

**A CROSS SECTIONAL STUDY OF PROCEDURAL  
SEDATION IN ADULTS IN EMERGENCY  
DEPARTMENTS WITH FULL TIME CLINICIANS IN  
THE CAPE TOWN METROPOLE**

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Thesis presented in partial fulfillment of the degree of  
Master of Philosophy in Emergency Medicine

University of Cape Town

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**Declaration**

**A CROSS SECTIONAL STUDY OF PROCEDURAL SEDATION IN ADULTS IN  
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METROPOLE**

I, Peter William Hodkinson, hereby declare that the work on which this thesis is based is my original work unless stated otherwise, and that neither the substance, or any part of this work, has been or is being submitted for another degree at this or any other university.

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Signed .....

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## Abstract

Cape Town's emergency departments are overcrowded, understaffed and generally poorly equipped to deal with the patient numbers presenting. Many minor procedures may be carried out in less than ideal circumstances with no formal protocols in place laying out guidelines for safe practice.

The aims of this study were to describe procedural sedation practice in EDs, with specific emphasis on facilities for PS, characteristics of clinicians performing PS, monitoring equipment and personnel, drug regimes, complications and clinician satisfaction with present PS practice. A second aim was to propose evidence-based protocols for the use of PS for those EDs where current practices are found to be outdated and not evidence based.

This is a cross sectional descriptive study of procedural sedation in adults in emergency departments in the Cape Town Metropole. For each ED included in the study, the unit manager and all full time medical personnel currently working in the ED's who primarily practice emergency medicine were interviewed. Practitioners or units where there were no full time (minimum 40 hours a week) personnel in the ED were excluded.

13 units (5 public and 8 private sector) were included within the study criteria. 76 clinicians (just over a third from the private sector) were interviewed. The results showed that the private sector has facilities and staffing that are equivalent to international EDs, although there is widespread variation in PS practice with no consensus and some suboptimal regimes in use. The public sector has many inexperienced junior clinicians, as well as a complement of emergency medicine registrars with greater knowledge and experience. Facilities are generally poor with limited equipment, no dedicated area for PS, and a dire shortage of qualified nursing staff for assistance with PS.

Drug choice for PS was largely limited to midazolam and propofol in the study, with up to a quarter of clinicians (and significantly the more senior and experienced) using propofol commonly (although almost half of clinicians were aware of propofol use in PS and would

request it to be used on themselves). The major complications experienced were hypotension, hypoxaemia, and nausea and vomiting, with few serious complications requiring intervention, and no link found between drugs used and complications. Satisfaction with all aspects of PS was rated as largely positive, again with no significant difference between drug groups, although use of propofol was likely not enough to show significance.

Specific problems mentioned with PS include inadequate staffing (largely nursing), lack of equipment (public sector units) and lack of protocols and training for PS.

The recommendations of the study are to implement universal protocols for PS in the ED and specific training in PS at both undergraduate and postgraduate level. Further studies would then be indicated to assess the implementation of these programs, and to better quantify PS practice as the major limitation of this study is the anecdotal nature of the data due to the lack of records of PS in the ED.

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## Abbreviations

ASA	American Society of Anesthesiologists'
BP	blood pressure
CONS	consultant
COSMO	community service medical officer
DOA	duration of action
ECG	electrocardiogram
ED	emergency department
EM REG	emergency medicine registrar
EN	enrolled nurse
ICU	intensive care unit
MO	medical officer
NA	nursing assistant
NIBP	non invasive blood pressure
PS	procedural sedation
RN	registered nurse
SD	standard deviation

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# Chapter 1 INTRODUCTION

## **1.1 Problem**

Cape Town's emergency departments (EDs) are overcrowded, understaffed and generally poorly equipped to deal with the patient numbers presenting. Many minor procedures may be carried out in less than ideal circumstances with no formal protocols in place laying out guidelines for safe practice. Commonly performed procedures requiring ED sedation in adults are reduction of dislocations (shoulder and elbow largely) and reduction of closed fractures (commonly Colle's fractures and lower leg fractures). Suboptimal performance of procedural sedation (PS), could result in inadequate sedation with consequent difficulty in performing the procedures (excess muscle tone), poor patient experience (masked in many cases only by the amnestic properties of midazolam) and long delays in awakening of the patient with consequent prolonged medical and nursing time or more often inadequate monitoring until the patient is fully conscious (Burton et al 2006).

