the potential for requests to have been overlooked, resulting in missing data. In addition, since this was a secondary analysis of the SPRINTT data collection, the details of the computer algorithm used to search the CAD database was not shared with the researcher and any shortcomings in its design,

accuracy or software can not be critiqued. There is, therefore, no way of knowing whether cases were missed by this algorithm, although it seemed thorough from our interrogation.

Whilst this study had no comparison or exposure groups, the strobe checklist for observational studies was considered (addendum); however, this study (and its databases used) does however, meet quality standards for recommended medical chart reviewing as listed by Worster et al (2005).[17]

## Conclusions

International literature has focused on the use of CPAP in remote settings as well as its cost effectiveness in relation to mechanical ventilation, however, the focus of future research in LMIC countries should be directed towards adequate staffing availability; education and training of staff; as well as cost effectiveness. CPAP has the potential to reduce the need for intubation and mechanical ventilation for transfer in the paediatric and neonatal population, and this is particularly relevant in low resources settings with limited access to intensive care. Despite the challenges (rural areas, distance, resources, and education) faced by South African EMS personnel, this study highlighted that CPAP can be utilized before and during transfer by specialised retrieval units like SPRINTT and these teams are able to make autonomous decisions regarding CPAP utilization. More studies are needed looking at whether safety, cost and adverse outcome is reduced with CPAP compared with mechanical ventilation.

## Conflicts of Interest

There are no conflicts of interest in this study.

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# Part C: Addenda

## Addendum 1: Research Proposal

# RESEARCH PROPOSAL

Description of the pattern of requests and utilization of nasal continuous positive airway pressure (nCPAP) during ground transport of children younger than 13 years of age in the Western Cape Provinical Ambulance Service (state sector), South Africa. A retrospective cross-sectional study.


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Date: 17 September 2019

## Research Question/statement

A closer look at the pattern of requests and utilization of Nasal Continuous Positive Airway Pressure (nCPAP) during ground transport of children younger than 13 years of age, in the Western Cape Provincial Ambulance Service (state sector)of South Africa.

## Background/Literature Review

### *Introduction*

nCPAP can be used to treat a variety of respiratory conditions that result in respiratory distress.(1) It can also be used to treat neurologic and pulmonary conditions in infants and children as well as heart failure and cardiac related conditions in the same patient population.(2) It is widely accepted as a safe method of non-invasive ventilation (NIV) in an optimal clinical environment such as the Intensive Care Unit (ICU).(1) However, it's use outside of ICU settings is rising and consequently there has been a rise in the need for transferring young children, especially neonates, while on nCPAP.(1,3,4)

### *South African Context*

In the South African (SA) setting, the ability to safely transfer paediatric patients to secondary and tertiary institutions is crucial as many sick children present to the peripheral clinics and hospitals, where the level of care is not sufficient to provide high-care or paediatric intensive care. In the Western Cape (WC) province of SA these transfers are by the METRO Emergency Medical Services (EMS) with unstable or critically-ill children being transferred by the Specialised Paediatric Retrieval Including Neonatal Transfer (SPRINT) team.(5) nCPAP in this regard may be commenced as a new medical therapy or an intervention that needs to be continued on route to the more appropriate level of care.(2)

### *Physiology*

nCPAP can only be applied to a spontaneously breathing person.(2) The physiologic goal is to improve ventilation-perfusion and thereby oxygenation by means of keeping the alveoli open during expiration.(2) This allows for optimal gaseous exchange through alveolar recruitment.(6) Improved clinical parameters include an increase in functional residual capacity which improves lung volume, thereby further improving gaseous exchange with an increase in PaO2 and a decrease in PaCO2.(6) Hypoxic vasoconstriction in the pulmonary vasculature is improved along with pulmonary vascular resistance and hence improved pulmonary blood

flow.(6) When clinically indicated for heart failure and pulmonary congestion, CPAP reduces preload and afterload, hence these patients see an improvement in cardiac output and pulmonary oedema.(2) Specifically in neonates, CPAP has been shown to generate more regularity in breathing patterns due to stabilization of the chest wall.(6) Also in neonates, the inspiratory and expiratory times (I:E ratios), are increased and in the case of Respiratory Distress Syndrome (RDS), surfactant release appears to be strengthened by CPAP.(6)

### *CPAP in transport*

The majority of paediatric cases requiring nCPAP during transport will need for a blend of oxygen and medical air. Due to concerns about the harmful effects of oxygen toxicity in newborn babies and small infants, there is a move towards respirtatory support using the lowest possible amount of oxygen, ideally air. Thus it has become essential to have a source of air as well as oygen during transport.

