# Paediatric procedural sedation and analgesia in the emergency centre: a description of the fasting status

by
Cornelle Dunn
MBChB (UP), DipPEC (SA)
DNNCOR001

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Supervisors:
Dr PG Cloete
Dr C Saunders
Dr K Evans

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## Dedication

To my parents, Pieter and Mariette, this dissertation is for you. Thank you for the support, sacrifices and love. Without you this would not have been possible.

## Acknowledgements

To my amazing supervisors, Philip, Katya and Colleen, thank you for supporting me every step of the way. Your unwavering patience and support is inspiring!

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# PART A : Literature review

## Paediatric procedural sedation and analgesia in the emergency centre: a description of the fasting status

## Abbreviations:

| | |
|---|---|
| PSA: | Procedural sedation and analgesia |
| EC: | Emergency Centre |
| ASA: | American Society of Anaesthesiology |
| WHO | World Health Organisation |
| NPO: | Nil per os |
| CT Scan | Computed Tomography scan |
| MRI: | Magnetic Resolution Imaging |
| CNS: | Central Nervous System |
| GABA: | Gamma aminobutyric acid |
| EEG: | Electroencephalogram |
| MO: | Medical officer |
| PEM: | Paediatric Emergency Medicine |
| LMIC: | Low-and Middle-income Countries |
| BP: | Blood Pressure |
| EtCO2: | End tidal carbo dioxide |
| AAP: | American Academy of Paediatrics |
| ECG: | Electrocardiogram |
| ICU: | Intensive Care Unit |
| RCWMCH: | Red Cross War Memorial Children`s Hospital |
| IV: | Intravenous |
| IMI: | Intramuscular injection |
| NHRD: | National Health Research Database |
| COSMO: | Community service medical officer |
| SASA: | South African Anaesthesia Society |
| NHRD: | National Health Research Database |
| HREC: | Human Research Ethics Committee |
| ESM- Ketamine: | Every second matter for mothers and babies – Ketamine |
| EMR: | Electronic medical records |
| EDIS: | Emergency Department Information System |

## Introduction

This literature review will be presented in two parts. Firstly, a general introduction to procedural sedation and analgesia (PSA), the various components of this as well as the value of it, especially in the resource-limited setting.

Secondly, a directed literature review which aims to review published literature relating to PSA in the paediatric patient in an emergency setting, with particular attention being paid to the fasting state and adherence to fasting guidelines.

## Literature search

A search was performed using the PubMed Database via the University of Cape Town library website on 13 July 2020. The search was conducted broadly and then narrowed down. Search strings (1-4) are shown below.

1. "Procedural sedation and analgesia"[Mesh] AND "emergency department"[Mesh]
2. "Procedural sedation and analgesia"[Mesh] AND "emergency department"[Mesh] AND "paediatric"[Mesh]
3. "procedural sedation and analgesia"[Mesh] AND "emergency department"[Mesh] AND "paediatric"[Mesh] AND "South Africa"[Mesh]
4. "Procedural sedation and analgesia"[Mesh] AND "emergency department"[Mesh] AND "paediatric"[Mesh] AND "fasting status"[Mesh]

The following filters were applied: articles published in the last ten years, English language as well as the availability of the full-text article. Duplicate articles were removed. Search results were assessed based on title and abstract for relevance, before interrogation of the full-text article of those not initially excluded. The literature review also included any other relevant studies identified during the inspection of included articles reference lists.

Published practice guidelines by the Emergency Medicine Society of South Africa as well as guidelines for paediatric procedural sedation published by the New South Wales government health department were also included in the literature review. In total, 359 articles were identified, and 67 were subjected to full-text assessment.

## Background

Emergency medicine was first introduced in the South African setting in the late 1990s. In 2003, Emergency Medicine was included in the list of recognized specialties(1). As the field of emergency medicine has developed locally as well as internationally, the services provided by the relevant physicians also evolved.

In South Africa, as in many resource-limited settings, specific challenges are ever-present - high patient loads and long waiting times for operating theatres and specialists - thus PSA forms a critical part of emergency care (2,3). Patients present to the Emergency Centre (EC) on an unscheduled basis, often with complex complaints that necessitate emergent management (3). PSA is considered a core competency for any emergency physician and is performed routinely (3). Patients who attend the EC are diverse, not only in race, gender, and ethnicity but also in age, and it is reasonable to expect that all doctors working in the EC must be competent in providing not only care but safe PSA in all age groups.

In many resource-limited settings, including sub-Saharan African, there is a large mismatch between anaesthetic services required and the availability of such services(4). This anaesthesia gap is even more pronounced for children than for adults, as provider training and comfort with PSA in the young is uncommon(5). Apart from training and provider comfort, these regions often have a magnitude of other barriers contributing to the problem including unreliable electricity supply, inadequate facilities, unreliable oxygen supply and inconsistent availability of medication(4). This often leads to delay in procedures and/or transfer of patients from one facility to another, adding cost or procedures being done without adequate analgesia and or sedation (4–6).

## Definitions and terminology

Procedural sedation and analgesia

PSA is defined as a pharmacologically induced state that allows patients to tolerate painful procedures while maintaining protective reflexes (i.e. gag and cough) and adequate airway control (7). The purpose of PSA is to attenuate pain, anxiety, and motion to facilitate the performance of necessary diagnostic or therapeutic procedures while providing appropriate amnesia or decreased awareness, and ensuring patient safety (8). Relief of procedural pain and anxiety in children is an ethical imperative given the short and long-term physical, physiological, and psychological effects if left untreated (9,10). The intent of the sedation procedure, be it anxiolysis, analgesia, or both, determines the choice of medication (11).

PSA has two aspects – sedation as well as analgesia. Sedation reduces the state of consciousness, while analgesia reduces or eliminates the perception of pain. Analgesics often have some sedative effects, but few sedatives have the property of analgesia (12).

Depth of sedation

Depth of sedation has been described as a continuum, progressing from mild through moderate to deep sedation and ultimately to general anaesthesia (8).

In 2002 the American Society of Anaesthesiology (ASA) defined four levels of sedation.

1. *Minimal sedation (anxiolysis):* a state induced by medication in which the patient responds to verbal commands although cognitive function may be impaired. Cardiovascular and respiratory systems remain unaffected (12,13).
2. *Moderate sedation and analgesia* (often referred to as conscious sedation): drug-induced state in which a patient still responds purposefully to verbal commands but may lose the ability to respond to light tactile stimulus. Cognition is impaired. Cardiovascular system and respiratory function remain unaffected (12,13).
3. *Deep sedation and analgesia*: drug-induced decrease in consciousness in which a patient is aroused by repeated or painful stimuli only. Patients' ability to maintain their airway becomes impaired, and spontaneous ventilation may be inadequate. Cardiovascular function is maintained (12,13).
4. *General anaesthesia*: loss of consciousness, patient not rousable. Airway and ventilation cannot be maintained, and cardiovascular function may be impaired (13).

Paediatric populations

It is challenging to define the paediatric patient as the paediatric patient is defined differently depending on the setting. The South African Department of Health uses the following in their document defining age categories published 2012 on their website (14):

- Neonates: younger than 28 days
- Infant: 28 days and older up to and including one year old
- Paediatric: >1 year - ≤ 14 years old

- Juvenile: >14 years - ≤ 16 years old
- Adolescence/ Puberty: ≤ 19years old

In 2012, the World Health Organization (WHO) defined the terms as follows (15):

- Neonate: 0-30 days
- Infant: 1 month to 2 years
- Young Child: 2 – 6 years
- Older child: 6 – 12 years
- Adolescence: 12 - 18 years

In the Western Cape Government Department of Health, a child or paediatric patient is defined as an individual who is younger than the age of 13 years. Once the patient is 13 years old, he or she is considered an adult patient, and management happens within the adult healthcare services streams.

<u>Fasting</u>

Fasting is defined as the restriction of food and fluid intake before general anaesthesia or sedation and is considered as a component contributing to patient safety in anaesthesia (16). The induction of anaesthesia results in depression of airway protective reflexes, i.e., cough, gag, and swallow. The loss of these reflexes places the patient at an increased risk of pulmonary aspiration, pneumonia, or even death (17). Fasting guidelines have been released by the ASA with regards to general anaesthesia. Consensus guidelines were initially developed in 1980 by the ASA based on expert opinion. These guidelines were developed for general anaesthesia but have been extrapolated to all other sedation practices (18). Guidelines require the patient to be nil per os (NPO) for six hours for solids, four hours for breast milk, and two hours for any clear fluids (17).

## Indications for procedural sedation and analgesia

The general indication for PSA is to facilitate painful procedures. However, when dealing with the paediatric population, it can be required to facilitate an excellent clinical examination of the patient and for minor procedures which can lead to a traumatic experience for the child as well as parents (13). These indications can be divided into three main categories

- *Surgical intervention*: abscess incision and drainage, central line placement, chest tube placement, burn care and most commonly laceration repair (13,19).
- *Investigations*: lumbar punctures, Computed Tomography scan (CT scan), Magnetic Resonance Imaging(MRI), examination following an assault (imaging procedures)(13,19).
- *Procedures:* Foreign body removal, fracture manipulation and casting, joint dislocation reduction, wound dressing changes (13,19).

## Risk

Risk stratification not only identifies possible risk factors but also helps identify patients where general anaesthesia might be more appropriate (20). An important consideration when risk stratifying patients is whether a delay of the procedure to meet fasting guidelines will reduce the risk for morbidity and mortality (19,21). One of the biggest questions with regards to PSA in the paediatric EC population is whether fasting guidelines as put out by the ASA should be strictly enforced (19,21,22).

The pre-procedure risk assessment often occurs simultaneously with the initial evaluation. A medical history of previous surgeries or anaesthetic related complications will identify a patient as high risk as well as any anatomical abnormalities (e.g., craniofacial abnormalities like cleft palate) and patients with syndromes (e.g., Down`s syndrome). Furthermore, it is essential to take note of any recent respiratory infections, a history of croup or asthma as well as ask about night time snoring (20).