## **1.2 Rationale and Justification for Research**

There is a current surge of interest in the international literature of interest and studies on procedural sedation in the ED. PS is now well established worldwide as a rapid turnaround, emergency physician-led service, with many protocols on how, where and who may administer PS with what drug (Bahn & Holt 2005). The literature focus is on the newer and more effective drugs that are available, largely developed for use by anaesthetists in the rapidly evolving field of outpatient anaesthesia with their goals of a rapid and clear-headed awakening from a general anaesthetic (Green & Krauss 2003, Miner et al 2003).

Many drugs are moving from the domain of the anaesthetist in theatre to wider use, particularly in the ED with increasing skills of emergency practitioners in dealing with procedures in the ED and in managing airway problems and other potential complications of "deep" sedation.

South Africa has lagged in this regard, largely due to the ED still being the domain of the generalist and often manned by the most junior doctors in the hospital, with little input from international emergency medicine trends, or modern anaesthesia. This is now changing with the new speciality of emergency medicine (Balfour 2006) which provides appropriate high-level skills training for doctors, including dedicated time in anaesthetics.

Specialist led dedicated EDs will soon be the standard of care in South African Hospitals. As yet there are no studies on ED PS practice, and no evidence based or shared protocols in place in South Africa.

### **1.3 Aims and objectives**

#### **1.3.1 Aim**

To describe current PS practice in adults in hospital EDs in Cape Town. The study will focus on a description of procedural sedation facilities, protocols, procedures and complications, as well as the drugs used for procedural sedation. Only EDs that employ doctors who work full time practising primarily emergency medicine will be described.

#### **1.3.2 Objectives**

The objectives of this study are to:

(i) Describe PS practices in adults in EDs of hospitals (public and private) in the Cape Town metropole in 2007 in terms of:

- Number of hospitals performing ED PS
- Number of times PS is performed per ED per unit time
- Details of protocols, facilities, equipment, personnel, drugs available, back up facilities (theatre, ICU) and costs involved.

- Current practices and perceptions of clinical medical officers who perform PS about its efficacy.
- Use of propofol for ED PS

(ii) Document stated reasons for PS practices

(iii) Propose evidence-based protocols for the use of PS for those EDs where current practices are found to be outdated and not evidence based. .

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## Chapter 2 LITERATURE REVIEW

A Medline search using the Ovid interface was carried out for the period 1996-6/2007 for English language references using the search terms "procedural sedation", "emergency procedural", "emergency sedation", "propofol" in various combinations after which appropriate references were hand selected. The Emergency Medicine Journal, Annals of Emergency Medicine and Academic Emergency Medicine journals were also hand-searched for the period January 2006 – June 2007.

### 2.1 Definition of Procedural Sedation

Procedural Sedation is the technique of using drugs to induce a state where a patient will tolerate noxious stimuli, while maintaining his/ her own cardio-respiratory function without invasive support and monitoring (Godwin *et al*, 2005). Procedures commonly performed in the ED include reduction of dislocations (shoulder, hip, elbow, jaw commonly), reduction of fractures, and cardioversion, as well as suturing and certain diagnostic procedures in paediatric patients (Sacchetti *et al*, 2007).

The aims of PS are to alleviate anxiety, minimize pain and discomfort, maximize analgesia, expedite the procedure, minimize the negative psychological impact of the procedure and to maintain patient safety throughout (Bahn & Holt, 2005).

PS has been shown to be safe and effective and improves patient care in that it provides rapid access to procedures, many of which would previously have been performed in theatre with consequent delays, expense and demand on personnel (or perhaps in the local setting more commonly performed in a haphazard fashion with little analgesia, much pain, and some force in the front room). Large studies have shown that the side effects and complications of PS performed in the ED are minimal and can be safely managed by emergency medicine personnel (Burton *et al*, 2006). Less than 4% of patients experience any sort of complication and the complications rarely have any direct long term effect on the patient's disposition (Miller *et al*, 2005).

There is a continuum of sedation which has traditionally been classified (Chudnofsky & Lozon, 2006):

- Minimal sedation – anxiolysis only – patient responds normally to verbal commands.
- Moderate/ conscious sedation – patient responds purposefully to commands
- Deep Sedation – patient cannot be easily aroused but responds purposefully to repeated painful stimuli. May require assistance in maintaining airway and spontaneous ventilation.
- Very Deep Sedation/ General Anaesthesia- patient not rousable with impaired cardio-respiratory function requiring support.
- Dissociative Sedation- cataleptic state induced with ketamine where the perception to stimuli is altered but patients generally maintain airway reflexes and cardio-respiratory function.

