

Paediatric dental chair sedation

A Gauteng-based pilot study

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A research report submitted to the Faculty of Health Sciences,
University of the Witwatersrand,
in partial fulfilment of the requirements for the degree

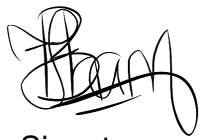
of

Master of Medicine in Anaesthesia

Johannesburg, 2014

DECLARATION

I, Faizal Bham, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

A handwritten signature in black ink, appearing to read 'Faizal Bham', written in a cursive style.

Signature

Signed at: University of the Witwatersrand, Johannesburg

On this date: 30 January 2014

PRESENTATIONS ARISING FROM THIS STUDY

- Poster presentation at the Paediatric Anaesthesia Congress of South Africa, Durban, November 2013.

ABSTRACT

BACKGROUND: Procedural sedation and analgesia (PSA) is generally safe, and often necessary to successfully undertake dental procedures in children. Providing PSA in dental rooms avoids expenses generated by having to perform procedures in operating theatres, but this must not be done at the cost of patient safety. Although rare, severe adverse events that occur are usually preventable. Death and permanent neurological injury are unacceptable outcomes for healthy children being sedated for minor procedures.

OBJECTIVES: The objectives of this study were to determine the proportion of dental practitioners making use of paediatric dental chair PSA in Gauteng, describe their PSA practice, and to determine adherence to recommended safety standards.

METHOD: A prospective, contextual, descriptive survey study design was used. Two-hundred and thirteen Gauteng-based dental practitioners were randomly selected from the list of 1152 practitioners listed on the South African Dental Association's website and contacted telephonically to determine whether they offer paediatric dental chair PSA. Practitioners offering PSA were then sent an email containing a link to a web-based data collection sheet assessing various aspects of their PSA practice.

RESULTS: Ninety-four of 213 dental practitioners contacted provide PSA to children (44.13%; 95% CI, 0.37-0.51). Fifty-two of the 94 practitioners completed the data collection sheet. The dental practitioner is most commonly responsible for administering PSA (45.83% of dental practices), with anaesthetists or medical practitioners also performing this task in some practices.

The modalities of PSA provided vary between dental practices. Procedures are usually performed under minimal or moderate sedation (used in 56.25% and 52.08% of practices respectively), although deep sedation and general anaesthesia are also provided in dental rooms (10.42% and 2.08% respectively). Midazolam, nitrous oxide and propofol are the most popular agents used for sedation. Sedative agents are

administered mainly via the oral, intravenous and inhalational routes (52.08%, 45.83%, and 41.67% of practices respectively). Most PSA providers (68.75%) administer a combination of two or more sedative agents.

Of the dental practitioners responsible for administering PSA, 54.55% have had sedation training, 90% have attended a Basic Life Support course, 10% have attended Advanced Paediatric Life Support or Paediatric Advanced Life Support courses, and 20% are aware of the South African Society of Anaesthesiologists' guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children. Most respondents (81.82%) indicated that they are interested in attending a sedation course.

Patients are mainly ASA physical status 1 and 2 and fall mainly into the 1 to 5 year old age group. However, there are dental practices that offer PSA to infants and ASA 3 and 4 patients. Fasting recommendations vary, with some patients being inadequately starved and others being inappropriately starved for 8 hours or longer.

Of the dental practices that provide sedation, 41.30% do not use any monitoring equipment, 43.18% do not keep any of the recommended emergency drugs in stock and 19.57% do not have any emergency equipment available.

Reported adverse events during dental chair PSA are rare, with no major adverse event reported in this study.

CONCLUSION: Paediatric dental chair PSA is offered by 44.13% of dental practitioners interviewed in Gauteng. The modalities of PSA provided vary between dental practices. Many facilities do not adhere to recommended safety standards for prevention and management of adverse events. Particular areas of concern are the high number of practices in which no monitoring equipment, emergency equipment, or emergency drugs are available. There is however an interest in sedation training among dental practitioners.

ACKNOWLEDGEMENTS

My thanks go to the following people:

To my supervisors, Helen Perrie, Juan Scribante and Clover-Ann Lee, for their support, guidance and patience.

To Professor Eduard Oosthuizen and Dr Will Robertson for reviewing the data collection sheet.

To Professor James Roelofse for his valuable input.

Lastly, I would like to thank my wife and family for their support and encouragement.

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LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
APLS	Advanced Pediatric Life Support
ASA	American Society of Anesthesiologists
BLS	Basic Life Support
COD	Committee on Drugs
DOA	Duration of action
HREC	Human Research Ethics Committee
N ₂ O	Nitrous oxide
PALS	Pediatric Advanced Life Support
PSA	Procedural sedation and analgesia
SADA	South African Dental Association
SASA	South African Society of Anaesthesiologists
SASA PSA GUIDELINES	Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children (2010)
SOSPOSA	Society of Sedation Practitioners of South Africa
URTI	Upper respiratory tract infection
WHO	World Health Organisation

CHAPTER ONE

OVERVIEW OF THE STUDY

1.1 Introduction

In this chapter the following will be discussed: a background to this study; the problem statement, aim and objectives of the study; research assumptions; demarcation of the study field; ethical considerations; a summary of the research methodology; the significance of the study; and validity and reliability of the study.

1.2 Background

Procedural sedation and analgesia (PSA) provided in dental rooms is cost-effective as it avoids extra expenses generated by having to perform dental procedures in operating theatres. It allows the dentist to practise in the familiarity of his or her own rooms (1), and overcomes the need to rely on the limited availability of anaesthesiologists.

Dental chair PSA should not, however, be performed at the cost of patient safety. An American-based critical incident analysis of 118 reported serious adverse paediatric sedation events (more than 80% of which began with some respiratory compromise) revealed a final outcome of death or permanent neurological deficit in 92.8% of these cases in out-of-hospital facilities versus 37.2% of hospital-based cases. Drug interactions, drug overdose, inadequate monitoring, inadequate resuscitation, inadequate medical evaluation and premature discharge were found to be the most common contributory causes of these adverse sedation events. (2)

Death and permanent neurological injury are unacceptable outcomes for healthy children sedated for minor procedures. This suggests the need to adopt guidelines which could reduce the risk of adverse events associated with PSA (3). The South

African Society of Anaesthesiologists (SASA) published guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children in 2010 (SASA PSA guidelines) (4). The aim of the guideline is to provide a reference to enable practitioners to act within a framework that ensures patient safety and the successful performance of procedures. They are intended for use by all medical practitioners, including dentists, to provide safe sedation, analgesia and anxiolysis in all environments and to provide guidance on patient selection, recommended drugs and dosages, equipment, monitoring, documentation and discharge criteria. (4)

1.3 Problem statement

PSA is generally safe, and is often necessary to successfully undertake dental procedures in children. Severe adverse events and outcomes that occur are mostly preventable. The guidelines formulated by SASA serve to provide a framework for practitioners to safely provide PSA to children in all environments (4).

No data could be identified as to how many dental practices in Gauteng make use of PSA and how many sedation practitioners are aware of the available SASA PSA guidelines (4). Practising outside the framework of these guidelines may place children at increased risk of adverse events and outcomes.

1.4.1 Aim

The aim of this study was to determine the proportion of dental practitioners making use of paediatric dental chair PSA in Gauteng and to describe paediatric dental chair PSA practice, awareness of the 2010 SASA PSA guidelines (4), and adherence to the guidelines.

1.4.2 Objectives

The objectives of this study were to:

- determine the proportion of dental practitioners in Gauteng that utilise paediatric dental chair PSA;
- identify the professional category of person primarily responsible for administering PSA;
- describe the modalities of PSA administered in dental rooms
 - depth of sedation
 - drugs used
 - number of sedative agents used in combination
 - routes of administration;
- describe the sedation and resuscitation training of PSA providers;
- determine adherence to recommended safety standards for prevention of adverse events
 - age groups of children sedated
 - American Society of Anesthesiologists (ASA) physical status
 - pre-sedation assessment and informed consent
 - fasting
 - person responsible for patient monitoring
 - monitoring equipment
 - level of consciousness or depth of sedation monitoring
 - recovery;
- determine adherence to recommended safety standards for management of adverse events
 - emergency drugs
 - emergency equipment;
- determine the occurrence of complications of PSA.

1.5 Research assumptions

The following definitions were used in this report:

Child or paediatric patient: An individual 12 years or younger falls into this category for the purpose of this study. A patient in this report refers to a child.

Dental practice or practice: Refers to the dental rooms. The dental practitioner may or may not be the person responsible for PSA administration in this practice.

Dental practitioner: The person who performs the dental procedure, but may or may not be the person responsible for PSA administration in a particular dental practice.

Procedural sedation and analgesia (PSA): The alleviation of pain or discomfort and/or a drug-induced altered state of consciousness ranging from minimal to deep sedation, provided for a variety of diagnostic and therapeutic procedures (4).

SurveyMonkey™ (5): A commercial online survey site which facilitates the creation of surveys. It hosts the survey, collects results and analyses data.

As reference is drawn to the SASA PSA guidelines (4), the following definitions are as described in the guidelines:

Minimal sedation and anxiolysis: “Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function may be impaired, but ventilatory and cardiovascular functions are unaffected.”

Moderate sedation and analgesia: “Moderate sedation is a drug-induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by light, tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate.”

Deep sedation and analgesia: “Deep sedation is a drug-induced depression of consciousness during which the patient cannot easily be roused, but may respond purposefully following repeated or painful stimulation. (Reflex withdrawal from a painful stimulus is not considered a purposeful response.) The patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.”

General anaesthesia: “General anaesthesia is a drug-induced loss of consciousness during which patients cannot be roused, even by painful stimulation. The ability to maintain independent ventilatory function is impaired. Patients require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.”

The distinction between the levels of sedation was initially made for the purpose of describing appropriate physiological monitoring. One should be aware that, regardless of the intended level or route of drug administration, sedation represents a continuum, with a patient easily moving from a light to deeper level (6).

The SASA PSA guidelines (4) also differentiate between two sedation techniques:

- **Simple or basic sedation:** “Simple/basic sedation is induced by a single agent and not a combination of single agents, for example:

- Oral, transmucosal or rectal drugs, e.g. a small dose of an oral benzodiazepine; or
- Inhalation of nitrous oxide (N₂O) in at least 50% oxygen.

Sedation can no longer be considered simple or basic once additional agents become necessary, and the depth of sedation may not be advanced unless the patient is fasted.”

- **Advanced sedation:** “Advanced sedation is induced by one of the following techniques:
 - Any combination of drugs, administered by any route; or
 - Any sedation administered by the intravenous route, using bolus or infusion techniques; or
 - Any inhalational sedation (e.g. sevoflurane), with the exception of N₂O used as the sole agent in a concentration of less than 50% in oxygen.

Advanced sedation can include both dissociative and nondissociative techniques.”

American Society of Anesthesiologists (ASA) physical status classification (7):

- “ASA Physical Status 1 - A normal healthy patient
- ASA Physical Status 2 - A patient with mild systemic disease
- ASA Physical Status 3 - A patient with severe systemic disease
- ASA Physical Status 4 - A patient with severe systemic disease that is a constant threat to life
- ASA Physical Status 5 - A moribund patient who is not expected to survive without the operation
- ASA Physical Status 6 - A declared brain-dead patient whose organs are being removed for donor purposes”

1.6 Demarcation of study field

This study was conducted in the Gauteng Province and included the dental practices of members of the South African Dental Association (SADA) practising in Gauteng (8). SADA represents the vast majority of active dentists in South Africa and is the most relied upon body regarding all aspects of dental practice in the country (9). Currently SADA lists 1152 Gauteng-based members on its website (8).

1.7 Ethical considerations

Approval to conduct this study was obtained from the Postgraduate Committee (Appendix 1) and the Human Research Ethics Committee (Medical) (HREC) (Appendix 2) of the University of the Witwatersrand.

This study did not involve any drug or therapeutic management and no patient was directly involved. It was conducted in accordance with the Declaration of Helsinki (10) and the South African Good Clinical Practice Guidelines (11).

1.8 Research methodology

1.8.1 Study design

A prospective, contextual, descriptive survey study design was used.

1.8.2 Study population

Qualified dental practitioners who were listed on the SADA website and practising in Gauteng formed the population group studied (8).

1.8.3 Study sample

1.8.3.1 Sample size

The names and contact numbers of 1152 Gauteng-based SADA members were listed on the SADA website (8). Two hundred dental practitioners were invited to participate in the study. This figure (n=200) would be increased following initial data collection if necessary, until a minimum of 20 completed data collection sheets were received.

1.8.3.2 Sampling method

A simple random sampling method was used in this study.

1.8.3.3 Inclusion and exclusion criteria

All Gauteng-based dental practitioners who were members of SADA and listed on the SADA website on 23 June 2012 were included in the study (8). Members who declined to participate were excluded.

1.8.4 Data collection

A web-based data collection sheet (Appendix 3) was designed for data collection using SurveyMonkey™. Prior to developing the data collection sheet, a review of the literature was done in order to identify the potential safety pitfalls in the field of paediatric dental chair sedation. The SASA PSA guidelines (4) served as the main reference point for the development of the data collection sheet, which was reviewed by three anaesthesiologists in order to ensure accuracy and validity.

1.8.5 Data analysis

Incoming data was analysed as it was received by SurveyMonkey™, the website hosting the data collection sheet. Descriptive statistics using frequencies and

percentages were used to analyse the data. A proportion and confidence interval were determined with support from a biostatistician.

1.9 Significance of study

The World Health Organisation (WHO) has identified the need for research to improve patient safety as a global priority (12). Comparing data with recommended safety standards has identified areas of concern, and may serve as a guide to developing measures that will enhance safety during paediatric dental chair sedation.

No study could be identified that determined the proportion of practices providing dental chair PSA or evaluated dental chair PSA practice in a South African setting. The 2010 SASA PSA guidelines (4) were the first of its kind to be published in this country. A review of the literature revealed flaws in safety standards in an American setting prior to the development of sedation guidelines and an improvement in outcomes thereafter.

This study determined the proportion of dental practitioners contacted in the Gauteng Province that utilise paediatric dental chair PSA and their awareness of the SASA PSA guidelines (4). It helped to shed light on the professional category of person responsible for patients during and after PSA, patient selection and assessment, modalities of sedation used, patient monitoring, the availability of emergency drugs and equipment, the resuscitation training of practitioners, and safety issues pertaining to the recovery area and discharge. The study also served to identify the need for training in the field of paediatric dental chair PSA.

1.10 Validity and reliability summary

Validity and reliability of the study and data collection sheet were ensured by the following:

- A representative sampling frame comprising SADA members;
- Randomisation of the sampling frame to minimise sampling bias;
- Instruments used and variables assessed in similar studies were used as a guide in the development of the data collection sheet, which was then reviewed by three experts in the field;
- An anonymous, short and concise data collection sheet.

1.11 Project outline

This report consists of five chapters: chapter one represents an overview of this research report; chapter two is a review of the current relevant literature; chapter three covers the research methodology and study considerations in more detail; chapter four presents the results and discussion; chapter five summarises the study, addresses its limitations, makes recommendations and presents a conclusion.