Risks for PSA on history include (13)

- Asthma
- Cardiovascular disease
- Congenital syndromes
- Allergies
- Current medication that might interfere with proposed PSA
- Reactions to previous anaesthesia or sedation
- Illicit drug use

The purpose of the pre-sedation history is to assist in risk stratification and identifying risk factors for PSA. As mentioned above many factors on history can identify high risk patients (13,20). As pre-sedation history is of vital importance, using a mnemonic can serve as a mental cue to ensure no vital information is neglected. Two such examples are 'SAMPLE' and 'SOAPM' (Table 1) (12).

*Table 1: Mnemonics for pre-sedation history*

| | |
|---|---|
| SAMPLE | |
| S | Signs and symptoms of current pathology |
| A | Allergy to medication, food, or latex |
| M | Medication being taken, whether continuous or not |
| P | Past medical history --- comorbidities, previous complications related to sedative agents |
| L | Liquids and solids --- fasting time and which type of food ingested.<br>Last oral intake – most guidelines recommend 6hrs for solids, 4 hours for breastmilk, and 2 hours for clear fluids(17). It is important to note that fasting vs non-fasting has not been shown to change the incidence of adverse events(7). Please see section on fasting for further details. |
| E | Events related to the need for sedation |
| | |
| SOAPM | |
| S | Size appropriate suction catheters and functioning suction apparatus |
| O | Oxygen supply – needs to be adequate with fully functioning flow meter |
| A | Airway equipment including BVM, nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (functionality confirmed), endotracheal tubes, stylets, face mask. |
| P | Pharmacy – all drugs needed |
| M | Monitors – pulse oximeter, end-tidal carbon dioxide monitor, and other monitors as appropriate(e.g., non-invasive Blood Pressure, ECG, stethoscope)(23) |

## Procedure

Phases of PSA: The process of PSA can be divided into three phases – pre-procedure, procedure, and the post-procedure/ recovery phase.

*Pre-procedure:* This stage includes the planning of PSA – where, when, what, why, who? The emphasis in this stage should be placed on patient assessment as well as planning of the procedure. A review of the indication for PSA during this stage is important (20,24). Pre-sedation assessment includes a focused history and physical examination to determine factors that may influence the selection of the sedation technique and affect the safety of the sedation. This evaluation includes a history of past and current medical problems, the indications for sedation, previous patient experience with sedation or anaesthesia, and the presence of airway or other conditions that may affect the efficacy of the sedation.

*Procedure:* PSA should be provided in a well-equipped area with all necessary resuscitation equipment readily available and in working condition. Local guidelines vary considerably depending on the setting, but each provider should follow the applicable guidelines for their setting (20).
The minimum available resuscitation equipment should include a bag-mask ventilation device, pulse oximeter, oxygen supply, and resuscitation drugs (4). Apart from equipment to monitor patients physiological state it is important to provide interactive monitoring to avoid oversedation and ensure patient comfort. This includes continuous observation of the patients airway patency as well as the quality of their ventilation (21). Equipment to obtain vascular access should be readily available, if not obtained before the procedure(13).

Efficacy of sedation is defined as the creation of conditions necessary to safely facilitate the completion of a procedure through attenuation of pain, anxiety, and movement with amnesia or decreased awareness (8). All of the following criteria must be present for sedation to be considered efficacious (25):

a) The patient does not have an unpleasant recall of the procedure.

b) The patient did not experience sedation-related adverse events resulting in abandonment of the procedure or a permanent complication. The patient did not require an unplanned admission to the hospital or prolonged observation in the EC.
c) The patient did not actively resist or require physical restraint for completion of the procedure.

The presence of any of the above criteria is considered a sedation failure. Personnel capable of managing threats to the airway, breathing and circulation should be available whenever PSA is performed (26).

*Post-procedure:* The patient should be kept in a monitored bed with observations being recorded until the patient is rousable (20,24). The patient is deemed ready for discharge when they are able to achieve a satisfactory state of wakefulness and maintain a patent airway without respiratory depression. Motor function and vital signs should also return to baseline functioning before discharge and pain should be controlled adequately(8). Post-procedure analgesia should be arranged before discharge, and the patient should be discharged into the care of a responsible adult (20).

## Pharmacology

The choice of drugs used during PSA should take the following into account: indication, procedure, duration needed, as well as pre-morbid functioning and any comorbidities (12). Various classes of drugs can be used either in isolation or as a combination to prove both sedation and analgesia as indicated.

Each drug or class of drugs are associated with a specific side effect profile and can be administered using various routes. Deciding which drug to use is often guided by the indication and procedure but also by the level of experience of the provider (27).

*Benzodiazepines:* These include diazepam, lorazepam, and midazolam and are hypnotic sedative agents. Mechanism of action occurs through their inhibitory effect on the central nervous system (CNS)(12). Post-synaptically they bind to gamma-aminobutyric acid receptors and increase the permeability to chloride ions, leading to hyperpolarization and stabilization of the neuronal membrane(12). Pharmacological effects include sedation, hypnosis, anxiolysis, amnesia, muscle relaxation, and anticonvulsant effects. It is important to remember that this class of drug has no analgesic properties, so should be used in conjunction with an analgesic if painful procedures are planned (12,27).

*Opioids:* Opioids are used mainly as analgesics for moderate to severe pain, with the most frequently used being morphine and fentanyl. This class of drugs modulates the cortical perception of pain by binding to the central and peripheral alpha, delta and mu receptors (12,28). This causes cellular hyperpolarisation, which in turn reduces the release of neurotransmitters (12). Morphine stimulates the release of histamine and inhibits the compensatory sympathetic responses. Effects of histamine release includes bronchospasm and hypotension and morphine is therefore to be used with caution in asthmatics. Gastrointestinal side effects include nausea, vomiting as well as constipation and can occur in up to 40% of patients (12). Fentanyl, a synthetic opioid, is highly liposoluble which explains its rapid onset of action. It is approximately 100 times more powerful than morphine(12). Side effects include bradycardia, which could lead to decreased cardiac output and haemodynamic instability (12). Another rare adverse effect is chest wall rigidity, associated with high doses above a 5mcg/kg bolus (12). Respiratory depression is a side effect common to all opioids and is associated with the administered dose. The incidence increases when opioids are used in combination with benzodiazepines (12).

*Ketamine:* This dissociative anaesthetic agent induces a cataleptic state that provides analgesia, sedation, and amnesia while maintaining airway patency and protective reflexes as well as cardiovascular stability (12,29). It is widely used for short, painful procedures, and acts on the N-methyl-d-aspartate-glutamate receptor, disconnecting the limbic and thalamocortical systems, dissociating the central nervous system from external stimuli (12).

*Propofol:* This hypnotic sedative agent is frequently used in brief procedures with or without analgesics like ketamine or fentanyl. It exerts its hypnotic action through the activation of a central inhibitory neurotransmitter, gamma-aminobutyric acid (GABA) (12,30). It is short-acting but should it be needed for a longer duration one can start a continuous infusion. Risks associated with this drug are hypotension which can be of concern in the patient population with congenital heart abnormalities as well as respiratory depression. Monitoring both these systems is therefore of the utmost importance (12,30).

*Etomidate:* This imidazole derivative binds to GABA receptors in the CNS and is used as an ultra-fast acting hypnotic agent. In particular, it is used as part of rapid sequence intubation, as well as for non-painful short procedures. When used as a sedative in painful procedures, an analgesic should be added (12,31). Etomidate is haemodynamically stable, and respiratory depression is rare (12).

*Dexmedetomidine*: This is an alpha-2 adrenergic agonist. Dexmedetomidine`s action is not mediated by GABA, and this promotes sedation without decreasing the respiratory drive. It is used for short procedures as well as prolonged sedation (12,32). It can be used as a single agent or in combination with midazolam, ketamine, or opioids. Side effects include hypotension, bradycardia, and sinus arrhythmia (12). Dexmedetomidine on its own has been largely unsuccessful in providing adequate analgesia but can be used in combination with Ketamine with fast onset of analgesia, sedation, amnesia and while maintaining haemodynamic stability (32). It is used frequently in the critically ill patient, especially the ventilated patient in the intensive care unit (33).

The choice of the drug being used should be guided by the procedure. One can categorize procedures as non-invasive, procedures associated with light pain but a high degree of anxiety or a high degree of pain as well as anxiety, and this can guide the decision regarding drug choice. Examples of each category are (12):

1. Non-invasive: CT scan, Ultrasounds (u/s), Electroencephalogram (EEG). Drug choices include midazolam, dexmedetomidine, as well as non-pharmacological measures (12).
2. Procedures associated with light pain and a high degree of anxiety: Tracheostomy exchange, gastrostomy change, dental procedures, sutures, lumbar puncture. Comfort measures (keeping child on parents lap, distraction, comfortable position, allowing them to keep a favourite toy etc), Midazolam, Ketamine, Topical or local analgesia (12).
3. Procedures associated with a high level of pain, high level of anxiety, or both: Abscess drainage, arthrocentesis, bone marrow aspirate, cardioversion, central venous line

placement, burn wound care, thoracentesis, paracentesis, fracture reduction. The aim is sedation, analgesia, motor control as well as reduction of anxiety and amnesia. Drug choices include Fentanyl, Midazolam + Fentanyl, Ketamine + Propofol, or Propofol + Fentanyl (12).

## Non-pharmacological strategies

The use of adjunctive strategies to alleviate the pain and distress of the paediatric patient, as well as their family members, are often neglected. Barriers to the use of these strategies includes time constraints, availability, and knowledge (34). In 2012 Emergency medicine Australia published a practical communication guide for the paediatric patient (34). Emphasis was placed on the different language that should be used for children of different ages and stages of development as this directly affects their ability to understand procedures. Children often do not understand the language used; this lack of understanding adds to their distress as well as a feeling of loss of control (35). Caregivers should also be instructed with regards to what to say and what not to say, avoiding bribery and phrases or statement that might imply the procedure does not hurt (26). Strategies mentioned, apart from language, are to position the patient in comfort (e.g. on parents lap), or allowing them to partake in the procedure (e.g. assisting with connecting monitors)(34). Other non-pharmacological strategies include hypnosis, distraction (including bubbles, books or technology such as iPad or phones) and topical anaesthetics (12). These strategies, as well as using the right language and allowing yourself enough time for the procedure for it not to be rushed, decreases pain, anxiety as well as the stress experienced, not only by the patient but also the parents (12,34).