Whilst oxygen cylinders are easily available for transport in most places, medical air cylinders are much more problematic. These are not available in the Western Cape (WC) of South Africa in a configuration that would reliably permit delivery of nCPAP for anything but very short journeys. Even ensuring an adequate number of oxygen cylinders can be problematic, especially if the patient requires high concentrations of inspired oygen and/or there is a long duration of travel.(2) This is primarily due to the lack of space in an EMS vehicle for multiple cylinders.

The newer generation of transport ventilators, such as the Hamilton T1 ventilator used by the SPRINT team, have built-in air turbines that entrain room air.(7)

### *Indications for CPAP*

CPAP can only be applied to a spontaneously breathing patient and it maintains airway patency when there is airway collapse. Airway collapse is seen in conditions such as Obstructive Sleep Apnoea (OSA) which may occur as a result of childhood obesity, enlarged adenoids and hypotonia. (8) In neonates, CPAP can be used to treat RDS as a result of surfactant deficiency.(8) It is also indicated in hypoxia secondary to infection such as pneumonia and bronchiolitis, where work of breathing can be increased.(8) Positive results with CPAP have also been noted in children with collapsible airways such as those with tracheomalacia.(8) Children with cardiac disease who may present in congestive heart failure and associated hypoxic respiratory failure will also benefit from CPAP as it improves ventilation/perfusion (V/Q) matching and augments cardiac output.(8) CPAP can also assist with improved

oxygenation prior to intubation and mechanical ventilation and conversely, after extubation when individuals may still need additional positive pressure without invasive ventilation.(8)

### *Clinical benefits of CPAP*

The use of NIV has many benefits including the avoidance of invasive procedures such as tracheal intubation which historically may only have be required for the short period during transfer to avoid the risk of transporting a potentially unstable child which may decompensate on route.(1,9) The use of NIV may also be less uncomfortable for the paediatric patient in that it preserves speech and swallowing abilities.(9) When compared with invasive ventilation such as intubation, the relative ease of use and minimal to no need for sedating drugs during transport also makes nCPAP/NIV a more attractive option.(2) This is particularly important where more inexperienced and junior staff are involved in transport.

### *Paediatric transport CPAP literature*

Literature on the safety and efficacy of NIV in children outside of ICU settings is limited, and this is especially the case with respect to NIV use during transport of children.(3) A recent systematic review found that NIV is a potentially safe mode of ventilation during transfer of children between the ages of 0 – 18 years with respiratory distress.(4) This review found that intubation and escalation of care during transport were only required in 0.4% of cases and an in-transport adverse event rate of 1-4% was reported.(4)

This review included a series of 207 neonates and infants in Australia, it was shown that these children were safely transported during interhospital ground transfer for conditions that included bronchiolitis, chronic lung disease and congenital heart disease.(10)

In a smaller series that focused on 25 children with pulmonary and neurologic complications, NIV was also shown to be safe.(9) T hese children were more likely to be transported from a tertiary paediatric high care or ICU to a step-down facility for maintenance care, thus demonstrating the need for NIV use in interhospital transfer in the opposite direction of the referral pathway. NIV/nCPAP could therefore, become an important tool in children who are chronically ill that require multiple transfers between primary and acute care and inpatient and outpatient management.(2)

### *Adult transport CPAP literature*

Although no paediatric studies were found during the literature search that compare mechanical ventilation with CPAP during transport, there is evidence from adult transport literature on the benefits of CPAP in this setting.