1.12 Summary

In this chapter the following was addressed: a background to this study; the problem statement, aim and objectives of the study; research assumptions; demarcation of the study field; ethical considerations; a summary of the research methodology; the significance of the study; and validity and reliability of the study. The next chapter comprises a review of the current relevant literature.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

In this chapter the literature relevant to this study will be reviewed. Firstly, a background to the development of sedation guidelines will be provided, followed by a discussion about the vulnerability of children to adverse sedation outcomes. The pharmacology of various PSA agents will be summarised and the risks associated with sedation considered thereafter. The 2010 SASA PSA guidelines (4) will then be discussed in detail, followed by an overview of the Society of Sedation Practitioners of South Africa. A similar study auditing dental chair sedation will then be reviewed. Lastly, the benefits of applying guidelines to the practice of sedation will be considered.

2.2 Background

“Every year, tens of millions of patients worldwide suffer disabling injuries or death due to unsafe medical care.” (Sir Liam Donaldson, Chair, WHO Patient Safety). Little is known about the burden of unsafe care in out-of-hospital settings, where the bulk of health care is delivered. The WHO has identified the need for research aimed at improving patient safety as a priority, especially in developing and transitional countries. (12)

Although most people find dental procedures unpleasant, the majority can be performed under local anaesthesia alone. Sedation is needed in dentistry to facilitate treatment of anxious or phobic patients, enable unpleasant procedures to be performed without distress, and to avoid the need for general anaesthesia. Despite PSA making healthcare procedures more acceptable to patients, it still carries the potential to cause life-threatening complications. (13)

Dental chair sedation and anaesthesia dates back to the discovery of N₂O in 1844 (14). In the early 1980s, within a one year period three healthy American children suffered adverse events after being sedated for dental procedures (the details of these adverse events are not elaborated on in the literature). This spurred the development of the first sedation guidelines. (15) The Committee on Drugs (COD) of the American Academy of Pediatrics (AAP) was concerned about the continued appearance of reports, almost always from non-medical sources (word of mouth, newspapers), of morbidity and mortality in children after sedation for seemingly harmless procedures (16). In 1983 case reports were published (discussed in more detail below) in the United States of a number of deaths in the dental office, and for this reason the COD worked closely with its dental colleagues to develop the guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients (16-19). The first sedation guidelines thus contained specific reference to dentists (17).

The guidelines provided a framework for the entire sedation process, from patient selection and evaluation to the recovery area and discharge. It also discussed fasting, informed consent, documentation, patient monitoring, emergency equipment and drugs, and recommended a safe approach to patient care at the different depths of sedation (16). It then became apparent that sedation was provided in a variety of settings by individuals with different degrees of expertise and when the guidelines were updated in 1992, reference to dentistry was removed since the COD did not want to single out one speciality (6, 17). Since then various professional bodies have developed their own paediatric sedation guidelines or revised existing ones (4, 6, 20-25). Although they may differ in their content, they share the same common theme of patient safety.

2.3 Why focus on children?

Paediatric patients require sedation or anaesthesia for dental procedures more often than adults and are at a higher risk of adverse events than any other patient subgroup (26). Sedation in children is different to sedation in adults. In children

sedation is usually administered to control behaviour in order to achieve optimal conditions for the completion of a procedure. Behaviour control and cooperation depends on the individual's developmental and chronological age. (20) Importantly, children are anatomically and physiologically different to adults, and at higher risk for life-threatening hypoxia as a result of both respiratory depression and airway obstruction (26, 27). Children younger than six years of age and those with developmental delay often require deeper levels of sedation to control their behaviour and are particularly vulnerable to sedating medications' effects on their respiratory drive, airway patency, and protective reflexes (20). Children also tend to pass into a level of sedation deeper than intended (3, 20, 28). This is associated with increased risks, which are discussed in more detail later in the report.

2.4 Pharmacology

Sedation practitioners should understand the pharmacodynamics and pharmacokinetics of the drugs they use. There should be a uniform level of vigilance regardless of drug dose, class or route of administration. Practitioners must be equipped with the skills and instruments needed to manage an adverse drug event should it occur.

The potential for adverse outcomes is significantly increased when three or more drugs with sedative properties are combined (4, 20, 29). A sedative has the potential to cause respiratory depression regardless of its route of administration (17, 29), and even medication which is considered "safe" can depress the patient's ability to respond normally to airway obstruction once the drug depresses the central nervous system (30, 31). A lack of stimulation, delayed drug elimination following non-intravenous administration (21), and the use of long-acting agents (4, 29) may lead to residual sedation and complications during the recovery period and after discharge.

In an analysis of 95 paediatric sedation adverse events, Cote et al. (29) did not find any correlation between a specific drug class and adverse outcome. In some cases, adverse events occurred despite drugs being administered within recommended dosing ranges. Negative outcomes also took place at home or in a car on the way to the facility after drugs were administered by non-medically trained persons at home. (29)

The relevant pharmacology of some of the agents used during PSA and the potential problems associated with their use will briefly be outlined. This will put the adverse events discussed later in the report into perspective. This section is not aimed at providing an in-depth discussion of the pharmacodynamics and pharmacokinetics of the drugs listed.

2.4.1 Inhalational agent: nitrous oxide

Inhaled N₂O provides sedation and mild analgesia (32). It is available in its pure form or may be pre-mixed with oxygen in a 1:1 ratio (Entonox®) (4). In older children it may be safely administered via a self-held demand-valve mask which is only activated when the child inspires (4, 32). A continuous flow system is needed in children unable to operate a demand-valve (4). The SASA PSA guidelines (4) recommend a dose of 50% N₂O mixed with oxygen, with higher concentrations placing the child in a state of moderate, rather than minimal, sedation. The implications in terms of monitoring and adverse events attached to depth of sedation are discussed later in this report. Other sources describe N₂O concentrations of up to 70% with preservation of haemodynamic status, spontaneous breathing and protective airway reflexes (32).

Although N₂O possesses analgesic activity, it usually needs to be supplemented with an opioid and or local anaesthetic agent (32). It is generally considered a safe agent, but when combined with any other depressing medication, even in normal dosing ranges, this may lead to a state of deep sedation or general anaesthesia (29), with

ensuing respiratory depression and or loss of protective airway reflexes. Minor adverse effects of N₂O include nausea, dizziness, voice change, euphoria and laughter (32).

Nitrous oxide should not be used in certain patients. It diffuses into air-filled cavities and should be avoided in patients with closed-space diseases, e.g. suspected bowel obstruction, pneumothorax or middle ear disease (4, 32). Children with cardiovascular and respiratory disease should not be given N₂O as it may alter the response to hypoxia or cause harmful haemodynamic changes. The use of N₂O is therefore only recommended in ASA 1 and 2 patients. (4)

None of the other inhalational anaesthetic agents (e.g. sevoflurane) are described in the SASA PSA guidelines (4) and will not be discussed here. These agents necessitate administration by specialised equipment and are not compatible with the typical office situation (33).

2.4.2 Sedative-hypnotics

The following agents will be discussed: chloral hydrate, barbiturates, benzodiazepines and propofol.

- Chloral hydrate:

Chloral hydrate is a pure sedative-hypnotic drug without analgesic properties and its use is recommended for non-painful procedures only (4, 32). It is generally a safe drug in the recommended dosing range, but respiratory depression and airway obstruction may occur at higher doses (above 75 mg/kg) or when combined with other depressant drugs. Combining chloral hydrate with other agents is thus not recommended. (4) The duration of action (DOA) of chloral hydrate is 60 to 150 minutes with a possibility of motor imbalance and agitation persisting for several hours thereafter (32). The need for prolonged monitoring makes chloral hydrate a

poor choice for dental chair sedation. Its sedative effects are also unreliable in children over three years of age. (4)

- Barbiturates:

Drugs in this class include pentobarbital, methohexital and thiopental. They usually produce deep sedation (or general anaesthesia), hypnosis and amnesia and also have anticonvulsant activity (32). These drugs can cause potent respiratory depression and hypotension (32) and aren't listed in the SASA PSA guidelines (4).

- Benzodiazepines:

Midazolam and diazepam are among the drugs in this class and possess anxiolytic, amnestic, sedative, hypnotic, and anticonvulsant properties. They do not have analgesic properties and are commonly used with opioids, posing a much greater risk for apnoea as their combined effects are not just additive but synergistic. (32) Besides respiratory depression, benzodiazepines can also cause a loss of upper airway muscle tone with subsequent airway obstruction (4). Mild cardiovascular depression with hypotension may also occur (32). Flumazenil should be available as a benzodiazepine antagonist.

Diazepam was first used for PSA, but because of its shorter DOA and multiple routes of administration midazolam is now the benzodiazepine of choice (32). It can be administered via the oral, sublingual, intravenous, rectal, and intranasal routes with the DOA ranging from 20 to 120 minutes depending on route of administration (4). Patients require continuous monitoring irrespective of route of administration as respiratory depression can arise via any of these routes (32). A series of deaths from undetected apnoea were reported shortly after the release of midazolam and before the use of continuous interactive and mechanical monitoring, highlighting the importance of such monitoring (29, 32, 34).

Practitioners should be aware of the possibility of a paradoxical reaction. This is characterised by inconsolable crying, combativeness, disorientation, agitation and restlessness, and has been reported in up to 15% of children receiving midazolam. (32) There may be a tendency to then give additional doses of midazolam in an attempt to control the child, which will exacerbate the symptoms and eventually lead to a loss of consciousness and respiratory depression (4).

- Propofol:

Propofol is a potent induction agent with a rapid onset and short DOA (15 minutes), all desirable characteristics for PSA (32). It is administered intravenously either as a bolus or a continuous infusion (4).

Although propofol is an effective drug, it has a narrow margin of safety. Deep sedation or general anaesthesia with subsequent airway obstruction and apnoea can occur rapidly (4, 21). Hypotension may also result (21, 32). The SASA PSA guidelines (4) recommend that propofol should only be administered by an experienced sedationist with anaesthetic training and paediatric airway management skills. Use of the drug outside the operating theatre is controversial. (4)

2.4.3 Dissociative sedative: ketamine

Cortical dissociation is characterised by profound analgesia, sedation and amnesia. This allows painful procedures to be performed more effectively than with other PSA drugs and with an excellent safety profile. (32) Ketamine can be administered via the oral, intravenous, intramuscular or rectal route. Analgesic effects are achieved at subhypnotic doses. (4)

Ketamine may cause unwanted non-purposeful movements. Compared with other anaesthetic agents, patients have a relative preservation of protective airway reflexes and muscle tone, which may be lost with large doses. (4) Spontaneous

respiration is usually preserved (32). Ketamine causes an increased production of tracheobronchial secretions and saliva, which can predispose patients to laryngospasm (4). The SASA PSA guidelines (4) recommend prophylactic co-administration of an antisialogogue (atropine or glycopyrrolate) to diminish secretions. Furthermore, because of its dissociative properties, the usual clinical indications of sedation depth may not apply (e.g. a child's eyes may be open despite being in a state of deep sedation) (21).

Tachycardia and hypertension associated with the sympathomimetic action of ketamine are not usually seen at sedative doses, and emergence delirium is mild and less common in children than in adults (4).

2.4.4 Analgesics

Analgesics will be discussed in the following categories: opioids, simple analgesics and local anaesthetics.

- Opioids:

Opioids are primarily analgesic agents that can induce varying degrees of sedation as well as respiratory and cardiac depression. The opioid antagonist naloxone should be available. (4)

Fentanyl and alfentanil are potent short-acting agents, with a DOA of up to one hour for fentanyl (dose-dependent) and five minutes for alfentanil. Both are administered intravenously, while fentanyl can also be given via the oral or transmucosal route. The SASA PSA guidelines (4) suggest that practitioners administering these agents should be experienced sedationists with airway management skills due to the significant potential for respiratory depression, particularly when used in combination with other respiratory depressant drugs. (4)

Tilidine is an intermediate-acting opioid (DOA of 4 to 6 hours) available in droplet form for sublingual administration (4).

Fentanyl, alfentanil and tilidine are the only opioids discussed in the SASA PSA guidelines (4). Other agents include morphine, meperidine, remifentanil and alphaprodine. Morphine and meperidine are long-acting agents and may necessitate prolonged post-procedure monitoring. Remifentanil is currently not recommended for PSA in children (4). It is a potent short-acting opioid with a significant potential for respiratory depression. Alphaprodine is no longer manufactured (29), but is mentioned here as it appears later in the report.

- Simple analgesics:

Paracetamol and non-steroidal anti-inflammatory drugs appear in this category in the SASA PSA guidelines (4). They have no sedative effects (29).

- Local anaesthetics:

Local anaesthetics reduce the need for other PSA agents and should be used whenever possible. Practitioners using these drugs must be aware of their maximum safe doses, as toxicity could potentially be fatal (35). Local anaesthetics are membrane depressants, and excessive doses may lead to cardiovascular, respiratory and central nervous system depression. The SASA PSA guidelines (4) list the maximum safe dose of bupivacaine (2.5 mg/kg) and lignocaine (3 mg/kg and 7 mg/kg if adrenaline is added). If agents are combined, it should be done with caution as toxicity is additive. (4)

There are other sedating agents listed in the SASA PSA guidelines (4) which will not be discussed in detail here. These include trimeprazine (a phenothiazine derivative) and droperidol (a butyrophenone with antiemetic properties), which are not recommended for outpatient procedures due to their long DOA. Dexmedetomidine

(an alpha-2 antagonist) should only be used by practitioners with anaesthetic training and experienced in paediatric sedation. (4)

2.4.5 Antagonist drugs

Flumazenil, a benzodiazepine antagonist, and naloxone, an opioid antagonist, should not be routinely administered, but reserved for oversedation or severe respiratory depression. Close patient monitoring should continue following administration as symptoms may recur if the PSA drug is longer acting than its antagonist. (4, 32)

2.5 Risks associated with sedation

The SASA PSA guidelines (4) categorise and list the usual causes of sedation related adverse events:

- “Factors related to drugs:
 - Drug interactions.
 - Drug overdose, including local anaesthetic toxicity.
 - Incorrect selection of drugs (e.g. opiates for painless procedures).
 - Prescription errors, particularly with oral formulations.
 - Drug combinations.
 - Unanticipated (pharmacogenetic) responses to drugs.
 - Unsupervised administration (e.g. by a parent at home).
 - Lack of knowledge of the pharmacokinetics and pharmacodynamics of drugs.

- Factors related to skills:
 - Inadequate clinical evaluation, especially of the airway, and inappropriate patient selection.
 - Inadequate experience in paediatric sedation.
 - Inadequate problem recognition.
 - Inadequate support staff qualifications.