## Complications of procedural sedation and analgesia

PSA is regularly performed outside of the theatre complex and is generally regarded as safe, although serious adverse events have been reported (36). These serious adverse events range from bradycardia, asystole, pulmonary aspiration, permanent neurological impairment, and ultimately death (36). One of the biggest challenges in fully understanding the burden of adverse events is the lack of consistent surveillance. These serious adverse events have not been reported consistently in paediatric PSA performed in the EC (36). These serious adverse are often preceded by other adverse events including oxygen desaturation, vomiting, apnoea and laryngospasm (36). The occurrence rates for these events have been reported to be between 2% and 26% based on small, single center EC cohorts (36–38).

## Providers

In South Africa, like many other resource-limited settings, many ECs are staffed by non-specialists. The high burden of severe disease, as well as the total number of patients requiring care, more often than not exceeds the available number of emergency medicine specialists. It is therefore inevitable that PSA will be provided by non-specialists within the EC to both adults as well as paediatric patients(39). Wenzel-Smith et al. (2012) conducted a retrospective chart review in a level one hospital in the Western Cape which was aimed at assessing the safety of PSA provided by medical officers with no formal anaesthetic training(40). Their study included paediatric patients in addition to adults and concluded that PSA was provided safely by medical officers (MO) without formal training in anaesthesia (40). Burger et al. (2019) evaluated the current practice of paediatric PSA in the EC, and to identify possible obstacles (39). They identified two major pitfalls or obstacles: lack of training in paediatric PSA as well as the absence of practice protocols (39).

These were the first studies in our setting evaluating PSA in the paediatric population. Considering the burden of disease in our setting, and practicing with limited resources, it is easy to understand the need for appropriate guidelines, PSA training and monitoring of adherence to these guidelines.

The need for analgesia and anaesthesia during painful procedures are widely recognized, but worldwide the administration of such services is unevenly distributed. In certain regions such as sub-Saharan Africa these resources are extremely scarce (4,41,42).

<u>Experience level and Competency</u>

Emergency medicine is an evolving speciality and relatively new in many countries (43). Consequently, services provided by the speciality as well as units are evolving. The Netherlands, similar to South Africa, has a new and evolving Emergency Medicine program.

The first Emergency medicine training program in the Netherlands started in 2000. In 2005 PSA was included as a core competency, and in 2012 they established their PSA guidelines. In June 2016, a national survey of all registered emergency physicians was performed, and 41.3% responded (43). The survey study aimed to investigate current PSA practice and competencies of Dutch emergency physicians in both adult and paediatric patients. They found that nearly all emergency physicians (97.8%) performed PSA in adult patients, compared to only 59.1% who performed PSA in paediatric patients. Secondly, employing self-reflection, emergency physicians felt less competent in performing paediatric PSA when compared to adult PSA, leading to a significant gap between adult and paediatric PSA performance (43). The most common reason for not performing paediatric PSA was the lack of exposure, ascribed to be due to the relatively short 3-year training program. A Canadian Survey using a Stated Preference Discrete Choice Experiment was published by Bhatt et al. in 2010. The objectives of the study were to explore the tolerance of pediatric emergency medicine (PEM) physicians for risk in choosing when to perform procedural sedation and analgesia (PSA) as well as to describe adherence to preprocedural fasting guidelines and factors affecting the physicians' decisions.  Factors that affected the timing of PSA were years in practice, with those having 6 to 10 years more likely to minimize delays, as well as institutional fasting policies. Where policies were in place, practitioners were less likely to perform immediate PSA (18).

<u>Number of Providers</u>

The optimal number of providers necessary when providing PSA has yet to be determined. The literature review found that the number of providers is either not stated, is listed briefly, or is described in detail but not as an independent variable, so its effect on the outcome of the procedure cannot be determined (25).

## Monitoring

In the literature, there is inconsistency in the description of monitoring devices available and used during PSA. The consensus guidelines published by Green et al in 2019 (44) advocates for the use of blood pressure monitoring, cardiac monitoring as well as monitoring oxygen saturation level during procedural sedation. They also advocate for the use of capnography if it is available. As these monitors may be distressing to the paediatric patients, their guideline allows for the monitors to be applied to the patient after initiation of PSA to minimize the distressed caused (21).

Basic continuous mechanical monitoring with pulse oximetry, capnography and cardiac monitoring associated with respiratory rate and heart rate assessment are required. Several studies have reported there to be no need for continuous blood pressure detection when using Ketamine for PSA since ketamine releases catecholamines without depressing the cardiovascular system (45). The American Academy for paediatric (AAP) has published guidelines with regards to monitoring needed during PSA. They used a mnemonic, SOAPM (Table 1), as a mental cue, ensuring nothing is forgotten or left out (23).

In 2019, Wood-Thompson et al.(1) published a study in which the interviewed Emergency Centre managers or their designee at selected private-sector and public-sector hospitals in South Africa. The availability of various items and monitoring devices were documented (1). All units that completed the questionnaire reported the availability of a resuscitation trolley during procedural sedation, as well as the availability of intravenous fluids and drip sets, a bag valve mask resuscitator, oxygen supply, 3-lead electrocardiography (ECG), non-invasive blood pressure (BP) monitoring and pulse oximeters. Resuscitation drugs, a suction apparatus, endotracheal tubes and at least one laryngoscopy set were available at 94.1% (n=16) of ECs, while 88% (n=15) of ECs possessed a dedicated defibrillator device. Capnography was rarely available (1).

## Procedural sedation and analgesia in low resource settings

The provision of health services in the low- to middle-income countries (LMIC) setting is often delayed due to a lack of resources, inexperience, or fear of complications (46). By applying evidence-based medicine and newly developed guidelines, we can provide PSA safely with minimal delays and thus save time, money and other resources (41,46). It is therefore useful to examine in closer detail the literature investigating PSA in LMIC settings.

In 2016 Schwartz et al. (4) published the findings from a study performed in rural Western Kenya testing a pilot program – “Every second matter for mothers and babies – Ketamine” (ESM-Ketamine)(4,47). ESM-Ketamine is an evidence-based training package consisting of a 5-day hands-on training curriculum, clinical checklist, wall chart, ketamine, and equipment (e.g., bag-mask ventilation device, pulse oximeter) and was developed in conjunction with global health clinicians at Massachusetts General Hospital and Harvard Medical School. The program was implemented by the Kenya Ministry of Health in partnership with Maseno University School of Medicine (47). The study population included 90 children below the age of 18 (Mean age: 10.6 years) who underwent sedation with Ketamine for emergent procedures when no anaesthesiologist was available. They found that 17% of patients experienced minor adverse events which included hallucinations, hypersalivation and a fall in oxygen saturation to below 92% for less than 30 seconds. All adverse events self-aborted and none of the patients required any intervention. No serious adverse events were reported. The use of the ESM-Ketamine care package allowed procedures to be performed timeously and without pain, decreasing delays as well as suffering (4).

Coralic et al (2018) examined the implementation and safety of ketamine induced PSA in Tanzanian emergency units (48). Fasting requirements in the EC followed the latest emergency care guidelines recommending that procedural sedation should not be delayed for adults or children based on fasting times alone. As such, many included patients had oral intake within four hours of ketamine administration, however there were no cases of emesis nor pulmonary aspiration during the procedures. In total, 12% of the patients reported nausea and vomiting post-procedure. The indications for, and experience with, the use of ketamine for procedural sedation in their EC in Tanzania was observed to be similar to high-resource settings. There were no serious adverse events attributable to ketamine despite a high-acuity and frequently non-fasted patient sample(48). This highlights once again the safety of PSA within the EC supporting less strict fasting guidelines where indicated.

Red Cross War Memorial Children`s Hospital (RCWMCH) is the largest paediatric hospital in Africa and situated in Cape Town. Hospital staff identified the need for an out-of-theatre sedation service due to the increased need for PSA (49), and performed an observational study in 2019 with the primary aim of defining the number of cases of PSA performed outside of theatre. They excluded any PSA performed in the trauma unit and intensive care unit (ICU) as these units would not benefit from an out-of-theatre sedation service. The study included 288 sedations and the overall complication rate was low and in accordance with international literature. Reported complications included: Airway obstruction (4.9%), desaturation – defined as saturation <90% for >60seconds (4.2%), laryngospasm (0.3%) and nausea and vomiting (2.4%)(49). It is important to note RCWMCH is a tertiary centre where the patient population serviced has multiple comorbidities and the pathology present may have an impact on the complication rate (49). This study also excluded the EC making it difficult to apply its findings to our setting.

The use of procedural sedation has been associated with a reduction in hospital cost as well as hospital length of stay (1,50). In a resource constrained setting, this is of vital importance. The safe and effective implementation of PSA practices in South Africa and other resource-constrained environments, may therefore potentially reduce the burden on health care services (1).

## Fasting And Procedural Sedation and Analgesia

Safety of PSA in the paediatric population is well established. Multiple, international studies have been performed that have consistently shown that PSA can be safely and effectively provided by non-anaesthesiologist physicians in a paediatric patient in the emergency setting (7,37,51).

The first fasting guidelines used are believed to have originated in 1946 when Mendelson reported a high incidence of pulmonary aspiration in obstetric patients who underwent general anaesthesia (52,53). The ASA subsequently published fasting guidelines in the 1980s (18). These consensus guidelines were based on expert opinion with the intent to minimize the risk of aspiration in patients who undergo general anaesthesia (18). These guidelines have been the basis for adhering to fasting guidelines in PSA provided in the EC, although they have not been adjusted to specifically include PSA (18). Guidelines by the ASA have undergone review and in 1999 the ASA published guidelines that supported a more liberal preoperative fasting protocol, although the focus was still on general anaesthesia rather than PSA (52). The question of whether to adhere to ASA guidelines regarding PSA has, however, been under discussion since 1984 (21). A systematic review of PSA in the paediatric population identified a total of 16 children with sedation-associated aspiration reported in the medical literature after 1984, with no mortality (54,55). Of these 16, 13 children were fasting guideline compliant (54).