A recent systematic review done in the UK prehospital setting looked at 10 studies (8 of which were RCT) that compared standard prehospital care and CPAP in adults. The review aimed to establish cost effectiveness as well as clinical benefit for use of CPAP in the prehospital setting. The study found that the use of CPAP, although more expensive reduced the risk of overall mortality (*OR 0.41; 95% CI)* as well as the need for intubation (OR 0.32; 95% CI) compared to standard care.(11) It was noted that the long term cost effectiveness was not certain.

A cross over, observational, non-blinded study in an adult population (n=89) with acute respiratory distress (ARD) in the USA also showed great benefit in using CPAP in the pre-hospital setting in this patient group. Initial data before the implementation of CPAP showed that 7.9% of patients with ARD was intubated within 48 hours and the average length of the ICU stay was 8 days.(12) After the implementation of CPAP on the road, no patients were intubated and ICU admissions decreased as well as length of stay to 4.3 days.(12) More research is needed in the paediatric population to determine whether such results could be comparable.

## Research Proposal

### *Motivation*

The use of nCPAP in young children, particularly neonates, is well documented in the literature when studied in the intensive care unit (ICU) setting (1), however, there is a paucity of literature regarding its use in transport settings.

This study would provide information on current pattern of requests for nCPAP and data on the actual usage of nCPAP in children during transport in the WC Province of South Africa. The information provided will be of use to paediatricians, neonatologists, emergency physicians and paramedics, as well as to service managers, supply-chain logistics coordinators and policymakers working in the fields of EMS and paediatrics.

### *CPAP requested versus CPAP given*

It is well known amongst WC referring facilities, that asking for nCPAP for a child, results in dispatch of the SPRINT team, who often arrive faster than a normal operational ambulance. Thus there may be a perverse incentive to ask for this mode of ventilation even if not needed. It is not currently known what proportion of paediatric patients for whom nCPAP is requested actually received it during transport.

Another important unknown is: when nCPAP has been requested but is not given, what form of respiratory support is then utilised during transport? A further unknown aspect is the number of time nCPAP is applied by the transport team without any clinical request from the treating clinician at the time transport was booked.

This results in three potential groups of patients for this study:

1. Group 1: REQUESTED - Where nCPAP was requested, or mentioned in the request, for road transport by the treating clinical team
2. Group 2: GIVEN - Where nCPAP was utilized during transport – this will include 2 sub-groups:
    a) Where CPAP was requested and given
    b) Where CPAP was not requested but was given
3. Group 3: NOT GIVEN Where nCPAP was requested or mentioned in the request phone call, but not used during transport. These patients may subsequently have been transported on low-flow nasal cannula (LFNC) oxygen, Heated Humidified High-Flow Nasal Cannula (HFNC) oxygen, or they may have needed intubation and ventilation for transport.

## Aims and Objectives

### *Aims*

The aim of this study is to describe the pattern of requests and use of nCPAP during transfer of children under the age of 13 years in the state sector of the Western Cape, SA.

### *Objectives*

The objectives of this study are to determine

1. The proportion of nCPAP requests that resulted in nCPAP being used during transport (Group 2a/Group 1)
2. The proportion of nCPAP transports where nCPAP was commenced without a request made at the time of booking the transport (Group 2b/Group 2)
3. What was the mode of respiratory support given to patients in whom nCPAP was requested but not given (Group 3)
4. A general descriptive analysis of nCPAP utilization e.g. patient demographics and clinical conditions

## Study Methodology

### *Study Design*

This will be a cross sectional study using EMS electronic records for the period 1st April to 31st June, 2019. This time period was selected (i) there are time constraints in terms of how much data the principal investigator can feasibly review in detail during her research time allocation and (ii) because data on completed cases (including paper records) for this period ought to be avaiable for this time period by the time the study is initiated. Additionally this time period should roughly generate 300-350 cases which will suffice as an adequate patient sample.

The study will involve retrospective data collection from an existing database and there will be no follow up of patients over time. It is anticipated that the majority of records will be wholly electronic. However, in some instances e.g. cases outside the Cape Town Metropole such as Hermanus and the West Coast, electronic records from ePCR may not be available, in which case the paper records will need to be requested from the EMS division data division in question, by following normal EMS procedures. If paper records are not available this fact will be noted and reported.