PS generally aims at a level on this continuum somewhere between moderate and deep sedation, although some procedures will be expedited with transient sedation at a “very” deep level (for example reduction of a dislocated hip where there the muscle tone needs to be relaxed before reduction). The boundary between deep sedation and general anaesthesia has been upheld particularly in the United States as a critical one – emergency physicians are in many hospitals are “credentialed” to perform moderate and deep sedation, but their general anaesthesia “privileges” are limited to rapid sequence intubation. Whether this is semantics or a real clinical issue which effects patient outcome is uncertain. (Green & Krauss 2003).

Paediatric PS has evolved ahead of adult PS due to the many procedures on children which require PS for example suturing and diagnostic procedures such as lumbar puncture and radiological procedures/ imaging, where an adult would tolerate the procedure with counselling and/or local anaesthesia (Guenther *et al*, 2003). Although children are at higher risk for respiratory depression and hypoxaemia, large scale studies such as the Pediatric Sedation Consortium (Cravero *et al*, 2006) have shown that PS can be safe and effective in the ED if appropriately and correctly performed (Pershad & Godambe, 2004).

## **2.2 Facilities, skills and equipment required for Procedural Sedation**

### **2.2.1 Emergency Department**

The ED is defined as a specialized hospital department providing initial care for patients with emergencies, under the management of an Emergency Medicine Specialist who has core competency and experience in the recognition and management of life threatening events.

There is widespread international use of PS in the developed world, such that it is considered a core competency for Emergency Physicians in the US, UK and Australasia (Bahn & Holt, 2005). It is a rapidly evolving field with vast recent literature defining this new field. Guidelines have been developed in many countries, which prescribe the patient selection for PS in the ED, equipment, monitoring and personnel for PS as well as drug regimes to be used (Godwin *et al*, 2005).

### **2.2.2 Equipment**

Safe PS practice requires a separate area away from the main ED (generally a resuscitation area or ED theatre), equipped with resuscitation equipment and monitors.

Mandatory equipment to have available in the room with the patient undergoing PS is oxygen, suction for vomiting/ aspiration, equipment to intubate the patient if necessary (laryngoscopes, endotracheal tubes and standard associated ancillary equipment), a means of ventilating the patient, usually a bag-valve-mask apparatus, and advanced life support resuscitation equipment as contained in any ED resuscitation area/ trolley (including a defibrillator, emergency drugs, intravenous access equipment).

The equipment should be adequate to manage any expected complication of the sedation and procedure including airway management, anaphylaxis, drug overdoses, and respiratory and cardiac arrest (Miller *et al*, 2005).

### 2.2.3 Monitoring

Fundamental monitors for PS are a non-invasive blood pressure monitor (blood pressure needs to be taken at least before, during and after the procedure) and pulse oximetry to detect hypoxaemia. Monitoring and documentation of blood pressure, respiratory rate, heart rate and pulse oximetry are mandatory. Cardiac monitoring with an ECG has not been shown to be necessary except in patients predisposed to dysrhythmias (Chudnofsky & Lozon, 2006).

Other monitoring that may be considered is capnography. End tidal carbon dioxide monitoring will allow early and accurate assessment of ventilatory adequacy. There is however no evidence that this gives earlier detection than pulse oximetry and clinical acumen alone (Green, 2007; Walker, 2004). Some recent literature suggests that capnography is important to monitor for early respiratory compromise, especially in the presence of supplemental oxygen which may diminish the value of pulse oximetry in detecting hypoxaemia (Mayerle et al 2007). Interpretation of capnography is not a routine ED skill, and further training and understanding of this monitor is required for most practitioners without anaesthetic training (Baruch & Hess 2007). The bispectral Index is an anaesthetic monitor which is designed to give an objective measure of degree of sedation. A small study has shown no real practical use at present in ED PS (Miner *et al*, 2005 (b)).

### 2.2.4 Training and skills

Controversy exists as to a safe level of sedation to be performed in the ED by an emergency medicine specialist. Some believe that sedation should remain the domain of the anaesthetist in a theatre. Recent literature has proposed that this may be semantics and politics to some extent as the ED has the equipment and skills to deal with transient intentional or unintentional deeper sedation, verging on general anaesthesia. ED practitioners routinely perform rapid sequence intubations using anaesthetic drugs and equipment (Green, 2007; Duncan *et al*, 2006).