In 2002 a retrospective chart review published in *Paediatrics* tested the hypothesis that application of an AAP/ASA structured model would reduce the risk of sedation related complications (56). The study was performed by a quality improvement specialist and included all sedation records over three months. The authors concluded that failure to adhere to fasting guidelines did not increase the risk of adverse events (56). Similarly, Beach et al. (2016) evaluated the fasting status in paediatric patients undergoing PSA and whether adhering to standard NPO guidelines as set out by the ASA influenced the complication rate in these patients (57). The authors showed that aspiration was uncommon and that fasting status for both liquids and solids was not an independent predictor of major complications nor aspiration with PSA (57). In 2012, Lee et al. published their research specifically investigating Ketamine associated vomiting and strategies to overcome or later limit the occurrence thereof (58). The study compared two different interventions – the addition of atropine and metoclopramide – against standard care. One parameter assessed was the incidence of Ketamine associated vomiting and its association with the fasting status of the patient. They found no statistically significant difference in the incidence of vomiting related to fasting status (58).

In 2016, Woo et al. (59) conducted a study in South Korea at Soonchunhyang University Bucheon Hospital, to assess patient factors that might be associated with adverse events. The basis for their study was that ketamine is commonly used in the emergency department for paediatric sedation although patient factors associated with adverse events are poorly described. They found no significant association between the duration of fasting and adverse events (P=0.0735), or between food type and adverse events (P=0.734). However, they did find injection type, IV injection (OR, 16.77; 95% CI, 1.78 to 498.54; P=0.034) and ketamine dose (OR, 4.37; 95% CI, 1.59 to 22.9; P=0.018) are associated with adverse events in children sedated with ketamine in the emergency department(59). This study and research again highlight the importance of investigating PSA in the paediatric population

In more recent years there has been a shift towards more liberal approaches to fasting time and PSA. In 2014 the American College for Emergency Physicians published a clinical policy for PSA which does not recommend delay of procedures based on fasting time as no risk reduction of emesis or aspiration has been shown (60). In 2018, a large prospective cohort that assessed 2426 patients undergoing PSA within the EC found that the transition to shortened NPO guidelines did not result in increased vomiting (60). Patients in the shortened fasting group had a shortened length of stay in the EC, and no aspiration was reported in any patients (60). At this time, Green et al. (2018) published an editorial calling for the cautious but progressive application of more liberal fasting guidelines in the paediatric patient with regards to PSA in the EC (54). Prominent mention in their editorial is that aspiration in the healthy child is very rare, and the authors extrapolate that the risk of pulmonary aspiration in healthy children receiving PSA is functionally negligible. The authors conclude by stating that time for fasting reform is due (54). Subsequently, the multidisciplinary International Committee for the Advancement of Procedural Sedation was established in 2019 and developed the first fasting and aspiration prevention recommendations specific to procedural sedation (21). The committee, led by Green, used a Delphi methodology to develop fasting guidelines specifically pertaining to PSA in the EC (21). They defined PSA as "the use of anxiolytic, sedative, analgesic or dissociative drugs to attenuate pain, anxiety and motion to facilitate the performance of a necessary diagnostic or therapeutic procedure, provide an appropriate degree of amnesia or decreased awareness and ensure patient safety" (19,21). The literature (1985-2019) reviewed during this process showed that consistent, rigid adherence to ASA fasting guidelines was often associated with adverse outcomes, including irritability, hypoglycaemia and dehydration (21). They reiterate the fact that there is no direct observed association between fasting state and aspiration during PSA (21).

The committee further developed a risk assessment tool that risk stratifies patients and guides the practitioner with regards to the fasting state and the need to delay procedures (21). It is important to note that these guidelines do not replace provider experience, good clinical judgement and clinical circumstance - factors which may lead the attending physician to deviate from these guidelines (21). These guidelines addressed NPO status and the necessity for fasting in patients undergoing PSA in the EC and do not apply to general anaesthesia. This is a big paradigm shift from traditional guidelines (16,19,21).

As the debate regarding fasting status continues, many clinicians asked the question of whether other bedside investigations, such as ultrasound, may aid with decision making in this regard. In 2018, Levitar et al. published a prospective study assessing gastric volume and contents by using ultrasound prior to PSA (61). The purpose of their study was to assess how prolonged fasting intervals affected stomach volume and contents and if this could aid in the decision whether to delay sedation (61). The study was performed in the paediatric population with ages ranging from 2 to 17 years. A total of 69% of the patients in this study were classified as having a full stomach at the time of sedation despite a prolonged fasting time. Median fasting time was 5.8 hours, and each hour of fasting lowered the odds of a full stomach (odds ratio = 0.79, 95% CI = 0.65-0). The authors concluded that the knowledge of fasting time alone did not provide accurate information to allow discrimination between risk groups (61). It is, therefore, time for us to adjust our practices with regards to fasting and PSA, to practice the best evidence-based medicine.

## Conclusion:

PSA is a core skill that is essential for every emergency physician. The EC is often chaotic, noisy, and overwhelming for patients and their families. Therefore, the provision of good quality PSA allows patients to cope with this environment and ultimately lead to improved outcomes and higher success rates of procedures performed (1).

Prolonged fasting is not benign and leads to decreased parental and patient satisfaction (61). It is also associated with increased hunger, decreased intravascular volume, hypoglycaemia, prolonged length of stay, as well as increased stress and anxiety (61). It also directly affects both patient and parent satisfaction (61). Adhering to strict fasting guidelines leads to increased distress, delay of treatment and prolonged EC stay in a system where overcrowding is a daily challenge. Low resource settings have many challenges that serve as barriers when it comes to health care. Some of the most precious resources are time, beds, space, and the specialists available.

This led to many questioning whether the fasting status is important when considering delaying PSA in the paediatric patient. The literature reviewed showed not only a consistent interest in the topic but also that reform of suggested practice and fasting guidelines for PSA is due. Guidelines developed by the ASA in 1980 can now be replaced by the 2019 algorithm as published by Green et al. (44).

There are however caveats to this – in particular, patients with comorbidities, difficult airways as well as craniofacial abnormalities which do require special consideration. It remains important to note that clinical judgement and the individual patients' clinical condition must always be taken into consideration. If clinical concerns exist and the procedure requiring PSA can be delayed safely it is appropriate to do so. In conclusion, strict application of fasting guidelines is not supported by the current literature and clinical application of more liberal fasting states with PSA in the EC is supported by the literature reviewed.

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# PART B. MANUSCRIPT IN ARTICLE FORMAT

(prepared for submission to the International Journal of Emergency Medicine)

# Paediatric procedural sedation and analgesia in the emergency centre: a description of the fasting status

[1]Cornelle Dunn,[1]Philip Cloete, [1]Colleen Saunders, [1]Katya Evans

[1]Division of Emergency Medicine, Faculty of Health Sciences, University of Cape Town

Corresponding author: Cornelle Dunn, DNNCOR001@myuct.ac.za, Groote Schuur Hospital, Observatory, Cape Town, South Africa, 7701

## Abstract

Background

Procedural sedation and analgesia (PSA) is considered a core competency in emergency medicine as patients present to the Emergency Centre (EC) on an unscheduled basis, often complex complaints that necessitate emergent management (1). Previous evidence has consistently shown that procedural sedation and analgesia(PSA) in the EC in the paediatric population, even the very young, is safe if appropriate monitoring is performed and appropriate medications are used (2–5). The aim of the study was to describe the indications for PSA in the paediatric EC population, the fasting status of paediatric patients undergoing PSA, and the complications observed during PSA in a single Western Cape emergency centre.

Methods

A retrospective, descriptive study was conducted at Mitchells Plain Hospital, a district-level hospital situated in Mitchells Plain, Cape Town. All paediatric patients younger than 13 years of age who presented to the EC and received PSA during the study period (December 2020 – April 2021) were included in the study. Data was extracted from a standardised PSA form and simple descriptive statistics were used.

Results

A total of 116 patients (70,7% male) were included: 13 infants (<1 year of age), 48 young children (1-5 years of age) and 55 older children (5-13 years of age). There were only 2 (1,7%) complications documented, both of which were vomiting and did not require admission. The most of patients received ketamine (93,1%). The standardised PSA form was completed in 49,1% of cases. Indications for PSA included burns debridement (11,2%), suturing (17,2%), fracture reduction (23,3%), lumbar punctures (31,9%) and others (27,6%). The indications for PSA varied between the different age groups.

Conclusion

The study findings are in accordance with previous international literature. Emergency Centre PSA in the paediatric populations did not show an increase in interventions or complications, despite the fasting status (6). Safe, timely PSA with minimal pain and unnecessary suffering can become the norm in Emergency Medicine practice in South Africa

**Keywords**

Emergency centre, Procedural Sedation and Analgesia, Paediatrics, Fasting status

## Introduction:

Emergency medicine was first introduced in the South African setting in the late 1990s. In 2003 Emergency Medicine was included in the list of recognised specialties (7). Patients present to the Emergency Centre (EC) on an unscheduled basis, often with complex complaints that necessitate emergent management (1). As the field of emergency medicine has developed locally and internationally, the services provided by the relevant clinicians have also evolved and procedural sedation and analgesia (PSA) are now considered a core competency for any clinician working in the Emergency Centre (EC).

PSA is defined as the use of pharmacological agents, such as sedatives and analgesics, to alleviate anxiety, pain and fear during diagnostic and therapeutic procedures (8,9). The South African Society for Anaesthesiologists (SASA) defines the goals of procedural sedation as reducing the patient's fear, anxiety and distress while minimising physical discomfort, pain and psychological trauma, maintaining control of physiological parameters and ensuring patient safety (10,11). Relief of procedural pain and anxiety in children, in particular, is an ethical imperative given the short and long-term physical, physiological, and psychological effects if pain is left untreated (12,13).

There has been an increase in research evaluating current practice, guidelines as well as possible complications associated with the provision of PSA in the paediatric population outside of theatre (3). One of the recent areas of interest is the fasting status of the paediatric patient undergoing PSA and whether adhering to the standard guidelines in anaesthesia is necessary (3,14–16). Multiple studies have been performed assessing the safety and efficacy of PSA in the paediatric population, all showing that PSA can be safely and effectively provided by non-anaesthesiologists in a paediatric EC (2–4). However, the most of this research has been done in the United States of America and Europe, with minimal research performed in the low- and middle-income countries (LMICs). There is a significant difference between anaesthetic services required and the availability of such services in many resource-limited settings, including sub-Saharan Africa. This limitation in anaesthesia availability is even more pronounced for children than for adults, as provider training and comfort with PSA in the young is uncommon. As LMICs have unique challenges, including higher volumes of paediatric patients, fewer resources, higher acuity and less paediatric specific centres, it is of value to do more research in these settings (10,17). The current study will add to the body of research, specifically in LMICs.