### *Study Population*

#### *Characteristics of the study population (Including inclusion and exclusion criteria)*

All children under the age of 13 years transported in the Cape Town Metropole and greater Western Cape area by Western Cape EMS, during the study period, who either had nCPAP mentioned during the request for transport by the treating clinician, or who received nCPAP during transfer will be included in this study.

This includes nCPAP for all clinical conditions and not only respiratory indications. Children older than 13 years and adults will be excluded from this study. Only data on interfacility transport will be looked at and not primary transfers. Only completed transfers will be examined as it is often not possible to reliably determine from the EMS CAD system why requests for transport are cancelled by facilties.

Where patients with nCPAP mentioned during the request for transport was completed by AMS (private contracted service), the crude number of cases where AMS completed the transfer will be reported but will be as their electronc patient records are not accessible to the researchers – these case will be excluded from the analysis.

All completed road transfers will have either an electronic patient care record (ePCR) or paper patient report form (PRF) – the latter being captured and filed at the division where the crew were dispatched from. In cases where there is no overlap between mention of nCPAP during requesting call and ePCR nCPAP record showing nCPAP given – the ePCR or PRF paper record will be reviewed to find out if there what the mode of ventilation was during transport.

If there are any cases where no correlating ePCR or PRF paper records can be found these cases will be recorded as cases having insufficient information. It is anticipated that electronic data will be available for the vast majority of patients; PRF paper forms only being submitted in the rare event that ambulances were not equipped with electronic patient data terminals or these were out of action for some reason.

### *Study Setting*

#### Western Cape Emergency Medical Services Dispatch

The Tygerberg  Control Centre (TCC) has 2 divisions, Metro Control and Ambulance Control. Metro control is called on 021 937 0300 and this division of TCC dispatches the SPRINT team as well as paramedic teams for Mountain, Sea and Air Rescue.(13)  Metro Control also activate Air Mercy Services (AMS) for fixed wing and rotor retrievals.(13) Metro control can therefore be considered more specialized and call operators are medically trained individuals responsible for dispatching advanced level resources appropriately.

Ambulance control is the general ambulance service open to everyone including the public and is available on 021 937 0500.(13) Operators are not necessarily medically trained. The current expected time frame per call is approximately 120 seconds.

#### CPAP Capability in WC

There are two teams in WC EMS capable of giving CPAP to children 1) SPRINT team does road transport of CPAP cases and 2) AMS – private service contracted to provide fixed & rotor wing retrievals when the calls cannot be adequately serviced by road vehicles. Both of these teams are based in Cape Town metropole and dispatched by Metro control division of TCC.

The SPRINT team is based at EMS Western Division, Pinelands. The AMS is housed at Cape Town International Airport. SPRINT serves Cape Town, West Coast, Winelands and other rural areas of the Western Cape to a distance of 300km.(14) AMS provides a service to more distant locations but is restricted by weather and availability of suitable landing locations.(15)

### *Sampling Method*

The data will be extrapolated from the following sources:

1. Computer Aided Dispatch (CAD) system – used by the EMS communications centre to dispatch ambulances to calls.
2. Electronic Patient Care Records (ePCR) – used by EMS practitioners completing the calls to document the patients progress and their notes.
3. Patient Report Forms (PRF) paper records – also completed by EMS practitioners to document the patients progress where ePCR is not in use (rare).

Identification of CPAP Requests from CAD

From analysis done as part of SPRINT service and data improvement, one of the investigators (BC) is aware that there were a total of 243 unique requests for CPAP identified by a MS Excel search for the terms CPAP, C-PAP, CPEP and CPEP (latter two are common spelling errors) during transport in under-13 year old patients between 1st September to December 31st, 2018. Upon review 24 of these were incorrect pick-ups, leaving 219 correct identifications.

Subsequently this portion of the database was extensively reviewed for all variants of spelling of the acronym 'CPAP. An algorithm was developed to auto-search CAD for all these variants. When applied the alogrith identified all 219 previously picked up as well as a further 111 cases – all of which pertained to CPAP requests. This algorithm (or an updated version) will be used to search the CAD database for study period to identify CPAP requests.