## **2.3 Drugs for Procedural Sedation**

Drugs which have been studied for use in PS can be summarized by class:

### **2.3.1 Benzodiazepines**

Midazolam is the prototype short-acting sedative with amnestic and anxiolytic effects. It offers no analgesia and is commonly combined with an opiate. Midazolam has a fairly rapid onset of less than five minutes and duration of action (DOA) of less than 15 minutes. Adverse effects are minimal but high and cumulative doses will cause hypoventilation and hypoxaemia, and hypotension (Bahn & Holt, 2005).

### **2.3.2 Opiates**

Opiates offer analgesia but minimal sedation in usual doses. They are usually combined with a sedative, and this combination will allow lower doses of the sedative agent when properly timed. They are used particularly for procedures where pain is expected to remain after PS. In procedures such as reduction of a dislocation where pain is resolved following PS, analgesia is not so important during and after PS. The short acting opiates such as fentanyl, or better still ultra short acting such as alfentanil are ideal with rapid onset and short duration, but are as yet little utilized in the ED. Morphine is the standard analgesic used in the ED and seems to be used for PS, despite its slow onset (at least five minutes) and duration of more than four hours. The opiates all cause a dose-related hypoventilation and hypotension (Chudnofsky & Lozon, 2006, Miner et al 2007(b)).

### **2.3.3 Etomidate**

Etomidate is a sedative hypnotic agent commonly used for rapid sequence induction due to its rapid onset, short duration of action and minimal cardio-respiratory side effects. The advantage is that ED personnel are generally familiar with the drug and its effects, but

concern is being raised over adrenal suppression from the drug which may limit its use in future. There is also a high incidence of nausea and vomiting. (Chudnofsky & Lozon, 2006).

#### **2.3.4 Propofol**

Propofol is a sedative hypnotic agent widely used in anaesthesia. It has the advantages of extremely rapid onset (seconds) and offset (by rapid redistribution independent of renal and hepatic function), as well as anti-emetic and euphoric effects. Concern is that propofol has a narrow therapeutic index and consequent difficulty in predetermining the target depth of sedation (Miner et al 2007 (a)), and that it is easy to over-sedate a patient with consequent general anaesthesia requiring appropriate support. Initial concerns over this and the side effects of hypotension and hypoventilation prevented non anaesthetic use of propofol, but since 2004 there have been an increasing number of studies showing propofol to be a safe and ideal drug for PS. It is now in widespread use internationally with evidence of favourable safety profiles, and high clinician satisfaction. Patient satisfaction - awareness and recall after PS is minimal and provide excellent conditions for PS as shown by several studies. (Basset *et al*, 2003; Green & Krause, 2004; Frazee *et al*, 2005; Miner et al 2005 (a), Symington & Thakore, 2006, Swann et al 2007).

#### **2.3.5 Methohexital**

A popularly used barbiturate in the US, methohexital has an onset of less than one minute and duration of action less than ten minutes. It allows preservation of airway reflexes, but no analgesic effect. Dose-related hypotension is the major side effect. Studies comparing methohexital to propofol showed comparable profiles for PS (Miner *et al*, 2003).

Methohexital is not available in South Africa, and the commonly used barbiturate, thiopental, is not considered appropriate for PS because of its long DOA.

### **2.3.6 Ketamine**

Ketamine is a dissociative analgesia agent which prevents perception of painful stimuli, but muscle tone and thus airway reflexes and ventilation are maintained. It is commonly used in paediatric practice, but not widely advocated for adult PS because of emergence phenomena and hypertension (Howes, 2004). Recent interest has been shown in low dose ketamine (probably largely analgesic doses of less than 0.5mg/kg) used in combination with other sedatives such as propofol or midazolam which some reporters show allows lower sedative dosing with analgesia, and a rapid, complication free experience, although a review of 11 trials (Loh & Dalen 2007) showed no benefit over propofol alone. (Personal Communication Prof J.Roelofse, Messenger et al 2007). The British Association for Emergency Medicine (2004) has also compiled an excellent guideline (with a detailed step by step protocol) for ketamine sedation, mainly applicable to the paediatric population, but also with application to adults.

### **2.3.7 Nitrous Oxide**

Nitrous oxide is an anaesthetic gas with analgesic, sedative and anxiolytic effects. The main drawbacks are difficulty in administration to facilitate scavenging the gas – so as to avoid personnel being affected - high abuse of the drug, and limited depth of analgesia and sedation in the 50% mixture with oxygen used (Chudnofsky & Lozon, 2006). Of particular note in South African practice is that the 50% mixture exhibits minimal useful analgesia at altitudes above 1800 metres (e.g. Johannesburg) as the reduction in partial pressure renders it almost ineffective (James et al 1982). It is never the less a useful drug to consider for very short and easily performed procedures (for example reduction of a phalangeal dislocation (Personal Communication Dr M.Morris)).