- Inability of the sedationist to rescue a patient from an unexpected or undesirable deep level of sedation.
 - Inadequate resuscitation skills.
- Factors related to the environment:
 - Inadequate monitoring.
 - Inadequate equipment.
- Premature discharge, and not following discharge criteria.” (4)

The 1983 case reports, titled “Life-threatening reactions after paedodontic sedation: an assessment of narcotic, local anesthetic, and antiemetic drug interaction”, reviewed data from a combination of court records, case histories and published reports of 14 adverse outcomes following paediatric dental sedation, most of which resulted in death or neurological injury. Two of these cases will be described in an attempt to put into perspective the need at the time to put an end to such crises. (18)

In the first case a four year old boy (15.4 kg) had breakfast at 07:00 on the day of the procedure and was given 50 mg promethazine orally at home 15 minutes thereafter. Promethazine is a sedating antihistamine with antiemetic effects. It is not documented who wrote the prescription or who was responsible for sedation. On arrival at the dental rooms at 08:10 the boy was “injected with” 16 mg alphaprodine (an opioid) and a further 1.25 mg promethazine. The route of administration of these drugs is not stated. Topical lignocaine (unknown dose) was then applied and 144 mg of the local anaesthetic prilocaine injected. At this stage the child had already received three times the maximum recommended dose of promethazine and more than one and a half times that of both alphaprodine and prilocaine. The boy appeared well sedated and was making light snoring sounds. A rubber dam was placed by the dentist and 20% inhaled N₂O in oxygen initiated. No further details regarding the mode of administration of the N₂O appear in the case report. Ten minutes later snoring stopped and the child became completely flaccid with

unrecordable vital signs. Inspection revealed vomitus in the airway. The only subsequent measures documented in the report were suctioning of the vomitus and administration of the opioid antagonist, naloxone. It is unclear whether the child became apnoeic, obstructed his airway, or aspirated gastric contents. The duration of hypoxia was not documented but the boy survived with permanent neurological injury as a result. (18)

In the second case a three year old girl was given 25 mg meperidine (an opioid) and an unknown dose of hydroxyzine (a sedating antihistamine) as a pre-medication by her parents two hours prior to her procedure. It is not stated who wrote the prescription. On arrival at the dental rooms the dentist injected 30 mg alphaprodine (an opioid) subcutaneously into the buccal fold of the maxilla as the patient appeared to be in an excited state and her “condition suggested that the total amount of the oral medication was not completely ingested.” In addition to the unknown dose of hydroxyzine, the girl was given more than four times the maximum recommended dose of opioids. Her “respirations ceased” during the procedure and she was given sublingual adrenaline. The report does not mention any other resuscitative measures or the duration of apnoea. The girl recovered and the procedure was completed. She was discharged home following a two hour observation. Three hours later she was rushed back to the facility, with her father performing mouth-to-mouth resuscitation. The report does not discuss subsequent findings and treatment. The girl died several hours later. (18)

The primary adverse event in all 14 cases was respiratory depression, brought about by high drug dosages and a lack of knowledge surrounding the additive effects of combining central nervous system depressants. None of the reports documented any monitoring of respiratory function. (18)

There are no databases available to provide an estimate of the incidence of adverse events associated with paediatric dental procedures performed under sedation (35, 36). Various studies have looked at adverse events during paediatric sedation in

general, but there have been no multicentre studies sufficiently large enough to estimate the incidence of relatively rare events of major morbidity and mortality as a result of dental chair sedation, either locally or internationally (2, 18, 26, 30, 33-38). In most studies describing sedation safety and adverse events, the patient cohorts contain tens or hundreds of patients and are statistically underpowered to report on the frequency of events that should occur in no more than one in many thousands (2, 18, 26, 30, 34-37). These events do however occur and most of these occurrences are preventable. Since dental procedures are not perceived as potentially dangerous, the public does not accept the idea of a death in a dental chair (37).

In 2006 the Paediatric Sedation Research Consortium, a group dedicated to improving sedation and anaesthesia care for children globally, reported on the incidence and nature of adverse events during paediatric sedation and anaesthesia outside the operating room. A total of 26 institutions submitted data on 30 037 procedures. These included a variety of procedures of which only 1.1% were dental in nature. The information yielded, however, is important to all sedation performed outside the operating room. Serious events were rare, with no mortalities. One child required cardiopulmonary resuscitation and another aspirated gastric contents. Neither of these patients suffered any permanent injury. There was an overall complication rate of 5.3%. Oxygen desaturation, stridor, laryngospasm, unexpected apnoea, excessive secretions, and vomiting were among the complications. These adverse events were among those that occurred once in every 89 sedation encounters and which have the potential to do harm if timely rescue interventions are not instituted. Airway and ventilation interventions were required in 1 in 200 sedations, which ranged from insertion of an oral airway to mask ventilation to emergency intubation. The authors conclude that serious adverse events are rare in facilities with highly motivated and organised sedation services, like those participating in their study, and that safety depends on the system's ability to manage less serious events. (26)

In an attempt to study rare events in an efficient way, a critical incident analysis was carried out on 118 adverse sedation events derived from reports received by the

Food and Drug Administration and the US Pharmacopeia, and a survey completed by paediatric specialists. Data were compared for hospital versus out-of-hospital facilities, with 33.7% of these cases being sedated by dental practitioners (mostly in an out-of-hospital setting). In both settings, respiratory compromise was the initially observed clinical event in more than 80% of patients. Subsequent cardiac arrest was three times more likely in out-of-hospital facilities. A final outcome of death or permanent neurological injury occurred more frequently in an out-of-hospital (92.8% of serious adverse events) versus hospital (37.2%) setting ($p < 0.001$). These outcomes occurred despite children in an out-of-hospital setting being older and healthier. The most common contributory cause of these adverse sedation events was drug interactions (46.3% of cases). This occurred as a result of the additive effect of various PSA drugs on respiration. No particular drug or drug combination was singled out. Other common causes of adverse events included drug overdose (35.8%), inadequate monitoring (28.4%), inadequate resuscitation (20%), inadequate medical evaluation (18.9%), and premature discharge (11.6%). Inadequate resuscitation occurred more frequently (57.1% versus 2.3%) following out-of-hospital events. (2)

The authors of the above study acknowledge that their database represents only a small subset of adverse sedation events, because most of the reported cases resulted in death or permanent neurological injury. The study, however, highlights the need for uniform guidelines for monitoring children during and after sedation. (2) The only help or backup available in an out-of-hospital setting may be that of the emergency medical services, whose arrival would take a long time in the face of a significant adverse event (20). Emergency drugs and equipment should therefore be immediately available regardless of the location (2). Most sedation complications can be managed with simple interventions such as providing oxygen, opening the airway, suctioning, and using mask ventilation. Hypotension and cardiopulmonary arrest that may occur usually arise from poor recognition and treatment of respiratory compromise. (20) All health care providers who sedate children should be skilled in airway assessment and management and be able to resuscitate children in the event of an adverse sedation event occurring (2).

In another American study, adverse events and outcomes related to procedural sedation by non-anaesthesiologists were examined in order to identify patient factors and anaesthetic techniques that would predict an increased risk of sedation mishaps. Of the 1140 children sedated, 20.1% experienced at least one adverse event, whilst 150 (13.2%) children were inadequately sedated, which led to 43 failed procedures. (34) Inadequate sedation may lead to patient discomfort or injury because of a lack of cooperation or an adverse physiological or psychological response to stress (21). A respiratory event (respiratory depression, upper airway obstruction, or apnoea) leading to oxygen desaturation was experienced by 5.5% of children. Three of these children did not desaturate until after the procedure, with one having been awake throughout and then became sedated and subsequently desaturated in the recovery area. The cause of desaturation is not documented in the report. Other adverse events included hypotension, bradycardia, vomiting, paradoxical reactions involving agitation and excitation, and one case of supraventricular tachycardia. All adverse events were managed and no long-term sequelae transpired. An increased incidence of adverse events occurred in infants and ASA 3 or 4 patients (compared with ASA 1 or 2; $p < 0.0001$). (34) Amongst other findings, the importance of patient selection and appropriate recovery area monitoring arise out of this study, which are both emphasised in the SASA PSA guidelines (4, 34).

Due to the lack of systematic data collection on outcomes of paediatric dentistry, Lee et al. (36) analysed American media reports of children who died subsequent to receiving sedation or general anaesthesia for dental procedures between 1980 and 2011. Of the 44 reports analysed, most deaths occurred in children under six years of age (52.3%), in an office setting (70.5%), and with a dentist as the sedation or anaesthesia provider (56.8%). The authors indicate that due to a lack of systematic reporting, these deaths represent only a subset of a larger number of deaths. (36)

Children may pass into a deeper state of sedation than intended. A study of 960 children being sedated by non-anaesthesiologists for various procedures found that 18% of the 895 patients who required conscious (mild to moderate) sedation had inadvertently slipped into a state of deep sedation. In this study there was a 3.8%

rate of complications with planned conscious sedation compared to 9.2% with planned deep sedation (OR: 2.6). Sustained hypoxaemia, airway obstruction, apnoea, aspiration, hypotension, and prolonged sedation accounted for the excessive risk associated with deep sedation. (3) One cannot be certain what dose of a sedative will cause deep sedation in a child (39). Noxious stimuli may lighten sedation, while withdrawing stimuli at the end of a procedure can deepen it (32). A sedationist may be tempted to use larger doses of drugs in an uncooperative child. Sedatives that are said to have a wide margin of safety are generally not short acting and, should deep sedation occur, it may be prolonged. (39) It is therefore essential to have knowledge of the different levels of sedation (28), which should only be undertaken where facilities, equipment and personnel are always prepared and equipped to manage deep sedation (39).

Despite the risks associated with PSA, it is neither realistic nor necessary to restrict its provision to anaesthesiologists, who are insufficient in number to cater for the ever increasing need for paediatric PSA (31, 40, 41).

2.6 2010 SASA PSA guidelines

The ASA (21) states that: “Practice guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice.”

As dental chair sedation practices in Gauteng will be compared to the standards described by the 2010 SASA PSA guidelines (4), the relevant contents of these guidelines will be discussed in detail.

These guidelines were developed by a task team at the request of the Department of Health of the Western Cape. The team felt that the guidelines would be of benefit to the entire country and in line with the international trend towards the formalisation of sedation guidelines for children. It is based on international and national peer-reviewed publications and numerous other medical disciplines were consulted in the process. The emphasis of the document is on the provision of safe practice and a unified standard of care, regardless of location. The document is the first of its kind in this country and its information is relevant to South African practice. (4)

Outline of the content of the guidelines, with particular reference to this study are discussed in more detail below:

2.6.1 Introduction, objectives, definitions

The guidelines are intended for use by dental and medical practitioners across all disciplines providing sedation, analgesia and anxiolysis to paediatric patients undergoing diagnostic or therapeutic procedures. Safety should be ensured in all environments. (4)

The relevant definitions are those provided in the “Research assumptions” section of this report. The response of individual patients to drugs administered is difficult to predict, and practitioners must be able to rescue patients who inadvertently enter a deeper level of sedation than intended. The document states that deep sedation and general anaesthesia should only be performed by those with anaesthetic training, but does not specify what level of anaesthetic training is required. (4)

2.6.2 Patient selection

Children at increased risk for complications should at least be assessed by a specialist anaesthesiologist (or experienced sedation practitioner). This person does not need to be the sedationist but should be available for consultation and,

preferably, assistance. Such cases should preferably be sedated in a hospital setting and not in a dental practice. These patients include:

- “Age < 1 year.
- Prematurity with residual pulmonary, cardiovascular, gastrointestinal or neurological problems, or significant anaemia.
- Children with congenital syndromes.
- Obesity (> 95th percentile body mass index (BMI) for age).
- Children who need an advanced sedation technique.
- A previous failed sedation.
- A previous oversedation (unintentional deep sedation or general anaesthesia).
- Any known adverse effect (hyperactive or paradoxical response) or allergy to any of the sedation drugs.
- Any child who, following airway assessment..., is suspected of having airway problems.
- Children with respiratory problems, including an active URTI, low oxygen saturation, and a weak cough or cry.
- Asthmatic children who are clinically wheezing or whose regular treatment includes more than inhalational short-acting β_2 -agonists and inhalational steroids.
- Children with cardiac problems, including congenital cardiac disease, cyanosis, congestive heart failure and undiagnosed murmurs.
- Neurological conditions, including poorly-controlled seizures, neuromuscular disease, central apnoea or an unstable cervical spine.
- Increased intracranial pressure.
- Severe behavioural problems.
- Uncontrolled gastro-oesophageal reflux or other conditions predisposing to reflux.
- Active vomiting.
- Haematological conditions, including coagulation disorders and sickle cell disease.
- ASA class 3 and 4.
- Parental reluctance.

- Children with malignancies.” (4)

A few of the listed subgroups will be elaborated upon. A study by Malviya et al. (34) (discussed in more detail earlier in this report) looking at adverse paediatric sedation events found an increased incidence of adverse events among infants and ASA 3 and 4 patients. The risk of anaesthesia-related cardiac arrest is inversely proportional to age, with the highest incidence occurring among infants (42). An analysis of anaesthesia-related cardiac arrests from the American Pediatric Perioperative Cardiac Arrest Registry found that more than a third of paediatric cardiac arrests occurred in infants, while 75% of arrests occurred in ASA 3 to 5 children (43).

Congenital syndromes usually involve more than one body system. Depending on the particular syndrome, factors that may impact on patient safety may include a difficult airway (upper or lower airway obstruction or defects), impaired respiratory mechanisms (caused by skeletal abnormalities or altered respiratory drive), gastro-oesophageal reflux, cardiovascular disorders (structural defects or arrhythmias), neuromuscular problems, liver or kidney disease (with impaired drug clearance). (44)

With regards to obesity potential problems involve, amongst others, airway management (increased risk of airway obstruction with difficulty ventilating and or intubating patients should the need arise), a predisposition to hypoxia, and obstructive sleep apnoea with possible pulmonary hypertension (45). An American closed-claim analysis found obesity to be a significant risk factor for major morbidity or mortality from dental office anaesthetic procedures (37).

The incidence of laryngospasm during anaesthesia in children under nine years of age is 1.74%. Although this reference is made to anaesthesia and not sedation, it is during the period of induction and emergence, rather than during deep general anaesthesia, when patients are most vulnerable. Laryngospasm causes airway

obstruction and hypoxia, and if unresolved may eventually result in cardiac arrest. Children with an upper respiratory tract infection or active asthma have irritable airways and are approximately ten times more prone to developing laryngospasm. (27)

There are other children whom the sedationist should treat cautiously and have a low threshold for referring to a higher level of care. These children include those younger than five years old, children with a head injury, epilepsy, autism, an altered mental state, communication problems, delayed milestones, controlled gastro-oesophageal reflux, and children taking psychotropic medication. (4)

2.6.3 Patient assessment

Guidelines to a comprehensive history, airway and physical examination are provided. This facilitates identification of patients at increased risk (mentioned above), who would warrant additional consultation or referral. Informed consent should be obtained from a responsible person. (4)

2.6.4 Fasting guidelines

Information is given on standard fasting guidelines. Fasting is not required for simple sedation techniques. (4)

2.6.5 Drugs

A summary of the drugs used during PSA and their antagonists appear in this section. Practitioners are reminded of the synergistic effects of using drugs in combination and to allow a drug-specific period to elapse before administering repeated doses of a drug. Recommendations are made as to which drugs are not suitable for outpatient procedures and which agents should be used only by

practitioners with anaesthetic training. (4) This part of the guidelines is discussed in more detail in the “Pharmacology” section of this report.