Identification of CPAP given from ePCR

The ePCR database will be searched for CPAP as the chosen mode of ventilation for the study period. In addition, in order to capture any potential cases where the paramedic recorded the CPAP delivdery only in the free text areas of ePCR – these will be searched for the term CPAP and C-PAP. As these are medically trained personnel – there is much less variation in the terms used, therefore the full list of variants of the acronym CPAP will not be applied.

A request for the following information for the identified cases will be made to EMS to extract from the databases:

CAD – Incident type, demographics, diagnostic category, nCPAP recorded as being requested or not at initial call; geographical location of referring and receiving units and timings involved in the call.

ePCR – mode of ventilation during transport (none, nasal prong oxygen, high flow nasal cannula (HFNC), nCPAP or mechanical ventilation, ventilation settings (e.g. nCPAP pressure, if intubated Peak Inspiraotry Pressure (PIP) and Peak End Expiratory Pressure (PEEP) & FiO2), vital signs at start & end of transport (heart rate, respiratory rate, oxygen saturations) and any adverse outcomes mentioned in the ePCR during transport. Adverse outcomes can not be fully defined at this point as it will depend on the language used to record the encounters in ePCR. However, as previously described in studies of NIV during transport of children., expected adverse outcomes could possible include desaturation, anpoea, bradycardia, need for intubation etc.

It is important to note that the information is captured in these databases varies in quantity and quality, and therefore, the above elements are possible/ideal findings, however some data items may be limited in their availability. In addition, there may be some cases that were captured on paper when the electromic system was not functioning, and these will be requested through EMS if identified as such. However, the primary data source will be electronic.

## Data Collection, Management and Analysis

For the period 1st April to 30th June, 2019 in WC area, as specified above there are three groups of patients will be identified as follows

Group 1: All nCPAP requests in <13year old patients from CAD database -

Group 2 The WC EMS IM team will provide the Investigators with lists of all patients <13 years old where nCPAP was recorded as the mode of ventilation during transport in the form of an excel spreadsheet

Group 3: The 3rd group (patients where nCPAP was requested but not given) will be extrapolated from lists 1 & 2 above

These lists will initially contain patient identifiers in the form of 4-digit EMS reference numbers so that cross-referencing can be done between the two databases, (CAD & ePCR). The researcher will then access these patient records across the two databases to identify the needed informational categories.

The following information for each of the groups will be extracted: total number, demographic details (age & sex), diagnostic category, geographical locations (referring and receiving facilities), timings, highest qualification of EMS practitioner, SPRINT or non-SPRINT

transfer. For those that received nCPAP (or other mode of ventilation) the following settings will be recorded: Fractional Inspired Oxygen (FiO2) and ventilation pressures. Vital signs at start and end of transport will be noted. Once the information has been extracted into the study database, all identifiers will be removed.

The study database will be in the form of an excel spreadsheet. The anonymised data will be stored in a password protected file on the Principal Investigators password protected computer.

### *Statistical Analysis*

Statistical data analysis will be performed by the principal investigator using Microsoft Excel and exported to a statistical package programme if necessary in order to perfrom basic descriptive statistics. Summary statistics will be used to describe all variables. Means and standard deviations will depict continuous varables. Categorical data will be presented as frequency and proportions (%). Categorical data will be compared with the use of the Fisher's exact test or the $Chi^2$ test, depending on the characteristics of the variables. Parametric and non-parametric tests will be used where appropriate for standard inferential statistics. Confidence Intervals of 95% and a p-value of $<0.05$ will be considered significant in this study. Information summaries will also be depicted in the form of graphical representation such as pie charts, bar graphs and tables. Any other clinically pertinent or significant issues addressed will be mentioned in the discussion.

## Ethical considerations

### *Consent*

- Following ethical approval, permission will be requested from the NHRD to the Western Cape METRO EMS Acting Director (Dr Shaheem De Vries) for the Principal Investigator to access the CAD and ePCR database for this project (including paper cases where ePCR was not available). These databases are already registered with the University of Cape Town Human Research Ethics Committee (R014/2017) which will expedite this. The research will be a retrospective review of an existing database and involves no more than minimal risk to the participants and we therefore request a waiver of informed consent. As this will be a retrospective analysis of routinely collected data, taking individual consent will be impractical. There is no interest in individual patients, nor individual healthcare personnel.