## **2.4 Procedural Sedation practice**

The patient is assessed before the procedure in terms of a brief history and general examination, looking for co-morbidity, airway risk factors and mental state. Consideration must be given to the last oral intake of the patient- whether solid or liquid and the time interval since intake. Anaesthesia regimes (which are not entirely evidence-based) specify time periods of fasting before elective procedures, but these may not be applicable to emergency procedures that by their nature are urgent. The risk of significant aspiration from PS may not be comparable to general anaesthesia with airway manipulation, but the risk of aspiration needs to be weighed against the benefits of performing the procedure immediately. The literature documents only a single case of PS-related aspiration, and it can be attributed largely to the multiple drug and dosing regime used. (Green *et al*, 2007; Cheung *et al*, 2007).

A recent United States clinical practice advisory committee consensus of experts in the PS field has published a clinical practice advisory (Green *et al* 2007) where they classify procedures according to their urgency and the estimated risk of aspiration (which they associated largely to the depth of sedation and length of the procedure). They have emphasized a three hour fasting time threshold for a full meal to sedation time as opposed to the traditional anaesthetic fasting time of six hours. This is dependant on the procedural urgency – an emergent procedure (where delay is life threatening or associated with compromise of the limb/ intractable suffering) may be performed regardless of fasting time when the risk/ benefit ratio is appropriately assessed.

If the patient is considered eligible for PS, after explanation of the procedure and consent, intravenous access is obtained, and the patient is attached to the monitors. Supplemental oxygen should be considered if there is any pre-existing risk for hypoxaemia, but there is no evidence to make it mandatory. Some experts suggests that supplemental oxygen merely delays the oxygen desaturation of a patient who is hypoventilating and thus the monitor's warning alarm and response are belated (except for capnography which is

perhaps more important with the use of supplemental oxygen) (Dietch *et al*, 2007; Green, 2007).

A drug or combination of drugs is then administered by the doctor (who may be the same person performing the procedure or there may be a second doctor present, depending on the procedure, patient and expertise of the other non medical personnel; as long as there is a competent and adequately trained person solely responsible for monitoring the patient during the procedure.) (Hogan *et al*, 2006). When the patient is judged to be sufficiently sedated (either subjectively or by the use of a sedation scale) the procedure is performed. If the procedure is prolonged, or the patient is not sufficiently sedated, additional dose(s) of the drug(s) may be necessary.

At the completion of the procedure, with the correct drug and dose regime, the patient should ideally wake rapidly and be ready to leave the ED with in a short time. Individual monitoring must continue until the patient is rousable and maintaining his/her own airway and ventilation satisfactorily – the highest risk period for adverse event is after the procedure. Once fully orientated and co-ordinated the patient can be discharged home where appropriate. Efforts should be made to send the patient home with a responsible adult, and they should not drive or participate in dangerous activities for 24 hours. (Chudnofsky & Lozon 2006)

## **2.5 South African Practice**

There is currently no published literature on PS in the ED in South Africa. There has been considerable interest and debate on the use of conscious sedation by non anaesthetists, but this is generally used for elective procedures such as dentistry and endoscopy (Pinkney-Atkinson, 1997).

A recently published South African article (Steffanutto & Ruttmann 2006) written by anaesthetists, attempts to clarify the differences in levels of sedation, required qualifications and numbers of doctors and monitoring. Their rationale is that moderate sedation (referred to as "conscious sedation") can be administered by "an array of personnel such as nurses,

surgeons and paramedic assistants”, while deep sedation (referred to as “Monitored Anaesthetic Care”) is an “anaesthetic-led service requiring the presence of an independent second physician”. They state that the use of non-anaesthetic staff can lead to “grave cost in patient outcome”. On the minimum monitoring required, they suggest for moderate sedation blood pressure and pulse oximetry, and for deep sedation capnography in addition to supplemental oxygen. The authors have used largely anaesthetic sources for their article, and seem not to be aware of any emergency medicine literature (or perhaps the evolving speciality) which has covered the issues in far more detail recently. Although it is wise to caution practitioners of the implications, dangers and requirements of sedation, the article does not take into account the skills and knowledge in the modern ED, where deep sedation is practised by single practitioners daily (and without capnography in most cases) with an extremely low mortality and morbidity according to the international literature. (Hogan et al 2007, Duncan et al 2007)

While some of the EDs in urban academic hospitals in the Cape Town metropole are headed by specialists and staffed by specialists in training, more peripheral and smaller units may be run and staffed by very junior medical officers, with little or no training in procedural sedation. They may learn from colleagues or extrapolate their brief anaesthetic and ED exposures as undergraduates/ interns to develop their own PS practises.