2.6.6 Environment

Sedation should only be performed in an environment capable of handling emergencies. A comprehensive list is provided of the minimum equipment that must be available and regularly checked. These include equipment to:

- open and protect the airway (a range of sizes)
- confirm endotracheal intubation (including stethoscope and end-tidal carbon dioxide monitoring)
- assist with difficult intubation
- deliver oxygen and ventilation
- diagnose and treat dysrhythmias
- gain intravascular access
- infuse fluids
- monitor airway, breathing and circulation. (4)

2.6.7 Monitoring

- Clinical monitoring:

This includes observation of chest wall and face, assessment of level of consciousness, colour, respiratory rate and pattern, and signs of pain or anxiety. The document contains a description of the above variables. (4)

- Equipment:

During simple or basic sedation pulse oximetry is necessary. During advanced sedation pulse oximetry, ECG and non-invasive blood pressure monitoring is necessary and capnography (or a praecordial stethoscope) recommended. (4)

- Personnel:

During simple or basic sedation the patient must be monitored by someone other than the operator. As advanced sedation is more complicated closer monitoring is required. Someone other than the operator must administer sedation, monitor the patient, and be responsible for rescuing the patient should complications arise. A medical practitioner is recommended to perform this role. (4)

2.6.8 Discharge

Premature discharge has been identified as a major cause of severe morbidity and mortality. A scoring system for discharge readiness from the recovery area to the ward (in the case of inpatient sedation) is provided as a guide. It assesses level of consciousness, respiration, oxygen saturation, movement, temperature and pain. Additional criteria need to be met should children be discharged home. These include the absence of surgical complications, ability to drink fluids, no nausea or vomiting and an analgesia management plan. A simple questionnaire to aid in this process is provided. (4)

Children may be only discharged from the facility into the care of a parent, guardian, or another responsible person. This person must have access to a telephone and be given clear instructions which should include:

- not leaving the child unattended in a car
- slow initiation of eating and drinking
- avoiding play requiring coordination for 12 hours
- supervising all activity for 12 hours
- where to seek immediate help or a telephone number to phone
- how to give prescribed medication. (4)

2.6.9 Documentation required

“It is important to remember that, unless it has been written down, it never happened!” (4)

Documentation is necessary before, during and after sedation. This includes:

- a medical history questionnaire
- informed consent
- pre- and post-sedation instructions to the caregiver
- a pre-procedural checklist (including an equipment check)
- a sedation monitoring chart
- a post-sedation monitoring chart, with a discharge scoring system
- a discharge questionnaire.

Each of these documents is explained in more detail in the guidelines, with accompanying templates and suggested formats. (4)

2.6.10 Adverse events

The causes of adverse events are as listed and discussed in the “Risks associated with sedation” section of this report. Audits of procedures as well as critical events should be performed at least annually. A suggested adverse event reporting form is provided in the guidelines. (4)

2.6.11 Procedure specific recommendations

Pharmacological and non-pharmacological strategies are suggested. The latter includes psychological preparation of the child and caregiver, distraction, application of ice packs etc. PSA recommendations are made for various diagnostic and therapeutic procedures, of which only dental PSA will be discussed here. (4)

Recommended PSA techniques include:

- using topical and local anaesthesia for analgesia;
- a basic technique using not more than 50% inhaled N₂O in oxygen is one of the best techniques for minor paediatric dental procedures;
- oral drugs (e.g. midazolam) can be used (but must be administered on the premises and not at home);
- advanced techniques may be useful. (4)

Anaesthetic doses of drugs (i.e. doses large enough to induce general anaesthesia) should not be used and doses should be reduced if a combination of sedative agents is administered. The timing of administration of PSA drugs in relation to stimulation of a patient is important and will prevent excessive doses being given. This highlights the importance of the pharmacology section of the guidelines, which describes the time of onset and duration of action of the recommended PSA drugs. (4)

2.6.12 Setting up a sedation service

Aspects that deserve attention, irrespective of techniques employed are:

- environment, patient selection and assessment:

Patient selection and assessment, including a focused airway examination, must be done by trained healthcare professionals and documented. All facilities must comply with standards for patient safety. (4)

- training requirements:

All sedation practitioners must comply with SASA recommendations and contemporary standards of training. If administering moderate or deep sedation, Pediatric Advanced Life Support (PALS) or Advanced Pediatric Life Support (APLS) certification is highly recommended. (4)

- sedation practitioner: experience and ability to rescue:

Continuing professional development is important. Practitioners must be able to rescue patients who progress to an inadvertent deeper level of sedation. (4)

- record keeping:

A register of procedures performed and sedation techniques used must be kept (4).

2.7 Society of Sedation Practitioners of South Africa (SOSPOSA)

Being a useful source of support to sedation practitioners and the only sedation society in South Africa affiliated to SASA, it is worth making a short mention about SOSPOSA. It is a member of the International Federation of Dental Anesthesiology Societies and a special interest group of SASA, which brings together practitioners from various disciplines who are involved and interested in sedation practice.

Amongst other benefits, members have access to the latest information regarding safe sedation practice, are able to ask questions on sedation-related issues, and receive information regarding training opportunities. SOSPOSA endorses the SASA PSA guidelines (4) and promotes application of the guidelines to its members as an important step in ensuring safe sedation practice. (46)

2.8 Dental sedation survey

Goodchild et al. (47) conducted a study examining the use of outpatient dental sedation in the United States and Canada in May 2009. Their study is discussed here as it shares many similarities with this one in terms of design and information sought. An email was sent to 7246 dentists requesting participation in a short web-based survey. Responses were voluntary and kept anonymous. Participants were asked about their use of sedation, type of sedation used, drugs and their antagonists, route of administration, monitoring employed and availability of a defibrillator. There was a 9.84% response rate. The authors attribute the low response rate to email filters, participants not being acquainted with the authors and

that emails were sent from one of the author's personal email accounts. Of the 716 completed surveys, 76% of practitioners used sedation with 26% of the remaining dentists being interested in doing so. Nitrous oxide and oxygen was the most common type of sedation employed (77% of practices). Inhalation was the most common route of administration (75%) and parenteral sedation the least common. Blood pressure was monitored in 84% of patients and pulse oximetry in 81%, while 5% of respondents did not use any monitoring equipment. Benzodiazepines were the most frequently used drugs for enteral sedation (90%), although only 75% of respondents carried antagonist drugs. A defibrillator was available in 64% of facilities. (47)

2.9 The benefit of applying guidelines to sedation practice

Various professional bodies (e.g. ASA, AAP) have published guidelines in attempts to enhance the safety of PSA by the application of standards. Since these standards are based largely on expert opinion, differ from each other, and restrict practice, they have not been uniformly accepted and applied. (3)

No study could be identified that determined risk reduction from the application of the SASA PSA guidelines (4) per se. The content and safety recommendations contained in these guidelines are, however, similar in nature to those developed by other bodies. A co-author of the critical incident analysis (2) discussed earlier stated in another publication (31) that, since outcomes of death and permanent neurological events were quite uncommon, a much larger sample size (several hundred thousand or more) would be needed to demonstrate the efficacy of sedation guidelines in preventing such outcomes.

Cote (31) states that: "If you ask me how to measure the cost/benefit ratio of implementing the sedation guidelines, I say we cannot measure it. We can, however, say there is a heightened awareness of the problems associated with sedation, there is better evaluation of patients before sedation, there is more attention to developing

institutional guidelines... and I am sure some lives have been saved; we just can't measure this outcome." (31)

A study conducted at the Children's Hospital of Wisconsin found direct evidence that elements of the AAP/ASA guidelines for procedural sedation could be adopted by non-anaesthesiologists with a decrease in the occurrence of complications or adverse events. A quantitative scoring system assessed adherence to essential components of the guidelines during the sedation of 960 children for a variety of procedures. Analysis of the data revealed significant variation in practice.

Performance of a structured patient risk assessment (OR: 0.10) and adherence to all process guidelines (OR: 0) significantly reduced complications. Although the study does not determine which specific elements of the risk assessment were associated with risk, it does indicate that a guided assessment is important in identifying patients at risk for sedation complications. Repeated assessment of the depth of sedation, as recommended by the guidelines, also reduces the risk of inadvertent deep sedation.

(3)

Vade et al. (30) demonstrated the importance of applying guidelines in their entirety. The aim of their study was to compare the frequency of adverse events associated with different drug regimens during paediatric sedation for radiological studies. They selected 410 children, and monitored and managed them according to the AAP sedation guidelines at that time. Two patients suffered moderate to severe hypoxic events during sedation, which were appropriately managed. Errors were made during pre-sedation medical screening, as these children had significant co-morbidities and according to the guidelines were inappropriately selected to undergo sedation. Two important points that arose from this situation are relevant to this review. Firstly, it highlights the importance of appropriate patient selection and evaluation in preventing adverse events and secondly, as the authors conclude, adoption of the guidelines allowed for prompt detection and management of potentially life-threatening hypoxia. (30)

Guidelines cannot guarantee a specific patient outcome, but encourage high quality patient care (6). Exactly when a problem will develop can't be predicted with certainty, so if all patients are monitored equally it is less likely that an impending adverse outcome will be missed.

“Minor desaturation is much easier to correct than a hypoxic-induced cardiac arrest!” (31) Sedation practitioners must try to avoid adverse outcomes, and have the ability and equipment to rapidly diagnose and adequately manage them should they occur.

2.10 Summary

Dental chair PSA facilitates the successful completion of procedures in children, who would otherwise not be able to receive treatment or would require a costly general anaesthetic in a hospital setting. PSA is generally safe and although serious adverse events are rare, those that occur are mostly preventable. Children comprise a particularly vulnerable patient subgroup.

Cases of major morbidity and mortality during sedation for harmless dental procedures in healthy children were reported in the United States during the 1980's. This prompted authorities to develop sedation guidelines, which were shown to improve safety and reduce adverse outcomes associated with PSA.

In South Africa, SASA published the country's first PSA guidelines in 2010 (4), which provide a framework for the provision of safe sedation and analgesia for diagnostic and therapeutic procedures in children. However, little is known about the extent of adverse dental chair PSA outcomes in South Africa, the awareness of the SASA PSA guidelines (4), or the state of safety standards for PSA in dental rooms.

This chapter comprised a review of the current relevant literature. In the next chapter the research methodology and study considerations are covered in detail.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

In this chapter the following will be discussed: the problem statement, aim and objectives of the study; ethical considerations; research methodology; and the validity and reliability of the study.

3.2 Problem statement

PSA is generally safe, and is often necessary to successfully undertake dental procedures in children. Severe adverse events and outcomes that occur are mostly preventable. The guidelines formulated by SASA serve to provide a framework for practitioners to safely provide PSA to children in all environments (4).

No data could be identified as to how many dental practices in Gauteng make use of PSA and how many sedation practitioners are aware of the available SASA PSA guidelines (4). Practising outside the framework of these guidelines may place children at increased risk of adverse events and outcomes.

3.3.1 Aim

The aim of this study was to determine the proportion of dental practitioners making use of paediatric dental chair PSA in Gauteng and to describe paediatric dental chair PSA practice, awareness of the 2010 SASA PSA guidelines (4), and adherence to the guidelines.

3.3.2 Objectives

The objectives of this study were to:

- determine the proportion of dental practitioners in Gauteng that utilise paediatric dental chair PSA;
- identify the professional category of person primarily responsible for administering PSA;
- describe the modalities of PSA administered in dental rooms
 - depth of sedation
 - drugs used
 - number of sedative agents used in combination
 - routes of administration;
- describe the sedation and resuscitation training of PSA providers;
- determine adherence to recommended safety standards for prevention of adverse events
 - age groups of children sedated
 - ASA physical status
 - pre-sedation assessment and informed consent
 - fasting
 - person responsible for patient monitoring
 - monitoring equipment
 - level of consciousness or depth of sedation monitoring
 - recovery;
- determine adherence to recommended safety standards for management of adverse events
 - emergency drugs
 - emergency equipment;
- determine the occurrence of complications of PSA.

3.4 Ethical considerations

Approval to conduct this study was obtained from the Postgraduate Committee (Appendix 1) and the HREC (Medical) (Appendix 2) of the University of the Witwatersrand.

A sample of Gauteng-based members of SADA, whose names and contact numbers are available to the public on the SADA website (8), were invited telephonically by the researcher to participate in the study. Dental practitioners who agreed to participate, and who indicated that paediatric PSA was being performed in their rooms, were then sent an introductory email detailing the purpose of the study, content of the data collection email, rights to anonymity and withdrawal, and ethics approval (Appendix 4). Consent to participate was implied when the participant clicked on a link contained in the email to a web-based data collection sheet (Appendix 3) developed using the online survey site, SurveyMonkey™. Confidentiality and anonymity of information were ensured as all responses were uploaded anonymously onto an electronic database on the SurveyMonkey™ website. It was not possible to trace information back to individual participants and the researcher and supervisors were the only people with access to this database by way of a unique user name and password.

A CPD-accredited sedation seminar hosted by the Department of Anaesthesiology, Charlotte Maxeke Johannesburg Academic Hospital was offered to participants to be held upon completion of this study, as it would be unethical to continue providing PSA without awareness of recommended safety standards.

This study did not involve any drug or therapeutic management and no patient was directly involved. It was conducted in accordance with the Declaration of Helsinki (10) and the South African Good Clinical Practice Guidelines (11).

3.5 Research methodology

3.5.1 Study design

A prospective, contextual, descriptive survey study design was used.

A prospective study is defined as a study which measures variables that occur during the course of the study and not those that have occurred in the past (48). In this study, variables pertaining to paediatric dental chair sedation practice were measured at the time in which the study took place.

A contextual study is conducted in a specific location (48). This study was carried out in Gauteng only.

A descriptive study is used when more information is required in a particular field and describes the variables in order to answer the research question, with no intention of establishing a cause-effect relationship. The emphasis in the collection of data is on structured observation, questionnaires, interviews or survey studies. (48) This study was descriptive in nature as it aimed to gain information about paediatric dental chair sedation practice.

3.5.2 Study population

Qualified dental practitioners who were listed on the SADA website and practising in Gauteng formed the population group studied (8).

3.5.3 Study sample

3.5.3.1 Sample size

The names and contact numbers of 1 152 Gauteng-based SADA members were listed on the SADA website (8). Two hundred dental practitioners were invited to participate in the study. As it was not known what proportion of dentists utilise paediatric PSA, this figure (n=200) would be increased following initial data collection if necessary, until a minimum of 20 completed data collection sheets were received (i.e. until at least 20 of the practitioners contacted were found to utilise PSA in their rooms and completed the data collection sheet). The sample size was influenced by available resources (financial and time constraints) and the scope of the study.