## Aims:

The aim of this study was to describe the indications for PSA in the paediatric EC population, the fasting status of paediatric patients undergoing PSA, and the complications observed during PSA in a single Western Cape emergency centre.

## Methods

Study design

A retrospective chart review was conducted at Mitchells Plain Hospital, a district-level hospital situated in Mitchells Plain, Cape Town. The study was approved by the Human Research Ethics Committee of the University of Cape Town (HREC REF: 859/2019) and facility approval was granted by the National Health Research Database (WC_202104_029).

Study setting and patients

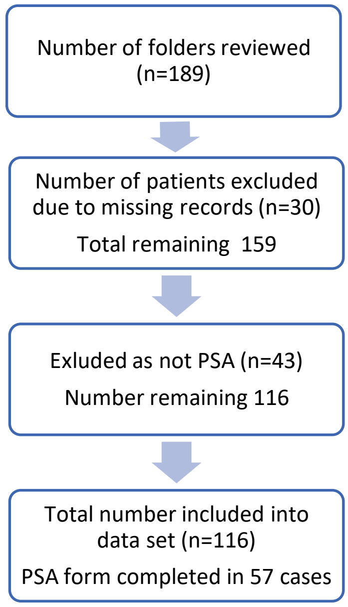
Mitchells Plain is a suburb in Cape Town, South Africa with a population of approximately 310 485 people. According to the latest Census in 2011, the majority of the population lives in formal dwellings (95%) with running water and electricity (18). Mitchells Plain hospital is a 230-bed hospital. The hospital provides care at a district level, including emergency care, obstetrics and gynaecology, medical, surgical as well as paediatric care. On average approximately 3926 patients attend the EC every month, 816 being paediatric (19). All patients (younger than 13 years of age) who presented to the emergency centre of Mitchells Plain Hospital and received PSA during the study period (December 2020 – Aril 2021) were included in the study.

Data collection and management

A standardised form for collecting clinical information on paediatric PSA was designed by the EC management team and implemented in February 2020 as part of clinical quality assurance procedures at the hospital (Appendix 3). This form was based on a similar form in use successfully at another local district hospital, as well as international documentation guidelines including the Royal College of Emergency Medicine, New South Wales Government in Australia, Mount Sinai School of Medicine PSA form and forms published by SASA for use in paediatric PSA (6,20–23). The PSA form has a barcode and is included in the standard documentation captured on the electronic content management (ECM) system. It is completed by medical staff for all paediatric patients undergoing PSA.

Paediatric patients who received PSA were identified by reviewing the scheduled drug register in the paediatric EC. All scheduled drugs are recorded with the patient name as well as folder number. Once eligible patients were identified, their medical records were reviewed. Those who received scheduled drugs for purposes other than PSA were excluded. Information was retrospectively abstracted from the standardised PSA forms and electronic patient care records for all paediatric patients who underwent PSA in the EC between December 2020 and April 2021 and data was subsequently deidentified prior to analysis. In cases where the standardised PSA form was missing, not utilised or incomplete, missing information was extracted from the medical records, including doctors notes, progress reports by nursing staff and referral letters. PSA forms that were missing information on the fasting state were included in order to provide information on secondary outcomes. Patients were excluded from the study if no notes or records could be traced relating to the procedure ( See figure 1). Patients were considered to be appropriately fasted if they met the American Society of Anaesthesiology (ASA) guidelines which require the patient to be nil per os (NPO) for six hours for solids, four hours for breast milk, and two hours for any clear fluids (35).

*Figure 1: Flowchart of patient selection*




Statistical analysis

Data was captured into a password protected, Microsoft Excel spreadsheet. Identifying information from the data set was removed before analysis.

Descriptive statistics were used to describe the demographics of the study sample, indications for PSA, drugs and dosages administered and complications associated with PSA. The patient population was divided into three groups: Infants (<1 year of age), younger child (1-5 years of age) and older child (5-12 years of age). Where applicable, categorical data was compared using the Chi-square test. The fasting state of the patients was also assessed within the context of various age groups. As this was the primary objective of the study, if the fasting state of the patient was unknown this was specifically noted and described.

Data analysis was performed using Microsoft Excel 365 ProPlus.

## Results

Demographics

A total of 186 patient folders were screened, of which 70 were excluded (incorrect folder number (n=11), drugs administered were not for the purpose of PSA (n=43), no clinical records found (n=15)). Therefore, 116 patients in three age categories were included in the study (Table 1): 13 infants (< 1 year of age);  48 young children (1-5 years of age); 55 older children (5-12 years of age). The majority of the patients were male (n=82, 70,7%) with a male predominance more apparent in the older children (80%) than in the infants (53,8%).

PSA was most commonly indicated for lumbar puncture (31,9%) and fracture reduction (23,3%), however indications varied between the different age groups with burns debridement being the highest in the infant population (23,3%) and lowest in the older child group (3,6%)(Table 1). Fracture reduction was highest in the older child group (41,8%) and lowest in the younger child group (6,3%). LP`s had highest incidence in the infant group followed by the younger child group (53,8% and 47,9%) . The younger groups were also more likely to need admission.

*Table 2: Demographic and clinical characteristics of patients*

| | ***All N=116*** | ***Infants N=13*** | ***Young children N=48*** | ***Older Children N=55*** |
|---|---|---|---|---|
| **Sex,** *n (%)* | | | | |
| *Male* | 82 (70,7) | 7 (53,8) | 31 (64,6) | 44 (80) |
| ***Weight (*kg*; mean ± SD)*** | 17,3 ±7,6 | 8,1 ±2,8 | 13,1 ±3,6 | 23,3 ±6,3 |
| ***Performed afterhours n (%)*** | 85 (73,3) | 10 (76,9) | 37 (77,1) | 39 (70,9) |
| ***Indications n (%)*** | | | | |
| *Burns debridement* | 13 (11,2) | 3 (23,1) | 8 (16,7) | 2 (3,6) |
| *Fracture reduction* | 27 (23,3) | 1 (7,7) | 3 (6,25) | 23 (41,8) |
| *Suturing* | 20 (17,2) | 1 (7,7) | 10 (20,8) | 9 (16,4) |
| *Lumbar puncture* | 37 (31,9) | 7 (53,8) | 23 (47,9) | 7 (12,7) |
| *Other*[1] | 19 (16,4) | 1 (7,7) | 4 (8,3) | 14 (25,5) |
| ***Disposition n (%)*** | | | | |
| *Admit* | 24 (20,7) | 4 (30,8) | 16 (33,3) | 4 (7,3) |
| *Discharge* | 63 (54,3) | 5 (38,5) | 21 (43,8) | 37 (67,3) |
| *Refer to RCWCH*[2] | 25 (21,6) | 3 (23,1) | 9 (18,8) | 13 (23,6) |
| *Not documented* | 4 (3,4) | 1 (7,7) | 2 (4,2) | 1 (1,8) |

[1] Removal of foreign body, catheterization, Intercostal drain insertion, CT scan, Incision and drainage of abscess, Examination, Reduction of paraphimosis.
[2] RCWMCH: Red Cross War Memorial Children's Hospital

Of the 116 patients, only 57 (49,1%) patient folders contained a completed PSA form. Most of the patients in this study received Ketamine (108) with two children receiving midazolam and one receiving diazepam (Table 2). The drug of choice was not documented in five of the patients. Drug choice, and dose (mg/kg), did not vary significantly across the different age groups.

Most of the patients received PSA after hours (between 16:00 and 08:00).

*Table 3: Fasting status, complications, drugs used and providers*

| | All N=116 | Infant N=13 | Young child N=48 | Older Child N=55 |
|---|---|---|---|---|
| ***Appropriately fasted,*** *n (%)* | | | | |
| *Yes* | 15 (12,9) | 1 (7,7) | 6 (12,5) | 8 (14,5) |
| *No* | 21 (18,1) | 2 (15,4) | 10 (20,8) | 9 (16,4) |
| *Unknown* | 80(69) | 10 (76,9) | 32 (66,7) | 38 (69,1) |
| ***Complications, n (%)*** | | | | |
| *Vomiting* | 2 (1,7) | 0 | 0 | 2 (3,6) |
| *Nil documented* | 109 (94) | 13 (100) | 45 ( 93,8) | 51 (92,7) |
| *Unknown* | 5 ( 4,3) | 0 | 3 (6,2) | 2 (3,6) |
| ***Drug used n (%)*** | | | | |
| *Ketamine* | 108 (93,1) | 13 (100) | 43 (89,6) | 52 (94,5) |
| *Midazolam* | 2 (1,7) | 0 | 0 | 2 (3,6) |
| *Diazepam* | 1 (0,9) | 0 | 1 (2,1) | 0 |
| *Unknown* | 5 (4,3) | 0 | 4 (8,3) | 1 (1,8) |
| ***Number of doses(Median/ IQR)*** | 1 (1-1) | 1 (1-1) | 1 (1-1) | 1 (1-1) |
| ***Range of doses*** | 1-3 | 1-2 | 1-2 | 1-3 |
| ***Dosage (mg/kg)- Mean and SD*** | 1,48 ± 0,89 | 1,55 ± 0,96 | 1,60 ±1,05 | 1,36±0,69 |
| ***Most senior provider n (%)*** | | | | |
| *Intern* | 13(11,2) | 2(15,4) | 7(14,6) | 4(7,3) |
| *COSMO*[1] | 44(37,9) | 3(2,6) | 16(33,3) | 25(45,5) |
| *MO*[2] | 13(11,2) | 2(15,4) | 5(10,4) | 6(10,9) |
| *Registrar* | 15(12,9) | 4(30,8) | 5(10,4) | 6(10,9) |
| *Unknown* | 31(26,7) | 2(15,4) | 15(31,3) | 14(25,5) |

[1] Community Service Medical Officer; [2] Medical Officer

The majority of patients in this study were not appropriately fasted, as per ASA guidelines, or the fasting status was unknown. Despite this there was an extremely low rate of documented complications of 1,7%. The drug of choice was ketamine with a mean dosage of 1,48 ± 0,89 mg/kg.