- Various safeguards are in place to protect the identity of the patients included in this study. Please refer to the data safety section above.

### *Confidentiality*

Patient confidentiality will be fully respected as no identifiable patient information will be stored in the study database; therefore, consent is not needed from the patients. Confidentiality of medical staff will also be respected and no names/personal information of staff involved in the cases will be collected and thus specific informed consent from the medical staff is not needed.

Data security will be maintained by access via a personal computer with password protection by the principle investigator( NDP), and once the study is completed, data will be stored by the Supervisor in a secure, password protected computer for a period of 5 years after publication

### *Benefits and Risks*

There will be no clinical, psychological, emotional or legal risk to the patients whose information is being used. Similarly, although the study will be bringing no direct benefit to the specific patients in the study, the expected outcome from the data analysed will provide insight into the current use of nCPAP so that future patients may benefit. Although the study participants are minors, and a potentially vulnerable group, this research, being an entirely retrospective review puts them at no additional risk, and we believe the potential benefits of the findings could improve the system.

### *Re-imbursements*

Given the nature of the study, there will be no reimbursement strategies for patients as they are unaware of the study and information being used and there will be no additional re-imbursements for any Western Cape METRO employees.

### *Conflicts of Interest*

A possible conflict of interest in this study that should be noted is that the study supervisor is a direct employee of the Western Cape METRO EMS and is the clinical lead for the SPRINT team. This should not affect the results/outcome of the study since the data will be directly extrapolated from an existing database and transcribed by the principle investigator.

## Strengths and limitations

A strength of this study is that it is an affordable low cost, practical project, and will provide academically and clinically valuable information in a field currently lacking in literature. The main limitation of this study involves the accuracy and completeness of the recorded information in the databases, this has potential to be flawed by human error. Perhaps the diagnosis made was incorrect, perhaps the notes/disposition plan was incomplete or perhaps the diagnosis was not recorded clearly by the clinician. Many children being transported may also not have had a definitive diagnosis at the time of transport.

Additionally, because the initial known CPAP request data (as collected for ongoing SPRINT data collection improvement) was hand searched, there is potential for requests to have been overlooked, resulting in missing data. These are common flaws noted in medical chart reviews in emergency medicine studies.(17)

This study does however (and database used), meets quality standards for recommended medical chart reviewing as listed by Worster et al.(17) Namely, there is no greater alterantive database than the one being used in the study; the database has privacy protection laws; a standard operating procedure exists (SOP) for correct capturing of data into the database with ongoing improvement evaluations; and a detailed and thorough description of the database exists.(17)

## Time Frame and Budget

### *Project Time Line*

Time frame for data collection and analysis will depend on PI availability to analyse the information in the relevant databases. Cost of this project is minimal as it will mostly involve a solo researcher (NDP) working on a laptop.

| 2019-2020 | March | April | May | June | July | Aug | Sep | Oct | Nov | Dec | Jan |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **EM-DRC** | | | | | | | **X** | | | | |
| **Sx-DRC** | | | | | | | | **X** | | | |
| **Ethics** | | | | | | | | | **X** | | |

| | | | |
|---|---|---|---|
| **Data Collection** | **X** | **X** | |
| **Transcribing of Data** | | **X** | |
| **Data Analysis** | | **X** | **X** |
| **Compilation of Final Report** | | | **X** |
| **Submission** | | | **X** |

*Budget*

There will be no specialized funding from any institution for this project and no dedicated grants have been obtained. All projected costs will be paid for by the principle investigator (NDP). Cost incurred by the principle project supervisor e.g. phone calls, travel and stationery have not been considered here, but will also be re-imbursed by the principle investigator should the supervisor wish to claim these costs.