3.5.3.2 Sampling method

A simple random sampling method was used in this study. Simple random sampling involves a one-stage selection process in which each participant is listed separately and has an equal chance of being drawn (48). The sampling frame comprised the list of 1 152 Gauteng-based SADA members whose details are available to the public on the SADA website (8). SADA is the most recognised and representative body of dentists in South Africa (9). Furthermore, a randomly selected number from one to one million was allocated to each of the 1 152 members using the website Random.org (49). The reason for using one million possible numbers, despite a sampling frame of only 1 152 members, was to avoid allocating the same number to more than one member. The randomly allocated numbers were then arranged from smallest to largest, with the first 200 numbers (and corresponding SADA member on the list) comprising the study sample (Appendix 5). The same technique would be employed to select more participants from the remainder of the sampling frame should the need for a larger sample be identified following initial data collection.

3.5.3.3 Inclusion and exclusion criteria

All Gauteng-based dental practitioners who were members of SADA and listed on the SADA website on 23 June 2012 were included in the study (8). Members who declined to participate were excluded.

3.5.4 Data collection

A web-based data collection sheet (Appendix 3) was designed for data collection using SurveyMonkey™.

Prior to developing the data collection sheet, a review of the literature was done in order to identify the potential safety pitfalls in the field of paediatric dental chair PSA. The SASA PSA guidelines (4) highlight the standards required to safely administer PSA to children. These guidelines were reviewed in depth and served as the main reference point for the development of the data collection sheet, which for the most part assessed adherence to safety standards by comparing participants' PSA practice with the recommendations set out by the guidelines. Previous studies in which similar information was sought were used as additional guides in developing the data collection sheet (3, 47).

The data collection sheet was designed to be short and concise in an attempt to ensure a good response from participants. It assessed items in the following categories:

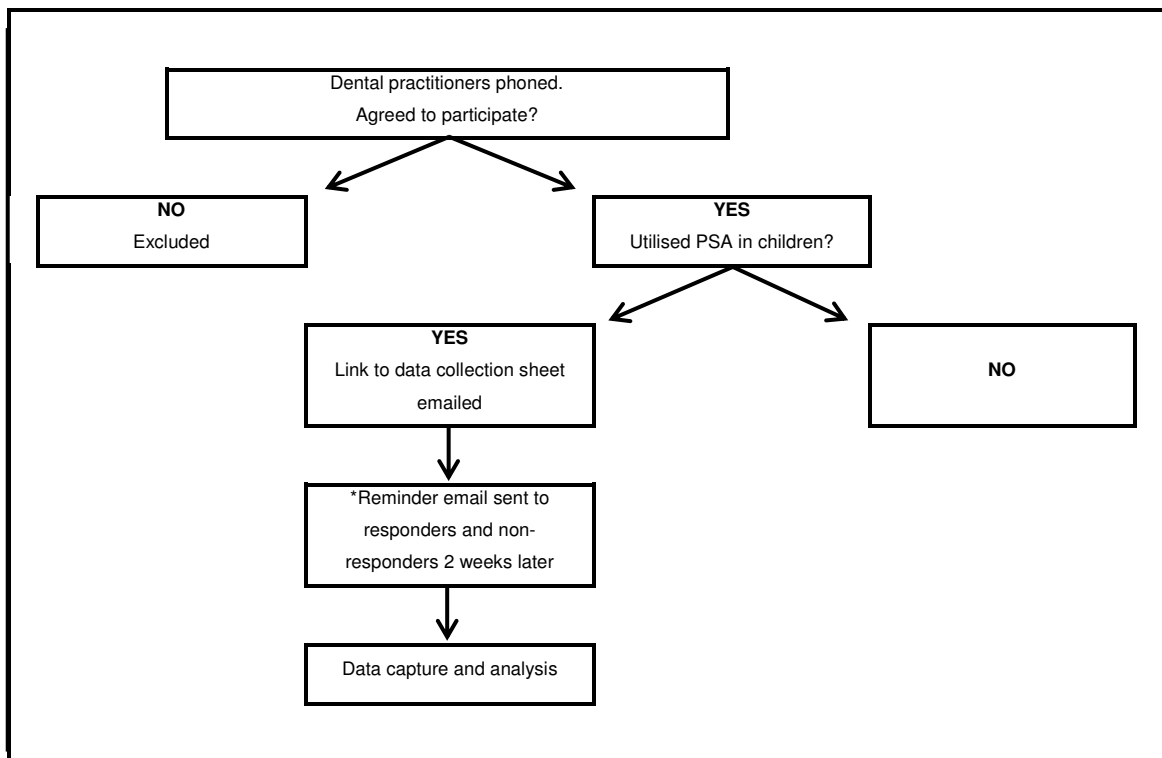
- professional category of person responsible for administering PSA
- modalities of sedation used
- awareness of the SASA PSA guidelines
- sedation and resuscitation training of the sedationist
- patient selection and assessment
- monitoring
- recovery area and discharge

- emergency drugs and equipment
- complications.

The data collection sheet was developed in consultation with three anaesthesiologists in order to ensure accuracy and validity. Two of these experts in the field are consultants in the Department of Anaesthesiology at the University of the Witwatersrand, with a special interest in paediatric anaesthesia. The third expert is part of a private-sector specialised sedation practice based in Johannesburg.

Once approval was obtained from the HREC (Medical), the dental practitioners randomly selected from the sampling frame were invited to participate in the study by means of a structured telephone conversation. Those practitioners who agreed to participate and who utilised PSA in children in their dental rooms were sent an email comprising an introductory letter (Appendix 4) and a link to the web-based data collection sheet (Appendix 3). The email address was set up specifically for the purpose of the study and did not contain the name of the researcher. Data received from completed data collection sheets was uploaded anonymously onto a database on the SurveyMonkey™ website, where it was analysed. Since all responses were received in an anonymous manner, it was not possible to ascertain which individuals did not respond. A reminder was emailed to all members two weeks after the initial email to thank those practitioners who had completed the data collection sheet and to serve as a reminder to those who had not yet done so (Appendix 6). The data collection process is illustrated in Figure 3.1.

Figure 3.1 Data collection process



PSA = procedural sedation and analgesia

*There was no way to ascertain who had not responded to the initial email as responses were anonymous.

3.5.5 Data analysis

Incoming data was analysed as it was received by SurveyMonkey™, the website hosting the data collection sheet. Descriptive statistics using frequencies and percentages were used to analyse the data. A proportion and confidence interval were determined with support from a biostatistician.

3.6 Validity and reliability

Validity and reliability of the study and data collection sheet were ensured by the following.

- A representative sampling frame. SADA members form a good representation of dental practitioners in South Africa.
- Randomisation of the sampling frame to minimise sampling bias.

- Content validity. The data collection sheet was designed following a careful review of the literature. It was developed in consultation with three experts in the field, all of them specialist anaesthesiologists. Two of these experts are consultants in the Department of Anaesthesiology at the University of the Witwatersrand, with a special interest in paediatric anaesthesia. The third expert is part of a private-sector specialised sedation practice based in Johannesburg.
- Criterion-related validity. Instruments used and variables assessed in similar studies were used as a guide in the development of the data collection sheet.
- A short and concise data collection sheet. This minimised the test effect of fatigue that occurs with lengthy surveys (48).
- An anonymous web-based data collection sheet.

3.7 Summary

In this chapter the following was addressed: the problem statement, aim and objectives of the study; ethical considerations; research methodology; and the validity and reliability of the study. The next chapter presents the results of this study and a discussion of the results.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

In this chapter the results of this study are presented as per the research objectives. The data presented include:

- the proportion of dental practitioners in Gauteng that utilise paediatric dental chair PSA;
- the professional category of person primarily responsible for administering PSA;
- the modalities of PSA administered in dental rooms
 - depth of sedation
 - drugs used
 - number of sedative agents used in combination
 - routes of administration;
- sedation and resuscitation training of PSA providers;
- adherence to recommended safety standards for prevention of adverse events
 - age groups of children sedated
 - ASA physical status
 - pre-sedation assessment and informed consent
 - fasting
 - person responsible for patient monitoring
 - monitoring equipment
 - level of consciousness or depth of sedation monitoring
 - recovery;
- adherence to recommended safety standards for management of adverse events
 - emergency drugs
 - emergency equipment;
- occurrence of complications.

4.2 Results

The sum of percentages presented in this section may not add up to 100% due to rounding off to two decimal places.

4.2.1 Sample realisation

During the two month data collection period (April 2013 to May 2013), 222 dental practitioners were contacted telephonically. Nine practitioners were excluded from the study as they are not in clinical practice or have retired. Thirteen practitioners returned phone calls after the first 200 practitioners had already been interviewed and were included in the study. The data analysis thus included 213 dental practitioners, which comprised 195 general dentists and 18 specialists (6 orthodontists, 5 periodontists, 4 maxillofacial surgeons and 3 prosthodontists).

Ninety-four of the 213 dental practitioners interviewed use paediatric dental chair PSA. The participant information letter (Appendix 4) and reminder email (Appendix 6) containing a link to the data collection sheet (Appendix 3) were sent to 93 of the 94 practitioners. One respondent indicated that he did not have an email address and was therefore not sent a data collection sheet.

Of the 93 data collection sheets issued, 52 (55.91%) were returned and uploaded onto the SurveyMonkey™ database for further analysis. Dental practitioners were not obliged to respond to each question in the data collection sheet. Respondents who did not answer individual questions were excluded from the analysis of data collected from those questions.

4.2.2 Demographics

Forty-four dental practitioners indicated their age and gender on the data collection sheet. The mean age of respondents was 44.91 years old (range 24 - 74 years old), with 29 (65.91%) males and 15 (34.09%) females.

Fifty dental practitioners indicated the frequency of PSA procedures performed. This data is presented in Table 4.1.

Table 4.1 Frequency of PSA procedures performed

Procedures per month	Dental practitioners	
	n	%
1-5	37	74
6-15	10	20
16-30	2	4
31-50	1	2
More than 50	0	0
Total	50	100

4.2.3 Objective 1: The proportion of dental practitioners in Gauteng that utilise paediatric dental chair PSA

Of the 213 dental practitioners interviewed, 94 (44.13%; 95% CI, 0.37-0.51) use paediatric dental chair PSA. Table 4.2 presents this data, which is broken down according to the dental subspecialists that were interviewed.

Table 4.2 Proportion of practitioners using paediatric dental chair PSA in Gauteng

Subspecialty	Dental chair PSA		Total interviewed
	YES n (%)	NO n (%)	
General dentists	91 (46.67)	104 (53.33)	195
Max-facs*	1 (25.00)	3 (75.00)	4
Prosthodontists	0 (0.00)	3 (100.00)	3
Periodontists	2 (40.00)	3 (60.00)	5
Orthodontists	0 (0.00)	6 (100.00)	6
Total	94 (44.13)	119 (55.87)	213

*Max-facs = maxillofacial surgeons

4.2.4 Objective 2: Professional category of person primarily responsible for administering PSA

Forty-eight respondents indicated the professional category of person primarily responsible for administering PSA in their dental rooms. Table 4.3 presents this data.

Table 4.3 Professional category of person primarily responsible for administering PSA

Responsible person	Dental practices	
	n	%
Dental practitioner*	22	45.83
Qualified nurse	0	0.00
Medical practitioner	1	2.08
Medical practitioner with sedation training	15	31.25
Anaesthetist	10	20.83
Total	48	99.99

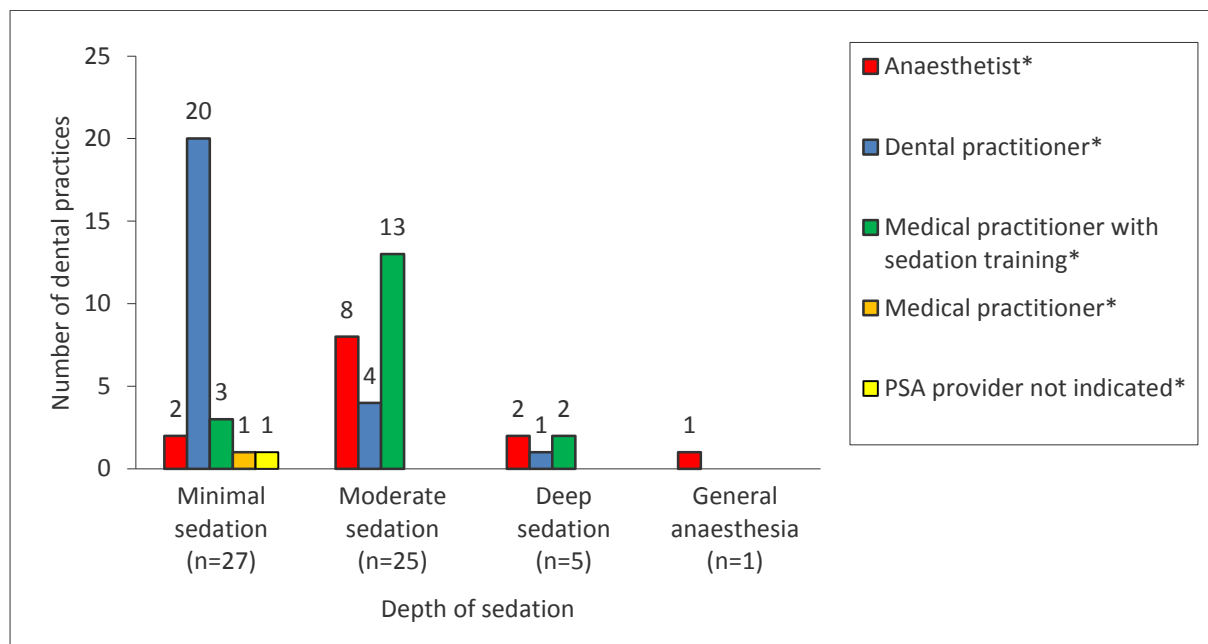
*The practitioner performing the dental procedure

4.2.5 Objective 3: The modalities of paediatric sedation administered in dental rooms

- **Depth of sedation**

Forty-eight dental practitioners indicated how deeply patients are sedated in their rooms. Respondents could select more than one depth of sedation if applicable to their practice. Twenty-seven (56.25%) practitioners perform procedures under minimal sedation and 25 (52.08%) utilise moderate sedation. Deep sedation (5 practices; 10.42%) and general anaesthesia (1 practice; 2.08%) are provided in fewer dental rooms. These results are broken down into professional categories of PSA providers and illustrated in Figure 4.1.

Figure 4.1 Depth of sedation used for dental chair PSA and the professional category of PSA providers



*Professional category of person primarily responsible for administering PSA

- **Drugs used for PSA**

Forty-eight dental practitioners indicated the drugs used for PSA in their rooms. Two of these practitioners indicated that they were not sure what agents are used by the PSA provider. Table 4.4 presents the drugs used for PSA and the professional category of person primarily responsible for administering the drugs. Respondents could select more than one drug if applicable to their practice.