## Discussion

Procedural sedation and analgesia form part of everyday management in the EC. Published literature consistently shows that PSA in the emergency centre in the paediatric population is safe if appropriate monitoring is performed and appropriate medications are used, even in the very young (3,4,24). The most important finding in this study is the apparent safety of PSA within the paediatric population in the EC. Out of the 116 patients, only two patients had documented complications, both being vomiting. There was no incidence of laryngospasm, no aspiration and neither of the patients that had vomiting required admission following this complication. This finding is consistent with previously published findings. Misra et al. (24) assessed the safety of PSA in the very young (patients less than two years old) and concluded that children under the age of two years can safely undergo PSA in the EC without increased risk of adverse events (24). In the current study both patients with documented complications were older children and no complications were observed in the very young.

In 2016 Woo et al. conducted a study in Korea to assess patient factors associated with adverse events. The basis for their study was that ketamine is commonly used in the ED for paediatric PSA although patient factors associated with adverse events are poorly described. They found no significant association between the duration of fasting and adverse events (P=0.073) or between food type and adverse events (P=0.734). However, administration route and dosage were associated with adverse events in children sedated with ketamine in the EC (25).

Beach et al. (16) evaluated the fasting status in paediatric patients undergoing PSA and whether adhering to standard nil per os (NPO) guidelines, as set out by the American Society of Anaesthesiology (ASA), influenced the complication rate in these patients. The authors showed that aspiration is uncommon and that fasting status for both liquids and solids is not an independent predictor of major complications nor aspiration during PSA (16). In 2018, Green et al. published an editorial calling for a cautious but progressive application of more liberal fasting guidelines in EC PSA (15). A prominent mention in their editorial was that aspiration in the healthy child is very rare, and they suggest that the risk of pulmonary aspiration in healthy children receiving PSA is functionally negligible. The authors concluded by stating that the time for fasting reform is due (15). The multidisciplinary International Committee for the Advancement of Procedural Sedation was established in 2019 and subsequently developed the first fasting and aspiration prevention recommendations specific to procedural sedation (), as well as guidelines pertaining to PSA in the EC (6). The South African Anaesthesia Society (SASA) first published guidelines for PSA in the paediatric population in 2010 and updated these guidelines in 2016 and 2021 (10). The guidelines for fasting in the SASA guidelines have also been amended in the latest version and now recommend standard anaesthesia fasting guidelines for advanced sedation, but where simple sedation is planned, no fasting is required (10).

Although many studies published within this field, few studies could be found specifically describing the relationship between fasting status and complications in paediatric ECs in LMICs (2,3,5,13,15,25). Low resource settings have many challenges that serve as barriers when it comes to health care. Some of the most precious resources are time, beds, space and the specialists available. It is therefore essential to provide PSA safely to the paediatric patient outside of theatre (1,7,9). Applying evidence-based medicine and newly developed guidelines, can provide PSA safely with minimal delays and thus save time, money and other resources (26,27).

Similar to other resource-limited settings, Tanzania has also done research into the implementation of ketamine PSA by the Emergency Centre, assessing patient safety, adverse events, and patient and provider satisfaction (28). Fasting requirements in the EC followed the latest emergency care guidelines recommending that procedural sedation not be delayed for adults or children based on fasting times. Many of their patients had oral intake within 4 hours of ketamine administration. There were no cases of vomiting or pulmonary aspiration during the procedures. A total of 12% of the patients reported nausea and vomiting post-procedure. The indications for and experience with ketamine for procedural sedation in their EC in Tanzania were similar to findings from high-resource settings. There were no serious adverse events attributable to ketamine despite a high-acuity and the frequency of non-fasted patients in the sample (28).

Fasting status in our study was only documented in a third of the patients (n=36, 31.0%), and only 15 (41.7%) of those patients were appropriately fasted according to the ASA guidelines. Yet, only two patients in this study had documented complications, vomiting in both cases.

Our findings therefore support the international published literature indicating that PSA in the paediatric patient did not show an increase in interventions or complications, despite the fasting status, in previously healthy children(2,6,15,16,29).

Medical records are a crucial part of a patient's journey. These serve as a permanent record of the patient's illness and medical care, enabling clinicians to make informed clinical decisions(30). As healthcare professionals, we need to strive for the highest standards of clinical documentation (30). It allows for the scientific evaluation of patient profiles, analysing treatment results and facilitate planning of treatment protocols. Medical records are also crucially important when one has to address issues of alleged medical negligence(31).

Various centres have developed their own standardised forms to be completed when performing PSA (10). During the data collection process, it was noted how the documentation regarding PSA in the EC varies. In the current study, the form was only used in 49,1% of cases despite its inclusion in the standard documentation captured on the ECM system and an expectation that it is completed by medical staff for all paediatric patients undergoing PSA. Documentation was found to be incomplete, information inconsistent and very succinct. Both doctors and nursing notes had to be reviewed in order to find detailed information about the procedure. Documentation of the complications were clear, concise with a clear disposition and follow up plan, acknowledging that in this study there were only 2. There are multiple possible reasons for this, including regular locum doctors, rotation of junior doctors not being aware of the form and the impact of the COVID-19 pandemic. The form was rolled out just before the first wave of COVID-19, and as the focus in health care shifted to managing the COVID-19 pandemic, it is reasonable to assume that this has also led to doctors not using the form or implementation not being as successful as expected.

Documentation remains a challenge, with medical records often being handwritten and liable to misinterpretation due to illegibility and misplacement. This can affect the patient's medical care and has medico-legal implications (30). In high resource settings, electronic medical recordkeeping have been utilised successfully for several years. The paediatric department at Queen's Hospital Burton successfully implemented a fully integrated electronic health record

(EHR) system. This EHR improved the paediatric clinical documentation standards to 100% in each domain compared with pre-implementation standards robustly and sustainably (30). Similarly, the Emergency Medicine Department at Muhimbili National Hospital (MNH) in Tanzania implemented the first Electronic Medical Record (EMR) tailored to the emergency centre (EC) in Tanzania in 2015 (32). They utilised an Emergency Department Information System (EDIS), which has improved access to data, EC reports and produced research projects (32).

In the current study, we observed that the majority of PSA was provided by community service medical officers (COSMO) and medical officers (MO). Wenzel-Smith and Schweitzer (8) assessed the safety of PSA (in all ages) provided by MOs in a district hospital in the Western Cape using a retrospective chart review (17). Their single centre study aimed to show that PSA can be provided safely and effectively by MOs with no formal training in anaesthesia. They found low complication rates with higher complication rates in the older population (median age 40 years) with more comorbidities and medication use compared to the young (median age of 22 years) (17). The authors speculated that MOs were more reluctant to use higher doses of medication in the paediatric population and used mostly single agents rather than a combination (17).

In 2016 Swartz et al. published their research done in rural Western Kenya. They developed a Pilot program - Every second matter for mothers and babies – Ketamine (ESM-Ketamine)(33,34). Their study included 90 children below 18 years who underwent PSA with Ketamine for emergent procedures when no anaesthetist was available. The mean age was 10.6 years. They found that 17% of patients experienced minor adverse events, including hallucinations, hypersalivation and desaturation to $SaO_2$ below 92% for less than 30 seconds. All adverse events self-aborted, and none of the patients required any intervention with no reported serious adverse events. The use of the ESM- Ketamine care package allowed procedures to be performed timeously without pain, decreasing delays and suffering(33). These findings are consistent with our results.

Red Cross War Memorial Children`s Hospital (RCWMCH) is the largest paediatric hospital in Africa and is situated in Cape Town. The hospital identified the need for an out-of-theatre sedation service due to the increased need for PSA(9). They did an observational study in 2019 with the primary aim of defining the number of cases of PSA performed outside of operating theatre. They excluded any PSA performed in the trauma unit and ICU seeing as these units will not benefit from the out-of-theatre sedation service. They reviewed 288 sedations, the overall complication rate was low and in line with international literature. These complications included: Airway obstruction (4,9%), desaturation (4,2%) ( defined as saturation <90% for >60seconds), laryngospasm (0.3%) and nausea and vomiting (2,4%)(9).

The evidence from these internationally conducted studies highlights the safety of PSA provision within the EC by MOs without formal anaesthetic training (17). The findings from our study are consistent with this literature, safely supporting less strict fasting guidelines for PSA in the EC. The use of PSA has been associated with a reduction in healthcare cost and hospital length of stay which will potentially reduce the financial burden on health care across Africa and other resource-constrained environments (7).

## Strengths and Limitations

The validity and reliability of the study findings were enhanced by using a single trained investigator to perform the data collection. All medical records of study patients were reviewed in order to limit the missing data. However, the study still had several limitations. Only data documented by practitioners could be collected. Not all patients had the standardised form completed. As the schedule drug book was used as a reference to trace patients receiving PSA, we relied on the information recorded there. Names, as well as folder numbers, were often incorrect, thus leading to exclusion of patients. There is also the chance that some patients might have received PSA without the drugs being documented within the scheduled drug book.

## Conclusions

Our study findings are in line with research conducted internationally. Emergency Centre PSA in the paediatric populations did not show an increase in interventions or complications, despite the fasting status(6). This has practice implications for our ECs. Keeping children in the EC to meet fasting guidelines as set out by the ASA leads to prolonged stay, increased cost, increased nursing burden and increased distress to the child and parents. By incorporating the findings described from our study combined with international literature, safe, timely PSA with minimal pain and unnecessary suffering can become the norm in Emergency Medicine practice in SA.

## Future directions

Utilising a standardised form as part of PSA within our setting will lead to the capacity to perform larger studies. Implementing this into practice, educating all practitioners regarding it and then performing audits could lead to a larger study population and allow more definitive results. This could lead to potential provincial or national implementation of the form or similar forms across all ECs and will facilitate a measurable standard of care in emergency PSA in the paediatric population.

## Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (HREC REF: 859/2019).

Availability of data and materials

The dataset used during the current study are available from the corresponding author on reasonable request and pending further ethical and facility approval.

Competing interests

The authors have no competing interests to declare.

Funding

This study was self-funded

Authors' contributions

CD and PGC conceptualised the original idea. All authors contributed to the planning of the study. CD collected the data, and CD, PGC and CS did the analyses. All authors interpreted the results. CD drafted the manuscript, and PGC, KE and CS provided critical insights. The final manuscript was approved by all authors.