| ITEM | DESCRIPTION | UNIT COST | TOTAL UNITS | TOTAL COST |
|---|---|---|---|---|
| Travelling to meet with supervisor | Claremont (home) to Pinelands (supervisor work base) or Tygerberg hospital (work) to Pinelands. Projection of approximately one meeting per month with an increase to two meetings closer to submission. | 1 meeting = 7.3km/ 1.46 litres of petrol (Claremont to Pinelands) or 20.9km/ 4.18 litres of petrol (Tygerberg to Pinelands)<br><br>R16.13 per litre | 12 (average 6 meeting driving from home and 6 driving from work)<br><br>Home = R141.30 | R545.80 (R546) |

| | | | | |
|---|---|---|---|---|
| | | | Work = R404.50 | |
| Phone calls to supervisor | Made from personal cellular telephone. Unable to accurately predict, however, it can be estimated that there will be 2 calls a month based on previous communication with an average length of 20-30 min. | 1 call = R21.00 (70c per minute as per Telkom network rates) | 10 | R210.00 |
| Internet/email | Wi-Fi (not an additional cost for the researcher as home internet subscription is already in place and is regarded as a fixed expense for the researcher. | R629 per month | 6 | R3774 |
| Office Supplies | Stationary, Printing, Filing etc | n/a | n/a | R1000 |
| Biostatistician (if necessary) | Specialized Professional Service | R200/hour | 10 | R2000 |
| **GRAND TOTAL** | | | | **R7530** |

## Dissemination of Results

The findings of the study and completed thesis will be submitted to the University of Cape Town as partial fulfilment for the MPhil degree for student progression. Findings will also be

disseminated in the form of a report to Western Cape METRO EMS, and presented and disseminated to key roleplayers in EMS and WC Emewrgency Medicine and Paediatrics. Lastly, the findings will be presented at conferences, and submitted to a peer reviewed medical journal, preferably paediatric, emergency medicine or critical care, for publication and potentially open access education.

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# Addendum 2: HREC approval

**UNIVERSITY OF CAPE TOWN**
**Faculty of Health Sciences**
**Human Research Ethics Committee**

**Room G 50 Old Main Building**
**Groote Schuur Hospital**
**Observatory 7925**
**Email:** hrec-enquiries@uct.ac.za
**Website:** www.health.uct.ac.za/fhs/research/humanethics/forms

16 January 2020

**HREC REF: 860/2019**

**A/Prof P. Hodkinson**
c/o Vathiswa Mzamo
Division of Emergency Medicine
F51 OMB GSH

Dear A/Prof Hodkinson

**PROJECT TITLE: DESCRIPTION OF THE PATTERN OF REQUESTS AND UTILIZATION OF NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE DURING GROUND TRANSPORT OF CHILDREN IN THE WESTERN CAPE PROVINCIAL AMBULANCE SERVICE, SOUTH AFRICA (MASTER - DR NICOLE DU PLESSIS)**

Thank you for submitting your new study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study subject.

**Approval is granted for one year until the 30 January 2021.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period. (Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

***The HREC acknowledges that the student: Dr Nicole Du Plessis will also be involved in this study.***

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

**Please quote the HREC REF in all your correspondence**

Yours sincerely

**PROFESSOR M BLOCKMAN**
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**
Federal Wide Assurance Number: FWA00001637.

**HREC Ref 860/2019**
**OL**

# Addendum 3: Strobe Checklist for Cross sectional studies

*Highlighted items not applicable to this study

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

| | Item No | Recommendation |
|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses |
| **Methods** | | |
| Study design | 4 | Present key elements of study design early in the paper |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure (not applicable), follow-up (not applicable), and data collection |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable (not applicable) |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group (not applicable) |
| Bias | 9 | Describe any efforts to address potential sources of bias |
| Study size | 10 | Explain how the study size was arrived at |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding |
| | | (*b*) Describe any methods used to examine subgroups and interactions |
| | | (*c*) Explain how missing data were addressed |

| | | |
|---|---|---|
| | | (*d*) If applicable, describe analytical methods taking account of sampling strategy |
| | | (*e*) Describe any sensitivity analyses |
| **Results** | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed |
| | | (b) Give reasons for non-participation at each stage |
| | | (c) Consider use of a flow diagram |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders |
| | | (b) Indicate number of participants with missing data for each variable of interest |
| Outcome data | 15* | Report numbers of outcome events or summary measures |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included |
| | | (*b*) Report category boundaries when continuous variables were categorized |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses |
| **Discussion** | | |
| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results |
| **Other information** | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based |