Table 4.4 Drugs used for PSA and the professional category of PSA providers

Name of drug	Dental practices n (%)	Primary PSA provider				
		Dental practitioner	Anaesthetist	Medical practitioner with sedation training	Medical practitioner	Not indicated
Midazolam	33 (68.75)	10	7	13	1	2
Local anaesthetic agents	28 (58.33)	12	5	10	0	1
Nitrous oxide	19 (39.58)	13	2	3	0	1
Propofol	13 (27.08)	1	2	9	0	1
Ketamine	12 (25.00)	1	1	9	0	1
Myprodol™	12 (25.00)	6	3	3	0	0
Diazepam	10 (20.83)	4	2	3	0	1
Stopayne™	9 (18.75)	4	1	3	0	1
Paracetamol	9 (18.75)	4	2	3	0	0
NSAIDs*	8 (16.67)	4	1	3	0	0
Alfentanil	5 (10.42)	1	1	3	0	0
Trimeprazine	4 (8.33)	1	1	1	0	1
Fentanyl	2 (4.17)	0	1	1	0	0
Dexmedetomidine	1 (2.08)	0	0	0	0	1
Meperidine	1 (2.08)	0	1	0	0	0
Lorazepam	1 (2.08)	1	0	0	0	0
Tilidine	1 (2.08)	0	0	0	0	1
Clonidine	0 (0.00)	0	0	0	0	0
Chloral hydrate	0 (0.00)	0	0	0	0	0
Morphine	0 (0.00)	0	0	0	0	0
Remifentanil	0 (0.00)	0	0	0	0	0
Droperidol	0 (0.00)	0	0	0	0	0

*NSAIDs = Non-steroidal anti-inflammatory drugs

- **Number of sedative agents used in combination**

Thirty-eight dental practitioners answered the question about the number of agents used in combination during PSA. Six respondents indicated that they were not aware of the combination used by the PSA provider. Table 4.5 presents this data.

Table 4.5 Number of sedative agents used in combination

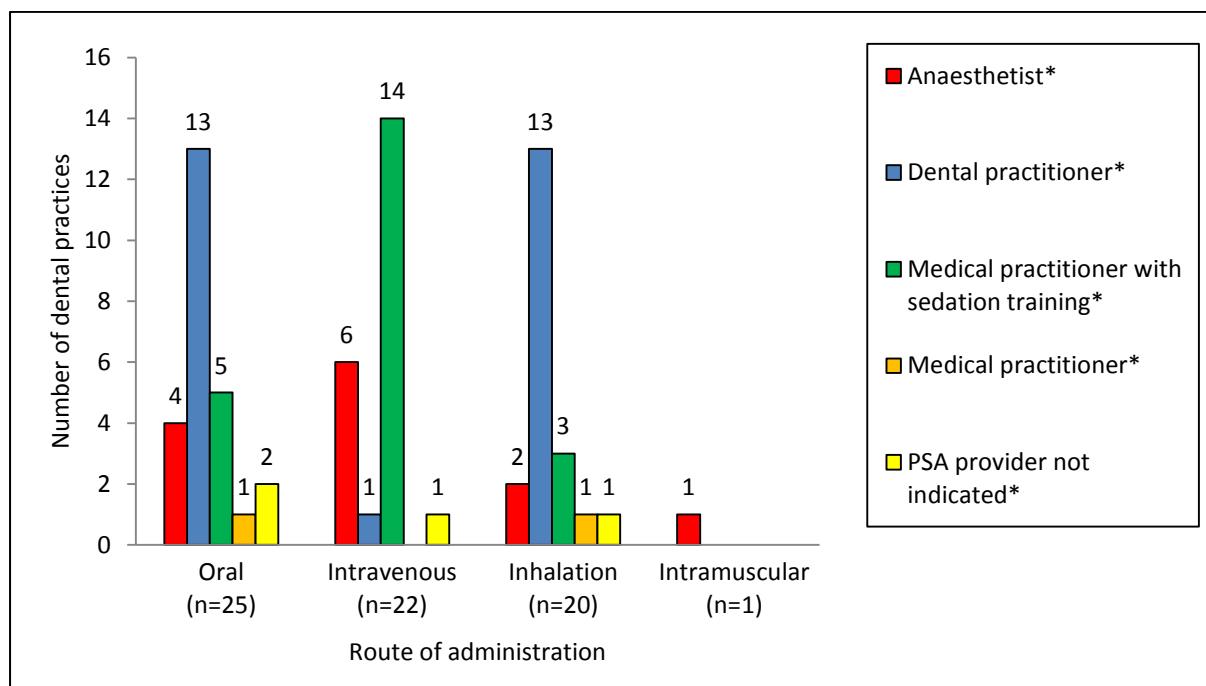
Number of agents	Dental practices	
	n	%*
1	10	31.25
2	13	40.63
3	8	25.00
4 or more	1	3.13
Respondent unaware	6	-
Total	38	100.01

*Percent of dental practices in which the dental practitioner is aware of the combination used

- **Routes of administration**

Forty-eight dental practitioners answered the question about the route of administration of sedative agents. Respondents could select more than one answer if applicable to their practice. Oral administration is most common and is used by 25 (52.08%) PSA providers. Intravenous (22 PSA providers; 45.83%), inhalational (20 PSA providers; 41.67%), and intramuscular (1 PSA provider; 2.08%) drug administration are the other routes used for paediatric dental chair PSA. None of the PSA providers administer drugs rectally. These results are broken down into professional categories of PSA providers and illustrated in Figure 4.2.

Figure 4.2 Routes of PSA drug administration and the professional category of PSA providers



*Professional category of person primarily responsible for administering PSA

4.2.6 Objective 4: Sedation and resuscitation training of PSA providers

- **Sedation training**

Twenty-two dental practitioners indicated that they are primarily responsible for PSA administration (Table 4.3), of whom 12 (54.55%) have had sedation training. One

respondent indicated that he received 6 years of sedation training in the United Kingdom. Thirty-six (81.82%) of 44 dental practitioners indicated that they are interested in attending a CPD-accredited sedation course.

- **Resuscitation training**

Forty-five respondents answered the questions about resuscitation training, membership with SOSPOSA and awareness of PSA guidelines. Of these respondents, thirty-eight (84.44%) have attended a Basic Life Support (BLS) course, and six (13.33%) have attended APLS or PALS courses. Two (4.44%) respondents are members of SOSPOSA. Twelve (26.67%) dental practitioners indicated that they are aware of the SASA PSA guidelines (4).

Of the 45 respondents, 20 (44.44%) dental practitioners are primarily responsible for administering PSA in their rooms. Eighteen (90%) of them have attended a BLS course, two (10%) have attended an APLS or PALS course, four (20%) are aware of the SASA PSA guidelines (4), and none are members of SOSPOSA. One respondent is a member of The Society for the Advancement of Anaesthesia in Dentistry, which is based in the United Kingdom.

4.2.7 Objective 5: Adherence to recommended safety standards for prevention of adverse events

- **Age groups**

Forty-seven dental practitioners answered the question about the age groups of children receiving PSA in their practices. Respondents could select more than one age group if applicable to their practice. The 1-5 year and 6-8 year age groups are most commonly sedated (76.60% and 74.47% respectively). The 9-12 year age group receives PSA in 20 dental practices (42.55%). Two dental practitioners perform procedures under PSA in children less than 1 year of age. These results are broken down into professional categories of PSA providers and presented in Table 4.6.

Table 4.6 Ages of children receiving dental chair PSA and the professional category of PSA providers

Age group (years)	Dental practices n (%)	PSA provider				
		Dental practitioner	Anaesthetist	Medical practitioner with sedation training	Medical practitioner	Not indicated
Less than 1	2 (4.26)	1	0	1	0	0
1-5	36 (76.60)	13	10	12	0	1
6-8	35 (74.47)	15	7	12	1	0
9-12	20 (42.55)	13	1	5	0	1

- **ASA physical status**

Forty-eight respondents indicated the ASA physical status of patients receiving PSA in their rooms. All dental practices provide a PSA service to ASA 1 patients, while 17

(35.42%) provide PSA to ASA 2 patients. Only 1 dental practitioner provides PSA to ASA 3 and 4 patients.

- **Pre-sedation assessment and informed consent**

Thirty-nine (82.98%) out of 47 PSA providers document details of the pre-sedation assessment. Informed consent for sedation is obtained from the caregiver by 34 (75.56%) out of 45 PSA providers.

- **Fasting**

Forty-five dental practitioners indicated their fasting recommendations prior to performing procedures under PSA. These results are presented in Table 4.7 with a breakdown of sedation modalities administered in these dental practices. According to the SASA PSA guidelines (1), the administration of deep sedation or general anaesthesia, sedation via the intravenous route, or the co-administration of two or more sedative agents necessitates that patients be starved prior to PSA.

Table 4.7 Fasting recommendations by PSA providers with a breakdown into sedation modalities that necessitate fasting

Fasting duration	Dental practices n (%)	Administers deep sedation or GA*?		Administers intravenous sedation?			Administers ≥2 sedative agents in combination?		
		YES	NO	YES	NO	NA°	YES	NO	NA°
Children are not starved	12 (26.67)	0	12	0	12	0	3	5	4
2 hours	8 (17.78)	2	6	4	4	0	3	3	2
4 hours	8 (17.78)	1	7	6	1	1	6	0	2
6 hours	11 (24.44)	1	10	8	3	0	6	1	4
8 hours	2 (4.44)	1	1	1	1	0	1	0	1
10 hours or longer	4 (8.89)	1	3	2	2	0	1	1	2
Total	45 (100.00)								

According to the SASA PSA guidelines (4), fasting is necessary prior to deep sedation, general anaesthesia, intravenous sedation, or the co-administration of 2 or more sedative agents;

*GA = general anaesthesia;

°NA = not answered

- **Person responsible for patient monitoring**

Forty-six dental practitioners indicated who is responsible for patient monitoring during procedures performed under PSA. Table 4.8 presents these results.

Table 4.8 Person responsible for patient monitoring during PSA

Responsible person	Dental practices	
	n	%
Dental practitioner*	19	41.30
Nurse	1	2.17
Medical practitioner	0	0
Medical practitioner with sedation training	16	34.78
Anaesthetist	9	19.57
Other°	1	2.17
Total	46	99.99

*The practitioner performing the dental procedure;

°Combination of a team

- **Monitoring equipment**

Forty-six dental practitioners indicated the monitoring equipment used during PSA. Respondents could select more than one answer if applicable. Table 4.9 presents their responses.

Table 4.9 Monitoring equipment used during PSA

Equipment	Dental practices	
	n	%
Pulse oximetry	25	54.35
Non-invasive blood pressure	16	34.78
Sedation monitoring chart	14	30.43
ECG	14	30.43
Capnography	4	8.70
Praecordial stethoscope	4	8.70
Thermometer	4	8.70
None of the above	19	41.30

Nineteen (41.30%) dental practitioners indicated that they perform procedures under PSA without using any of the listed monitoring equipment. Table 4.10 provides further information about these 19 respondents.

Table 4.10 PSA practices of dental practitioners not using any monitoring equipment

	Number of dental practices
Primary PSA provider	
Dental practitioner	19
Depth of sedation	
Minimal	19
Moderate	3
Deep or general anaesthesia	0
Patient age groups (years)	
<1	1
1-5	13
6-8	15
9-12	12
ASA status	
1	19
2	6
3	1
4	1
Number of drugs used in combination	
1	6
2	6
3 or more	0
Not indicated	7
Route of drug administration	
Inhalation	12
Oral	11
Other routes	0

- **Level of consciousness or depth of sedation monitoring**

Forty-five dental practitioners indicated how level of consciousness or depth of sedation is monitored in their practice. Respondents could make more than one selection if applicable. This data is presented in Table 4.11.

Table 4.11 Modalities used to measure level of consciousness or depth of sedation

Monitoring tool	Dental practices	
	n	%
Response to c/t/p* assessed at regular time intervals	30	66.67
Sedation scale	10	22.22
BIS°	7	15.56
Response to c/t/p* only when concern that patient is too deeply sedated	3	6.67
None of the above	13	28.89

*c/t/p = commands/touch/pain;

°BIS = Bispectral index monitoring

- **Recovery**

Forty-three dental practitioners responded to the question about having a recovery area. Twenty-six (60.47%) have a staffed recovery area in their dental rooms to monitor patients prior to discharge.

Forty-four dental practitioners indicated the parameters assessed in their practice during recovery and prior to discharge. Respondents could select more than one parameter if applicable. Table 4.12 presents this data.

Table 4.12 Parameters assessed during recovery and prior to discharge

Parameter	Dental practices	
	n	%
Level of consciousness	42	95.45
Movement	31	70.45
Respiration	27	61.36
Bleeding	27	61.36
Availability of a responsible caregiver	27	61.36
Pain	25	56.82
Nausea/vomiting	20	45.45
Oxygen saturation	17	38.64
Ability to drink	12	27.27
Temperature	9	20.45

4.2.8 Objective 6: Adherence to recommended safety standards for management of adverse events

- **Emergency drugs**

Forty-four dental practitioners indicated the emergency drugs available during PSA procedures. Respondents could make more than one selection. Nineteen (43.18%) respondents do not keep any of the listed drugs in stock. Flumazenil is stocked by 5 (15.15%) of the 33 respondents that use midazolam and 1 (10%) of the 10 diazepam users. Naloxone is stocked by 1 (20%) of the 5 respondents that use alfentanil and none of the fentanyl (2), meperidine (1) and tilidine (1) users. Table 4.13 contains a list of recommended emergency drugs to manage adverse sedation events and the number of PSA providers who keep the drugs in stock.

Table 4.13 Emergency drugs stocked by PSA providers

Emergency drug	Dental practices	
	n	%
Adrenaline	25	56.82
Atropine	14	31.82
Succinylcholine	8	18.18
Flumazenil	6	13.64
Naloxone	5	11.36
None of the above	19	43.18

- **Emergency equipment**

Forty-six dental practitioners indicated the equipment available for management of adverse events that may occur during procedures performed under PSA.

Respondents could make more than one selection. Table 4.14 presents this data.

Table 4.14 Equipment available for management of adverse events

Equipment	Dental practices	
	n	%
Oxygen supply	36	78.26
Face masks	33	71.74
Bag-valve ventilation device	22	47.83
OPA's or NPA's*	16	34.78
Intravenous fluids	16	34.78
Laryngoscope set	14	30.43
Endotracheal tubes	14	30.43
Intravenous cannulae	14	30.43
Glucose testing machine	10	21.74
Defibrillator	8	17.39
ETCO ₂ ^o monitoring	2	4.35
None of the above	9	19.57

*OPA's or NPA's = Oropharyngeal airways or nasopharyngeal airways;

^oETCO₂ = End-tidal carbon dioxide

4.2.9 Objective 7: Occurrence of complications

The only complication related to dental chair PSA documented by respondents is an allergic reaction (not anaphylaxis) experienced in the hands of one PSA provider.

4.3 Discussion

No South African data reporting the proportion of dental practitioners providing PSA could be identified. Similarly, little is known about the compliance of dental PSA providers with sedation guidelines. Goodchild et al. (47) conducted a study examining the use of outpatient dental sedation in the United States and Canada in May 2009. Their study is discussed in detail in chapter two of this report and shares many similarities with this one in terms of design and information sought.