Acknowledgements

Thank you to all practitioners who embraced the use of the standardised PSA form and for all those who adhered to good note keeping. Thank you to MPH for allowing us to conduct our study at their facility and thank you to the ECM team who uploaded all the documents as needed.

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# PART C. APPENDICES

## Appendix 1. Instruction to Authors (International Journal of Emergency Medicine)

This manuscript was formatted for submission to *International Journal of Emergency Medicine*; an open-access, peer-reviewed journal accredited by the South African Department of Higher Education and Training.

The instructions for authors are available at https://intjem.biomedcentral.com/submission-guidelines/preparing-your-manuscript/original-research

## Appendix 2. Research Protocol

# Paediatric procedural sedation and analgesia in the emergency centre: a description of the fasting status


Proposal submitted by

**Cornelle Dunn** (DNNCOR001)

Division of Emergency Medicine
Faculty of Health Sciences, University of Cape Town


In partial fulfilment of the requirements for the degree of
Masters of Medicine in Emergency Medicine


Supervisor: Dr PG Cloete

Co-Supervisor : Dr Katya Evans

Co-supervisor: Dr Colleen Saunders


Date of submission (version 2)

February 2021

## Table of Contents

## Declaration:

I, Cornelle Dunn, hereby declare that the work on which this proposal is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other University.

I authorise the University to reproduce for the purpose of research either the whole or any portion of the content in any manner whatsoever.

Plagiarism declaration:

1. I know that plagiarism is a serious academic dishonesty
2. I have read the document about avoiding plagiarism, am familiar with its contents and have avoided all forms of plagiarism mentioned there.
3. Where I have used the words of others, I have indicated this by the use of quotation marks
4. I have referenced all quotations and properly acknowledged other ideas borrowed from others
5. I have not and shall not allow others to plagiarize my work
6. I declare this is my own work

Signature: C Dunn

Date: 10/02/2021

## Abbreviations:

| | |
|---|---|
| EC: | Emergency centre |
| PSA: | Procedural sedation and analgesia |
| LMIC: | Low-and Middle-income Countries |
| MO: | Medical officer |
| SASA: | South African Anaesthesia Society |
| ASA: | American Society of Anaesthesiology |
| COSMO: | Community service medical officer |
| IV: | Intravenous |
| IMI: | Intramuscular injection |
| NPO: | Nil per os |
| NHRD: | National Health Research Database |

## Introduction:

Procedural sedation and analgesia (PSA) are often needed in the paediatric population during their visits to the emergency centre (EC)(1). PSA is used for a wide variety of indications be it therapeutic procedures (e.g. fracture reduction), diagnostic procedures (e.g. painful procedures like a lumbar puncture) or in order to do a thorough clinical examination. It is therefore important that all doctors in the EC are competent in providing PSA to the paediatric population in a safe and effective manner.

Emergency medicine as a speciality is ever evolving and as such the doctors in the EC, as well as the services provided by the EC must evolve. PSA in the paediatric population outside of theatre has shown an increase in research and publications evaluating current practice, guidelines as well as possible complications associated with the provision of PSA (2). One of the recent areas of interest is the fasting status of the paediatric patient undergoing PSA and whether adhering to the standard guidelines used in anaesthesia is necessary (2–5). Most of the above-mentioned research has been done in the United States of America and Europe with minimal research performed in the low- and middle-income countries (LMICs). As LMICs have unique challenges, including higher volumes of paediatric patients, fewer resources, higher acuity and less paediatric specific centres, it is of value to do more research in these settings (6,7).

## Background:

Procedural sedation and analgesia form part of everyday management in the EC. PSA is used to alleviate pain, anxiety and suffering during painful medical procedures. It is defined as a pharmacologically induced state that allows patients to tolerate painful procedures while maintaining protective reflexes (i.e. gag and cough) and adequate airway control (2). Various agents or combinations of agents can be used to optimize PSA to the appropriate level for the specific indication (8). Effective sedation enhances the performance of these procedures and improves the experience of the patient as well as the practitioner (9). Unsuccessful PSA leads to psychological trauma which could influence future patient behaviour (8). Multiple studies have been performed assessing the safety and efficacy of PSA in the paediatric population including a meta-analysis, all showing that PSA can be safely and effectively provided by non-anaesthesiologists in a paediatric EC (2,8,10). Various centres have developed their own standardized forms to be completed when performing PSA (7). This not only encourages good practice and acts as a checklist, but also allows the collection of consistent data and accurate deductions to be made from this data for audit and research, as well as for medico-legal purposes.

Areas of increased interest in paediatric PSA include the very young, specific drug protocols, efficacy of sedation and analgesia as well as complications and adverse effects (5,8,10). Findings consistently show PSA in the emergency centre in the paediatric population is safe if appropriate monitoring is performed and appropriate medications are used, even in the very young (2,8,11). Misra et al (7) assessed the safety of PSA in the very young (patients less than two years old) and concluded that children under the age of two years can undergo PSA in the EC safely without increased risk of adverse events (11).

Although there have been many studies (1-5, 8-9) published within this field, no studies could be found specifically describing the relationship between fasting status and complications in paediatric ECs in LMICs. Wenzel-Smith and Schweitzer (8) assessed the safety of PSA (in all ages) provided by medical officers (MO) in a level one hospital in the Western Cape by means of a retrospective chart review (6). Their study was performed in a single centre and the aim was to show that PSA can be provided safely and effectively by MO`s with no formal training in anaesthesia. They found that complication rates were low overall, but occurred more frequently in the older population than the young, with a median age of 40 years for those who experienced complications as compare to a median age of 22 years for those who did not (6). This was attributed to various factors including the higher frequency of comorbidities, using higher doses of medication and utilising drug combinations. The authors speculated that in the paediatric population MO`s were more reluctant to use higher doses of medication and used mostly single agents rather than a combination (6). This, and the overwhelming international evidence, allow us to conclude that PSA can be provided safely outside the operating theatre, in the EC by MO`s largely without formal anaesthetic training (6).

The South African Anaesthesia Society (SASA) first published guidelines for PSA in the paediatric population in 2010 and updated these guidelines in 2016 (7). They define the objective of PSA in paediatrics as follows: "PSA must provide a safe environment for the patient and result must be effective to control pain, anxiety and movement" (7). The guidelines include all steps that should be undertaken when planning PSA in the theatre environment, i.e. pre-sedation patient assessment, informed consent, planning your procedure as well as post-sedation management and discharge instructions (7). The guidelines for fasting in the SASA guidelines have also been amended in the latest version and now recommend standard anaesthesia fasting guidelines for advanced sedation, but where simple sedation is planned no fasting is required (7). These SASA guidelines include a pre-sedation checklist, informed consent forms, pre-discharge checklist, as well as a monitoring form. These forms and checklists are easily implemented in a theatre or sedation-only practice. The required assessment and monitoring are as important in the emergency setting but required some modification for the EC to facilitate the patient load and service delivery pressure, as well as the different resources and staffing constraints in EC's.

Beach et al (4) evaluated the fasting status in paediatric patients undergoing PSA and whether adhering to standard nil per os (NPO) guidelines, as set out by the American Society of Anaesthesiology (ASA), influenced the complication rate in these patients. The authors showed that aspiration is uncommon, and that fasting status for both liquids and solids is not an independent predictor of major complications nor aspiration during PSA (4). Green et al published an editorial calling for a cautious but progressive application of more liberal fasting guidelines in EC PSA (5). A prominent mention in their editorial was that aspiration in the healthy child is very rare and they suggest that the risk of pulmonary aspiration in healthy children receiving PSA is functionally negligible. The authors concluded by stating that the time for fasting reform is due, and the proposed study will add to the body of research, specifically in LMICs (5).

Emergency centre doctors manage paediatric patients that require procedural sedation for painful or distressing procedures on a daily basis. Adhering to strict fasting guidelines leads to increased distress, delay of treatment and prolonged EC stay(5) in a system where overcrowding is a daily challenge.

A standardised form for collecting clinical information on paediatric PSA was designed by the EC management team and implemented in February 2020 as part of clinical quality assurance procedures at the hospital.

## Aims and objectives:

The aim of this study is to describe the indications for PSA in the paediatric EC population, the fasting status of paediatric patients undergoing PSA, the impact of fasting status on the decision to perform or delay PSA, and the complications observed during PSA in a single Western Cape emergency centre.

In order to achieve this aim, the objectives of this study will be:

1) To describe the demographic details of paediatric patients requiring PSA in the EC
2) To describing the procedural details for these patients including indications, drugs used as well as documented complications
3) To describe patients' fasting status and assess how fasting status affected the physician's decision to delay PSA.

## Methodology:

### Study design:

This will be a retrospective, descriptive study describing the paediatric population undergoing PSA in Mitchells Plain district hospital (MPH) over a period of four months. The period of four months will provide a representative sample of routine practice of PSA in paediatric patients.

### Characteristic of the study population:

MPH is a large district hospital in the Cape Town metropole and they provide emergency care to approximately 1500-2000 paediatric patients per month. These children present with a wide spectrum of conditions and severity of disease which might require PSA. The MPH EC emergency clinical staff include interns, community service medical officers (COSMO), MOs, registrars as well as consultants. The study population will include all paediatric patients (age ≤13 years) that receive PSA in the MPH EC within the study period. We estimate that approximately 20 paediatric PSA are performed a week.

Recruitment and enrolment:

A standardised form for collecting clinical information on paediatric PSA was designed by the EC management team and implemented in February 2020 as part of clinical quality assurance procedures at the hospital (Appendix 1). It was based on a similar form in use successfully at Victoria hospital for more than five years, as well as international documentation guidelines including the Royal College of Emergency Medicine (RCEM), New South Wales Government in Australia, Mount Sinai School of Medicine PSA form as well as forms published by SASA for use in paediatric PSA (9,12–15). The PSA form has a formal barcode and is included in the standard documentation captured on the electronic content management (ECM) system. It is completed by medical staff for all paediatric patients undergoing PSA and inserted into the patient's folder. Patient records are currently still paper based, and all documentation in the patient folder is scanned into the ECM database by hospital clerks following every patient visit.

No patients will be recruited nor enrolled in this retrospective, descriptive chart review. The PSA forms for patients meeting the following inclusion and exclusion criteria will be included in this review:

Inclusion criteria:

- Paediatric patients that receive PSA (IV/IMI/Oral/ Inhaled/Intranasal) during the four month study period between December 2020 and March 2021

Exclusion criteria:

- Patient's age is older than 13 years.
- Patients in which the standardized form is illegible, not utilized or the minimum fields are incomplete (i.e., indications, drug and dose). Forms missing information on NPO

will be included as it will add value regarding the practitioner's perception of importance.

## Data collection procedure:

Paediatric patients who have received PSA will be identified by calling up all PSA forms uploaded to ECM during the study period. PSA forms are barcoded prior to use and linked to the respective patients' electronic patient care record. For the purposes of this study, deidentified information will be retrospectively abstracted from the standardized PSA forms and electronic patient care records for all paediatric patients undergoing PSA in the EC between December 2020 and March 2021.

Data will be captured into a Microsoft Excel spreadsheet. Should information be missing from the forms, the folders of the patients will be accessed. In order to prevent patients being missed, forms will be cross referenced with the schedule drug book for the same period. Cases in which the standardised PSA form is missing, not utilised or where the minimum required data fields are missing from the patient care record, will be noted (to describe the frequency at which this occurs) but excluded from the descriptive analyses. Forms missing information on NPO will be included as it will add value regarding the practitioner's perception of importance.

## Data safety and monitoring:

No patient care records, nor standardised PSA forms, with identifying information will leave the hospital premises. Deidentified data will be abstracted into a Microsoft Excel spreadsheet kept on the student investigator's password-protected laptop.

## Data analysis:

We estimate that 200-250 cases of PSA will meet the inclusion criteria in the study period, based on an estimated 20 PSA procedures performed per week. Descriptive statistics will be used to describe the demographics of the study sample, indications for PSA, drugs and dosages administered and complications associated with PSA. Where applicable, categorical data will be compared using Fisher`s exact test or the Chi-square test, depending on the characteristics of the variables. Should incomplete data include a significant number of patients (>5%), it will be described as a separate entity. Data entry into the electronic patient care record by hospital clerks contains mandatory fields and very few incomplete entries are therefore expected (<2.5%). Statistical significance will be defined as a $p<0.05$ and 95% confidence interval (CI) will be provided if applicable. Data will be analysed using IBM SPSS version 25 or STATA.

## Methodological limitations and challenges

We have assumed that implementing a new form as standard practice is likely to have met with resistance from practitioners, even though managers and senior clinicians emphasized the importance of the standardised PSA form. In addition, the number of paediatric patients seen at MPH EC during alert level 4 and 5 of the 2020 COVID-19 risk adjusted strategy decreased significantly. The proposed study period has been chosen in order to mitigate the limitations of missing data because of low compliance at the beginning of implementation and low compliance during the COVID-19 lockdown period.

## Description of risk and benefits:

As this is a descriptive study where data is collected retrospectively in an anonymous fashion, the risk to patient, hospital and clinician are negligible, since it will not change the indications of practice. The benefit to be gained from this study is significant and will assist in describing the current clinical practice as well as improving this practice. As the PSA form has been implemented in MPH as standard clinical practice, patient details, as well as practitioners involved will be recorded on the form. However, this information will not be collected during the study and will not be used in any way during the analysis, which will only evaluate the data and review specific cases of PSA. All the data will be deidentified. Ethical clearance will be sought through the University of Cape Town Human Research Ethics Committee.

Permission to conduct the study will then be sought through the National Health Research Database (NHRD) for Mitchells Plain hospital.

Risk to patient:

No identifying data will be collected. Only the ages of the patients will be included. As data will be collected on a standardised form as part of standard practice there will be no influence on patient management by our study. We will only be collecting data retrospectively evaluating the current practice.

Risk to the hospital:

The data will be captured as a single database. Feedback will be provided to the EC.

Risk to the doctor:

No doctor identifying data will be collected. We will only assess the current practice and documented findings as described at the aggregate level. The study poses no risk to the doctor nor facility.

The benefit of this study lies not only in the review of current practice but also in assessing compliance and use of the standardized form when providing PSA to the paediatric patient in the Emergency centre. Further research can aim to improve the documentation and practice of PSA in the LMIC setting as very little data currently exists.

## Informed consent process and confidentiality:

This will be a retrospective, descriptive chart review of PSA forms for paediatric patients who have received PSA. No patients will be enrolled in the study and therefore we request a waiver of informed consent.

No patient care records, nor standardised PSA forms, with identifying information will leave the hospital premises, and only deidentified data will be abstracted into a Microsoft Excel spreadsheet.

## Timeline:

| | 2021 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| EMDRC Approval | | x | | | | | | | | | | |
| HREC | | | X | | | | | | | | | |
| Data collection | | | | x | x | X | | | | | | |
| Data analysis | | | | | | | x | X | | | | |
| Final Write-up | | | | | | | | | X | x | | |

## Budget:

The costs of conducting the study will be minimal, as below and will be self-funded by the student investigator.

Internet access, transport, communication and printing – total cost estimated at R 1000.

Anticipated expenses of the study:

- Internet access R 300
- Telephone calls R150
- Transport (to hospital site x 4 visits) R250
- Printing R300

**TOTAL R1000**

## Dissemination:

The findings of the study will be disseminated to Mitchells Plain Hospital Managers and key role players, including the Heads of Departments of the various Emergency Centres across the Western Cape. The outcomes will also be shared through planned publication in a peer-reviewed publication.

## References:


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15. Green, Roback et al. Fasting and Emergency Department Procedural Sedation and Analgesia: A Consensus-Based Clinical Practice Advisory. Ann Emerg Med. 2007;49:454-461

**Appendix 3**

# Procedural Sedation and Analgesia – Paediatric patients

| | |
|---|---|
| Patient sticker<br>Name:<br>Folder nr:<br>DOB: | **DATE:**<br><br>**WEIGHT:** |

**Fasting Status:**

| **LAST ORAL INTAKE** | **TIME** |
|---|---|
| Clear fluids | H |
| Breastmilk | H |
| Formula / solids | H |

**Team members involved in Sedation**

| **Name & Surname** | | *(circle the correct answer)* |
|---|---|---|
| | Doctor | Consultant/Reg/MO/COSMO/Intern |
| | Doctor | Consultant/Reg/MO/COSMO/Intern |
| | Nurse | CNP/PN/EN/ENA |

**Procedure:** **0 Consent Done** **0 EMLA used yes/no**

| | |
|---|---|
| Lumbar Puncture | |
| Fracture reduction | |
| Suturing | |
| Removal ear/nose foreign body | |
| Examination | |
| Other:____________ | |
| | |

| **Procedure Notes:** |
|---|
| |

| Drug | Dose #1 | Time | Sign | Dose #2 | Time | Sign |
|---|---|---|---|---|---|---|
| | | H | | | H | |
| | | H | | | H | |
| | | H | | | H | |

**Monitoring**: 0 SpO2 0 ETCO2 0 ECG 0 BP

| | Pre-procedure | 5 Min | 10 Min | 15 Min | 20Min | 25Min | 30 Min | Final | |
|---|---|---|---|---|---|---|---|---|---|
| FiO2 | | | | | | | | | |
| BP | | | | | | | | | |
| Pulse | | | | | | | | | |
| SaO2 | | | | | | | | | |
| RR | | | | | | | | | |

Time fully awake:
Monitored by whom during recovery (e.g. mom/nurse/doctor)

Complications:

| | |
|---|---|
| Vomiting | |
| Apnoea | |
| Cardiac instability | |
| Laryngospasm | |
| None | |

Management: please provide brief summary

Note-keepers name & signature

Disposition:

| | | | | | |
|---|---|---|---|---|---|
| Discharge | | Admission | | Other | |

Commonly used drugs:

| Drug | IMI dose | IV dose | Oral dose |
|---|---|---|---|
| Ketamine | 4mg/kg | 0.5-1mg/kg | 4-5mg/kg |
| Fentanyl | | 1ug/kg | |
| Midazolam | | 0.05-0.1mg/kg | |
| Propofol | | 0.5-1mg/kg | |

## Appendix 4: HREC letter

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

**Room G50- Old Main Building**
**Groote Schuur Hospital**
**Observatory 7925**
**Telephone** [021] 406 6492
**Email:** hrec-submissions@uct.ac.za
**Website**: www.health.uct.ac.za/fhs/research/humanethics/forms

13 April 2021

**HREC REF: 859/2019**

**Dr P Cloete**
Division of Emergency Medicine
C/o Ms Vathiswa Mzamo
F-51 OMB
Email: flip.cloete@uct.ac.za
Student: cornelle.dunn@gmail.com

Dear Dr Cloete

**PROJECT TITLE: PAEDIATRIC PROCEDURAL SEDATION AND ANALGESIA IN THE EMERGENCY CENTRE: A DESCRIPTION OF THE FASTING STATUS (MMED DEGREE - DR C DUNN)**

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

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

**This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.**

**Approval is granted for one year until the 30 April 2022.**

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 acknowledge that the student: Dr Cornelle Dunn will also be involved in this study.***

**Please quote the HREC REF 859/2019 in all your correspondence.**

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

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.

Yours sincerely

**<u>PROFESSOR M BLOCKMAN</u>**
**<u>CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE</u>**
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

## Appendix 5: Facility approval

Western Cape Government

Health

**STRATEGY & HEALTH SUPPORT**

Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: WC_202104_029
ENQUIRIES: Dr Sabela Petros

**University of Cape Town**
**Anzio Road**
**Observatory**
**Cape Town**
**7925**

For attention: DR Flip Cloete, DR Cornelle Dunn, DR Katya Evans, DR Colleen Saunders

**Re: Paediatric procedural sedation and analgesia in the emergency centre: a description of the fasting status**

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

| | | |
|---|---|---|
| **Mitchells Plain Hospital** | **Dr Jacek Marszalek** | **021 377 4782** |

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

**DR M MOODLEY**
**DIRECTOR: HEALTH IMPACT ASSESSMENT**
**DATE:**
**CC**

Dr Melvin Moodley
Director: Health Impact Assessment
11 MAY 2021