Of the 213 dental practitioners interviewed, 94 (44.13%) provide paediatric dental chair PSA in their practice. This differs from the 75.7% of American and Canadian dental practitioners providing sedation as reported by Goodchild et al. (47). The discrepancy could partly be explained by the fact that the latter study included patients of all ages whereas our study is focused on paediatric patients only.

Deep sedation and general anaesthesia are less common (10.42% and 2.08% of dental practices respectively) than minimal and moderate sedation (56.25% and 52.08% respectively). The distinction in depth is important, as Hoffman et al. (3) found a 3.8% complication rate with planned mild to moderate sedation compared to 9.2% with planned deep sedation (OR: 2.6). Although Goodchild et al. (47) structured this question slightly differently, their data about “type(s)” of sedation administered can be compared. They found that N₂O (77% of dental practices), minimal enteral (57%), moderate enteral (40%), moderate parenteral (22%), deep sedation (13%) and general anaesthesia (10%) were administered. The SASA PSA guidelines (4) suggest that deep sedation and general anaesthesia should only be performed by those with anaesthetic training. In our study, of the five providers of deep sedation, the responsible PSA provider is either an anaesthetist (2 dental practices), a medical practitioner with sedation training (2 practices), or the dental practitioner (1 practice). The latter indicated having 6 years of sedation training in the United Kingdom and over 40 years of sedation experience. An anaesthetist is responsible in the only dental practice offering dental chair general anaesthesia.

Midazolam is the most commonly used agent, used by 68.8% of PSA providers. Local anaesthetic agents, paracetamol and non-steroidal anti-inflammatory drugs are not considered as sedative agents in this analysis. Nitrous oxide is used in 19 (39.6%) dental practices providing PSA and is the most common sedative agent administered in practices in which the dental practitioner is primarily responsible for PSA provision. Although N₂O is generally considered to be safe, any agent can depress the patient's ability to respond normally to airway obstruction once the drug depresses the central nervous system (30, 31). Remifentanyl, morphine, clonidine, chloral hydrate and droperidol are not used in the rooms of any of the respondents. Goodchild et al. (47) asked about the class of drugs most commonly used for enteral sedation, which was benzodiazepines (89.6%).

In this study three or more agents are combined in 28.13% of dental practices providing PSA. The potential for adverse outcomes is significantly increased when three or more drugs with sedative properties are combined (4, 20, 29). A critical incident analysis carried out on 118 adverse sedation events found drug interactions to be the most common (46.3% of cases) contributory cause of such events (2). This does not mean that drugs should not be combined, but emphasises the need for adequate monitoring and availability of emergency equipment when a combination of sedative agents are administered.

The oral route of drug administration is most frequently used in this study (52.08% of PSA providers). This requires adherence to safety guidelines, as a sedative has the potential to cause respiratory depression regardless of the route of administration (17, 29). In a review of paediatric dental sedation adverse effects from closed malpractice claims, Chicka et al. (35) found the administration of oral sedation to be involved in 10 of 13 sedation claims. Inhalational administration (75% of dental practices) was the most common route in the Goodchild et al. (47) study, followed by oral administration (69%).

The majority of dental practitioners (76.60%) provide PSA to children less than 6 years of age. This is the age group most vulnerable to the adverse effects associated with sedative medication (20, 35, 36). Two dental practitioners perform procedures under PSA in children less than 1 year of age. In one of these practices PSA is provided by a medical practitioner with sedation training, while the dental practitioner is the primary PSA provider in the other practice. The latter does have sedation training and is aware of the SASA PSA guidelines (4).

Only 1 dental practitioner provides PSA to ASA 3 and 4 patients. This practitioner is the person responsible for administering PSA and provides mild to moderate sedation to children between 1 and 8 years of age. This practitioner further indicates that he/she does not stock any of the emergency drugs listed in Table 4.13, nor does he/she use any of the monitoring equipment listed in Table 4.9.

Malviya et al. (34) reported an increased incidence of adverse events in infants and ASA 3 or 4 patients (compared with ASA 1 or 2; $p < 0.0001$). The SASA PSA guidelines (4) suggest that such patients should preferably be sedated in a hospital setting and not in a dental practice

Standard anaesthetic fasting guidelines should be applied prior to deep sedation, general anaesthesia, or advanced sedation techniques. Fasting is not necessary prior to minimal or moderate sedation, or simple sedation techniques. (4) Section 1.5 of this report describes these techniques in more detail. Three respondents indicated that children receive a combination of two sedative agents without being starved prior to sedation. Although these children do not receive deep or intravenous sedation, the administration of two or more sedative agents (advanced sedation) requires that patients be starved prior to sedation (4). The SASA PSA guidelines also recommend that children should not fast for unnecessary lengths of time and suggest a fasting period of 6 hours for children having formula feeds or solid food. Six (13.33%) dental practitioners recommend fasting for 8 hours or longer. Of the six practices, none have a blood glucose testing machine available.

The SASA PSA guidelines (4) suggest that patient monitoring should be undertaken by someone other than the operator. In 41.30% of practices providing PSA, the dental practitioner performing the dental procedure is also responsible for patient monitoring.

Of the dental practices that provide sedation, 41.30% do not use any form of monitoring equipment, 43.18% do not keep any of the recommended emergency drugs in stock and 19.57% do not have any emergency equipment available. According to the SASA PSA guidelines (4), sedation should only be performed in an environment capable of handling emergencies. Inadequate monitoring and equipment are among the usual causes of sedation-related adverse events. (4) In comparison, 5% of the sample surveyed by Goodchild et al. (47) did not use any monitoring equipment and 25% indicated that they did not keep any antidotal drugs (e.g. flumazenil and naloxone) in stock.

Pulse oximetry is a minimum requirement for patient monitoring, and the only equipment necessary irrespective of the sedation technique (i.e. simple or advanced) employed (4). A pulse oximeter is used by 54.35% of sedation providers in this study versus 81% in the study by Goodchild et al. (47).

Only one practitioner reported an adverse event. This was an allergic reaction which did not lead to major morbidity or mortality. It is possible that respondents may have underreported adverse events. As is the case in this study, the patient cohorts in most previous studies describing sedation safety and adverse events contained tens or hundreds of patients and were statistically underpowered to report on the frequency of events that should occur in no more than one in many thousands (2, 18, 26, 30, 34-37). The Paediatric Research Consortium reported an overall complication rate of 5.3% during paediatric sedation and anaesthesia outside the operating room. These included a variety of procedures of which only 1.1% were dental in nature. (26)

The data collection sheet yielded 52 responses according to statistics provided by SurveyMonkey™, with not all respondents providing answers to all questions. It is difficult to draw any conclusions about omissions being made by any specific group of respondents.

A number of dental practitioners volunteered useful information during the initial telephone conversation. There are practitioners who would like to offer PSA in their rooms, but feel that they first require training to be able to do so. Some practitioners make use of the theatre setting as they are of the opinion that dental room sedation is too risky. Common problems encountered by dental practitioners are the shortage of available theatre time and difficulty booking anaesthetists for dental procedures. Some dental practitioners also complained about the reluctance of medical aid schemes to pay anaesthetists for dental chair sedation or to cover the extra costs associated with performing dental procedures in the theatre setting.

Despite the risks associated with PSA, it is neither realistic nor necessary to restrict its provision to anaesthesiologists, who are insufficient in number to cater for the ever-increasing need for paediatric PSA (31, 40, 41).

Many facilities do not adhere to recommended safety standards for prevention and management of adverse events. Particular areas of concern are the high number of practices in which no monitoring equipment, emergency equipment, or emergency drugs are available.

4.4 Summary

This chapter dealt with an analysis of the data collected and a discussion of the results according to the objectives of this study. The data presented included the proportion of dental practitioners in Gauteng that utilise paediatric dental chair PSA; the category of person primarily responsible for administering PSA; the modalities of

paediatric sedation administered in dental rooms; sedation and resuscitation training of PSA providers; adherence to recommended safety standards for prevention and management of adverse effects; and the occurrence of complications.

In the final chapter a summary of the study is presented, along with the limitations, recommendations and conclusions of the study.

CHAPTER FIVE

SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSIONS

5.1 Introduction

In this chapter the aim, objectives, study design and results of the study will be briefly reviewed. The limitations of the study will be addressed, recommendations for clinical practice and further research made, and a conclusion presented.

5.2 Summary of the study

5.2.1 Aim of the study

The aim of this study was to determine the proportion of dental practitioners making use of paediatric dental chair PSA in Gauteng and to describe paediatric dental chair PSA practice, awareness of the 2010 SASA PSA guidelines (4), and adherence to the guidelines.

5.2.2 Objectives of the study

The objectives of the study were to:

- determine the proportion of dental practitioners in Gauteng that utilise paediatric dental chair PSA;
- determine the professional category of person primarily responsible for administering PSA;
- describe the modalities of paediatric sedation administered in dental rooms
 - depth of sedation
 - drugs used
 - number of sedative agents used in combination
 - routes of administration;
- determine sedation and resuscitation training of PSA providers;

- determine adherence to recommended safety standards for prevention of adverse events
 - age groups of children sedated
 - ASA physical status
 - pre-sedation assessment and informed consent
 - fasting
 - person responsible for patient monitoring
 - monitoring equipment
 - level of consciousness or depth of sedation monitoring
 - recovery;
- determine adherence to recommended safety standards for management of adverse events
 - emergency drugs
 - emergency equipment;
- determine the occurrence of complications of PSA.

5.2.3 Summary of the methodology used in the study

A prospective, contextual, descriptive survey study design was used. Qualified dental practitioners who were listed on the SADA website and practising in Gauteng formed the population group studied. It was determined that a minimum of 200 of the 1152 Gauteng-based SADA members would be invited to participate in the study. This figure (n=200) would be increased following initial data collection if necessary, until a minimum of 20 completed data collection sheets were received. The sample size was influenced by available resources (financial and time constraints) and the scope of the study. A simple random sampling method was used. Inclusion and exclusion criteria were defined.

A web-based data collection sheet was designed using SurveyMonkey™. The SASA PSA guidelines (4) served as the main reference point for the development of the data collection sheet, which assessed items in the following categories: the professional category of person responsible for administering PSA; modalities of

sedation administered; awareness of the SASA PSA guidelines (4); sedation and resuscitation training of the sedationist; patient selection and assessment; monitoring; recovery area and discharge; emergency equipment and drugs; and complications. The data collection sheet was developed in consultation with three experts in the field.

Participants that consented to participate and indicated using paediatric dental chair PSA during the initial telephone interview were then sent an email link to the data collection sheet. Anonymous data received from completed data collection sheets were uploaded onto a database on the SurveyMonkey™ website for analysis. Descriptive statistics were used, with support sought from a biostatistician.

5.3 Main findings of the study

Of the dental practitioners interviewed, 44.13% (95% CI, 0.37-0.51) provided paediatric dental chair PSA. The dental practitioner was primarily responsible for PSA administration in 45.83% of dental practices, with a medical practitioner with sedation training (31.25%), an anaesthetist (20.83%), or a medical practitioner without sedation training (2.08%) responsible in the remaining practices.

The modalities of sedation administered varied between dental practices. Minimal and moderate sedation (56.25% and 52.08% of dental practices respectively) were more widely used than deep sedation and general anaesthesia (10.42% and 2.08% respectively). Midazolam was the most commonly used sedative agent (used in 68.75% of dental practices), followed by N₂O (39.58%). The latter was the most common sedative agent administered in practices in which the dental practitioner was primarily responsible for PSA provision. More than two-thirds of PSA providers administered a combination of two or more sedative agents. The oral route was the most common route of administration (52.08% of dental practices), followed by the intravenous (45.83%) and inhalational routes (41.67%).

Of the dental practitioners responsible for administering PSA, 45.45% did not have any sedation training. Although 90% of practitioners had attended a BLS course, 90% had not attended APLS or PALS courses, and 80% were not aware of the SASA PSA guidelines (4). However, most PSA providers (81.82%) were interested in attending a CPD-accredited sedation course.

The majority of dental practitioners offered PSA to children in the 1-5 (76.60% of dental practices) and 6-8 year old (74.47%) age groups. Children were usually of ASA physical status 1 (100% of practices) or 2 (35.42%). Two dental practices provided PSA to infants, while one practice provided PSA to ASA 3 and 4 patients. Fasting recommendations varied, with some patients being inadequately starved and others inappropriately starved for 8 hours or longer.

Many facilities did not adhere to recommended safety standards for prevention and management of adverse events. Of the dental practices that provided sedation, 41.30% did not use any form of monitoring equipment, 43.18% did not keep any of the recommended emergency drugs in stock and 19.57% did not have any emergency equipment available. In 41.30% of practices the dental practitioner performing the dental procedure was also responsible for patient monitoring. There were staffed recovery areas to monitor patients prior to discharge in 60.47% of practices.

Reported adverse events during dental chair PSA were rare, with no major adverse event reported in this study.

5.4 Limitations of the study

Results from this study should be examined in light of certain limitations. The study was contextual and its scope was thus limited to a certain patient population. Results

obtained determined the practice standards of dental practitioners in Gauteng and may differ from those in the rest of the country.

Dental practitioners who are members of SADA may reflect a more compliant subset of practitioners. The response rate to emailed surveys and data collection sheets are generally poor, with 55.91% of issued data collection sheets completed and returned in this study. Telephone calls preceding issuing of data collection sheets, anonymity, confidentiality, a short and concise data collection sheet, and reminder emails were methods used to encourage a good response. The response to the email may have been better among the more dedicated dental practitioners who comply with safety regulations and continuously look to improve their practice.

Certain questions in the data collection sheet were omitted by some respondents, with no clear pattern emerging. A possible explanation for some of the omitted questions may be that dental practitioners who were not the primary sedation provider were unaware of the sedation practices of the anaesthetist or medical practitioner. Although anonymity and confidentiality were assured to participants, they may have incorrectly answered certain questions for fear of consequences to their practice.

This study uses the SASA PSA guidelines (4) as a reference point. Although most validated sedation guidelines are similar for the most part, there are minor variations among the various guidelines in terms of recommended safety standards. Dental practitioners were asked about sedation and resuscitation training, but were not asked about the nature or duration of the training received or whether their training was up to date.

5.5 Recommendations from the study

5.5.1 Recommendations for clinical practice

Performing dental procedures in children is often not possible without the aid of PSA, which if provided in dental rooms is cost-effective and avoids the extra expenses generated by having to utilise operating theatres. However, patient safety should not be compromised in any way.

As demonstrated in this study there is an interest among dental practitioners in sedation training. Increased emphasis on such training at undergraduate level and through postgraduate sedation courses can overcome the need to rely on the limited availability of anaesthesiologists.

There is a lack of awareness among PSA providers about the SASA PSA guidelines (4). Increasing awareness about the guidelines may improve adherence to recommended safety standards.

There is a reluctance of medical aid schemes to cover the costs of anaesthetists providing PSA for dental procedures. This contributes to dental practitioners with inadequate PSA and resuscitation training being forced to sedate patients. A review of such policies by medical aid schemes is needed in the interest of patient safety.

5.5.2 Recommendations for further research

Should the above recommendations about sedation training and enhanced awareness about the SASA PSA guidelines (4) be introduced, it is suggested that their impact be followed up.

PSA is a field not confined to dentistry. Comparing the findings of this study to procedures performed under PSA in other disciplines is a scope for further research.

As PSA-related adverse events during dental procedures are rare, a larger study focusing on the incidence of adverse events and contributory causes in a South African setting presents a focus for future research, as well as the impact of sedation training and the SASA PSA guidelines (4) on such events.

5.6 Conclusion

Paediatric dental chair PSA is offered by 44.13% of dental practitioners interviewed in Gauteng. The modalities of PSA provided vary between dental practices, with many facilities not adhering to recommended safety standards. There is an interest in sedation training among dental practitioners.

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APPENDIX 1

PERMISSION FROM POSTGRADUATE COMMITTEE



Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax:
Tel: 027117172040

Reference: Ms Mpumi Mnqapu
E-mail: mpumi.mnqapu@wits.ac.za

12 March 2013
Person No: 0202927A
PAG

Dr F Bham
P O Box 633
Zeerust
2865
South Africa

Dear Dr Bham

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Paediatric dental chair sedation: A Gauteng-based pilot study* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX 2

PERMISSION FROM ETHICS COMMITTEE



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Faizal Bham

CLEARANCE CERTIFICATE

M120735

PROJECT

Dental Chair Sedation: A Gauteng-Based Audit

INVESTIGATORS

Dr Faizal Bham.

DEPARTMENT

Department of Anaesthesiology

DATE CONSIDERED

27/07/2012

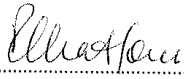
DECISION OF THE COMMITTEE*

Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 27/07/2012

CHAIRPERSON.....


(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Ms Helen Perrie

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES..

APPENDIX 3

DATA COLLECTION SHEET

Paediatric Dental Chair Sedation
1. Introduction
<p>Thank you for taking time to participate in this study. The survey has been designed specifically for dental practitioners performing procedures in children (upto 12 years of age) under sedation in their dental rooms.</p>
1. How many children are sedated in your practice per month?
<p><input type="radio"/> 1-5</p> <p><input type="radio"/> 6-15</p> <p><input type="radio"/> 16-30</p> <p><input type="radio"/> 31-50</p> <p><input type="radio"/> More than 50</p>
2. General information
1. Who is primarily responsible for administering sedation in your rooms?
<p><input type="radio"/> I am</p> <p><input type="radio"/> A qualified nurse</p> <p><input type="radio"/> A medical practitioner</p> <p><input type="radio"/> A medical practitioner with sedation training</p> <p><input type="radio"/> An anaesthetist</p> <p><input type="radio"/> Other</p>
<p>If "Other", please specify:</p> <input type="text"/>
3.
1. Do you have sedation training?
<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>
4. General information
<p>DEFINITIONS:</p> <p>MINIMAL SEDATION/ANXIOLYSIS: Patient responds normally to verbal commands. Cognitive function and coordination may be impaired.</p> <p>MODERATE SEDATION (formerly called conscious sedation): Patient responds purposefully to verbal commands (e.g. "Open your eyes", either alone or accompanied by light touch).</p> <p>DEEP SEDATION: Patient cannot easily be aroused, but may respond purposefully following repeated verbal or</p>

Paediatric Dental Chair Sedation

painful stimulation.

GENERAL ANAESTHESIA: Patients cannot be aroused, even by painful stimulation.

1. How deeply are your patients sedated? (Refer to above definitions. More than 1 answer may apply)

- Minimal sedation
- Moderate sedation
- Deep sedation
- General Anaesthesia

5. Patient selection and assessment

Answer the following with regards to sedation at your rooms...

1. What patient age groups are sedated? (More than 1 answer may apply)

- Age < 1 year
- Age 1-5 years
- Age 6-8 years
- Age 9-12 years

2. Which of the following patient groups are sedated? (More than 1 answer may apply)

- Normal healthy children
- Children with mild systemic disease who have no functional limitation (e.g. a well controlled asthmatic)
- Children with severe systemic disease, which limits activity but is not incapacitating (e.g. an asthmatic needing a bronchodilator)
- Children with severe systemic disease that is functionally incapacitating and a constant threat to life (e.g. congenital heart disease in cardiac failure)

3. Answer YES/NO...

	Yes	No
Are details of a pre-sedation assessment documented?	<input type="radio"/>	<input type="radio"/>
Is written informed consent for sedation obtained from the caregiver?	<input type="radio"/>	<input type="radio"/>

4. How long prior to sedation are children allowed to receive their last meal?

6. Drugs

With regards to sedation at your rooms...

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1. Which of the following drugs are used?

- | | |
|---|---|
| <input type="checkbox"/> Nitrous oxide | <input type="checkbox"/> Clonidine |
| <input type="checkbox"/> Midazolam (Dormicum) | <input type="checkbox"/> Dexmedetomidine |
| <input type="checkbox"/> Diazepam (Valium) | <input type="checkbox"/> Chloral hydrate |
| <input type="checkbox"/> Fentanyl | <input type="checkbox"/> Trimeprazine (Vallergan) |
| <input type="checkbox"/> Alfentanil (Rapifen) | <input type="checkbox"/> Droperidol |
| <input type="checkbox"/> Remifentanyl | <input type="checkbox"/> Paracetamol |
| <input type="checkbox"/> Tilidine (Valaron) | <input type="checkbox"/> Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. ibuprofen, diclofenac, ketorolac) |
| <input type="checkbox"/> Morphine | <input type="checkbox"/> Local anaesthetic agents |
| <input type="checkbox"/> Meperidine (Pethidine) | <input type="checkbox"/> Stopayne™ |
| <input type="checkbox"/> Propofol | <input type="checkbox"/> Myprodol™ |
| <input type="checkbox"/> Ketamine | |

Other (please specify)

2. A combination of how many of the above agents are used during most procedures? (EXCLUDING paracetamol, NSAIDs and local anaesthetics)

3. Which of the following drugs are kept in stock?

- Adrenaline
- Atropine
- Flumazenil
- Naloxone
- Succinylcholine
- None of the above

4. What route(s) of drug administration is used?

- Inhalation
- Oral
- Intramuscular
- Intravenous
- Rectal

Other (please specify)

7. Monitoring

Paediatric Dental Chair Sedation

During sedation in your rooms...

1. Who is responsible for patient monitoring?

- I am
- A nurse
- A medical practitioner
- A medical practitioner with sedation training
- An anaesthetist
- Other (please specify)

2. Which of the following is used?

- | | |
|--|--|
| <input type="checkbox"/> Pulse oximetry | <input type="checkbox"/> ECG |
| <input type="checkbox"/> Non-invasive blood pressure | <input type="checkbox"/> Thermometer |
| <input type="checkbox"/> Capnography | <input type="checkbox"/> Sedation monitoring chart |
| <input type="checkbox"/> Praecordial stethoscope | <input type="checkbox"/> None of the above |

3. How is level of consciousness or depth of sedation monitored? (More than 1 choice may be applicable)

- Bispectral index monitoring
- Using a sedation scale
- Response to commands/touch/pain assessed at regular time intervals
- Response to commands/touch/pain only when there is a concern that the patient is too deeply sedated
- Level of consciousness monitoring is not necessary in my setting

8. Equipment

1. Which of the following equipment is available at your rooms?

- | | |
|--|--|
| <input type="checkbox"/> Face masks | <input type="checkbox"/> Bag-valve ventilation device |
| <input type="checkbox"/> Laryngoscope set | <input type="checkbox"/> Defibrillator |
| <input type="checkbox"/> Endotracheal tubes | <input type="checkbox"/> Intravenous cannulae |
| <input type="checkbox"/> Oropharyngeal or nasopharyngeal airways | <input type="checkbox"/> Intravenous fluids |
| <input type="checkbox"/> End-tidal carbon dioxide monitoring | <input type="checkbox"/> Blood glucose testing machine |
| <input type="checkbox"/> Oxygen supply | <input type="checkbox"/> None of the above |

9. Recovery area and discharge

Paediatric Dental Chair Sedation

1. Are patients monitored in a staffed recovery area prior to discharge?

Yes

No

Other (please specify)

2. Which parameters are assessed during recovery or prior to discharge at your facility?

Level of consciousness

Respiration

Oxygen saturation

Movement

Temperature

Pain

Bleeding

Ability to drink

Nausea/vomiting

Availability of a responsible caregiver

10. Complications

1. Have any paediatric patients experienced any complications related to sedation in your rooms?

Yes

No

11.

1. What complications have they experienced?

Airway obstruction

Apnoea

Oxygen desaturation

Vomiting

Aspiration

Hypotension

Anaphylaxis

Other allergic reaction

Cardiac arrest

Death

Other (please specify)

12. General information

BLS: Basic Life Support

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APLS: Advanced Paediatric Life Support

PALS: Paediatric Advanced Life Support

SOSPOSA: Society of Sedation Practitioners of South Africa

SASA PSA guidelines: Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2010 (developed by the South African Society of Anaesthesiologists)

1. Indicate YES/NO (Refer to above definitions if necessary)...

	Yes	No
Have you attended a BLS course?	<input type="radio"/>	<input type="radio"/>
Have you attended an APLS or PALS course?	<input type="radio"/>	<input type="radio"/>
Are you a member of SOSPOSA?	<input type="radio"/>	<input type="radio"/>
Are you aware of the SASA PSA guidelines?	<input type="radio"/>	<input type="radio"/>

2. If you make use of any other sedation guidelines, kindly indicate which guidelines you follow...

13. Lastly...

1. What is your age (years)?

Age

2. What is your gender?

Female

Male

3. Are you interested in attending a CPD-accredited sedation course?

Yes

No

4. Any other comment:

APPENDIX 4

PARTICIPATION INFORMATION LETTER

Dear Colleague

My name is Faizal Bham. I am a registrar in the Department of Anaesthesiology at the Charlotte Maxeke Johannesburg Academic Hospital and registered for a Master of Medicine (Anaesthesiology) degree at the Faculty of Health Sciences, University of the Witwatersrand. As part of the course requirement, I am expected to conduct research under supervision.

I would like to invite you to participate in my research study, which is being conducted in the field of paediatric dental chair sedation. I intend determining the proportion of Gauteng-based dental practitioners making use of sedation in children and describing current practice. The study involves completing a short web-based survey, which should take no longer than 5 minutes to complete.

The study has been approved by the Human Research Ethics Committee (Medical) (HREC) (clearance certificate number M120735) and Postgraduate Committee of the University of the Witwatersrand. Your participation is voluntary and you may close the survey at any stage should you wish not to complete or submit it. All responses will be uploaded anonymously to an electronic database hosted by SurveyMonkey™. Information you provide can therefore not be traced back to you and published results will have no identifying data. Your contact number was obtained from the list of members and contact numbers available to the public on the South African Dental Association (SADA) website. SADA are, however, not involved with this research in any way.

Published results will be made available to all participants. The study may lead to positive changes in the field of paediatric procedural sedation and analgesia. A CPD-accredited sedation course, organised by the Department of Anaesthesiology, University of the Witwatersrand, will be offered to participants on completion of the study.

To participate, kindly click on the link to the survey at the end of this email. This will imply consent to participate.

Any queries may be directed to me on 082 768 3831 or the Chairman of the HREC, Professor Cleaton-Jones on 011 717 1234.

Thank you for taking time to read this email. Your participation in the survey will be much appreciated.

Yours sincerely

Dr F Bham

CLICK on the following link to complete the survey: [LINK]

APPENDIX 5

RANDOMISATION OF SAMPLING FRAME

Random	Order	Random	Order	Random	Order	Random	Order
266	1	48823	51	91109	101	123214	151
1531	2	49836	52	91632	102	123367	152
2628	3	50132	53	92638	103	125621	153
3343	4	51680	54	92679	104	126127	154
3833	5	51790	55	93589	105	126842	155
4639	6	52470	56	93797	106	128028	156
5542	7	53007	57	94866	107	128544	157
6257	8	53183	58	95318	108	129568	158
6557	9	53777	59	96217	109	130224	159
8804	10	54533	60	96399	110	130419	160
10259	11	54693	61	97109	111	131345	161
10850	12	55154	62	97786	112	131677	162
11473	13	55251	63	98958	113	132682	163
12194	14	56990	64	99820	114	133463	164
12844	15	58434	65	99860	115	134006	165
13775	16	58989	66	99950	116	134816	166
15130	17	59217	67	101438	117	135328	167
15749	18	59388	68	101889	118	137653	168
16121	19	59588	69	102176	119	138405	169
17712	20	59823	70	102328	120	138741	170
18471	21	60785	71	103721	121	139376	171
20284	22	60834	72	104016	122	140229	172
20720	23	64539	73	104916	123	142313	173
21051	24	64715	74	104967	124	142896	174
21873	25	65934	75	107808	125	143032	175
22645	26	65988	76	109766	126	144541	176
22990	27	66706	77	110809	127	145137	177
24011	28	67723	78	111671	128	145195	178
25250	29	68198	79	112441	129	146400	179
25475	30	68703	80	112556	130	147161	180
25481	31	68872	81	112584	131	147757	181
25747	32	69822	82	113503	132	147773	182
27606	33	70868	83	113740	133	150374	183
28560	34	71112	84	113920	134	150384	184
31031	35	71562	85	113984	135	151330	185
31775	36	72839	86	114570	136	151407	186
32631	37	76030	87	114893	137	151792	187
34692	38	78216	88	115582	138	152425	188
35088	39	80577	89	115763	139	155588	189
37498	40	81703	90	117109	140	156330	190
40078	41	83440	91	117197	141	156513	191
41127	42	83810	92	117864	142	157699	192
41616	43	84322	93	118306	143	157730	193
42330	44	84402	94	119693	144	157880	194
44252	45	85572	95	120425	145	158071	195
44610	46	86073	96	120618	146	160092	196
45314	47	87099	97	120940	147	160138	197
45883	48	87920	98	121098	148	160900	198
48669	49	88617	99	122580	149	161117	199
48670	50	89989	100	122857	150	162967	200

The 1152 members of the sampling frame were randomly allocated numbers from one to one million. The random numbers were then arranged from smallest to largest, with the first 200 being selected as the study sample.

APPENDIX 6
REMINDER EMAIL

Dear Colleague

This is a follow-up email to the one sent two weeks ago requesting your participation in a study in the field of paediatric dental chair sedation. The value of the study, which is a requirement in my training in the field of anaesthesiology, will be enhanced by a good response from prospective participants.

As all responses are received anonymously, there is no way to ascertain which individuals have not yet completed the survey. If you have not yet responded, kindly take the time to do so by following the link at the bottom of the page. The survey should take no longer than 5 minutes to complete. I would like to reiterate that all responses are uploaded anonymously to an electronic database and published results will have no identifying data.

If you have already completed the survey, kindly ignore the link at the bottom of the page. I would like to thank you for taking the time to participate. Your contribution to my training and to the field of paediatric sedation is much appreciated.

Thank you for reading this email. You will not be inconvenienced with any further reminders.

Yours sincerely

Faizal Bham

082 768 3831

If you consent to participate, click on the following link: [LINK]