Few units appear to have any written protocol for ED PS, and there seems to be scant regard for patient selection (particularly fasting criteria), monitoring or discharge criteria. There is as yet no formal training at any level in sedation practice.

## **Chapter 3 METHODS**

### **3.1 Study design**

This design was a cross-sectional descriptive study of procedural sedation in EDs. Approval for the study was obtained from the Department of Surgery Research Committee (DRC No. 2006/49) and the Ethics Committee at the University of Cape Town (REC REF 025/2007). Verbal consent was obtained from ED managers at each institution, prior to interviewing clinicians.

### **3.2 Study Setting and Population**

A list of all hospitals in the Cape Town Metropole with EDs operating 24 hours a day was compiled through verbal consultation with management staff of provincial Emergency Medical Services and with private sector hospitals. Each ED manager was approached personally or telephonically to establish whether they met the inclusion criteria. The study questionnaires were administered between April and June 2007.

### **3.3 Inclusion Criteria**

EDs were included in the study when they had a 24 hour/ 7 day a week department staffed by full time medical practitioners, treated adult patients, and were geographically within the Cape Town Metropolitan area (Appendix A). All EDs included in the study saw trauma patients routinely, as most PS is performed on traumatic injuries, other than some spontaneous dislocations (which would be managed in most trauma units), and cardioversion.

For each ED included in the study, the unit manager and all full time medical personnel currently working in the ED's who primarily practice emergency medicine were interviewed.

Practitioners or units where there were no full time (minimum 40 hours a week) personnel in the ED were excluded.

Practitioners who had not performed one or more PS in an adult in the previous three months were excluded.

### **3.4 Data Collection**

Data were collected from 2 sources, firstly ED Unit Managers, and secondly ED clinicians. In some, but not all, cases the ED managers were also active clinicians in the ED, in which case they underwent both interviews.

#### **3.4.1 ED Manager Data**

An appointment with each ED unit manager was made and each was personally interviewed at their ED. After a brief introduction and explanation of the study aims and objectives, verbal consent was obtained, and then a standard questionnaire (Appendix B) was administered by the investigator (PWH). All questionnaires were filled in by the investigator and questions were clarified where necessary during the interview.

Information collected included: size of unit, number of PS performed and type of PS (procedure, age group), venue for PS, resuscitation facilities and equipment available, monitoring equipment, personnel – nursing and medical staff numbers and expertise, protocols for PS in place, drugs available for PS, recovery area (monitoring, personnel, duration recovery), complications of PS, back up facilities (specialists/ ICU/theatre), perceived shortcomings of present PS practice, and knowledge and awareness of other drugs (specifically propofol) and international trends in PS.

An information sheet (Appendix C) was circulated to each ED at the time of the initial interview with the ED Manager to inform ED clinicians about the study. A list of eligible clinicians for each unit and their contact details was obtained from the ED manager.

### **3.4.2 ED Clinician Data**

A standard questionnaire (Appendix D) was administered to each eligible clinician either in person in the unit, or telephonically if the interviewee was not in the ED at the time of the initial or subsequent visits. All doctors were informed as to the purpose of the study and gave verbal informed consent. All interviews were conducted verbally by the investigator who personally filled in the questionnaire sheet, and clarified any misunderstanding of the questionnaires. Leading information was avoided other than the general aims and objectives of the study.

The information requested here included: work experience (years since basic medical qualification, years in ED, experience in anaesthetics or other international EDs), protocols used, usual drug regimes, number of personnel involved in PS, monitoring, time to recovery/ discharge, side effects and complications experienced, satisfaction with present practice (from doctors perspective- time to effect/ awakening, ease of administration, depth of sedation, ease of procedure, side effects and perceived patient satisfaction with PS). Clinicians were then asked which sedation agent they would choose to have used on themselves in a hypothetical scenario of having their own dislocated shoulder reduced (provided optimal skills and monitoring were available). Lastly clinicians were specifically asked about their knowledge and experience of use of propofol in ED PS and their opinion of its use.

Attempts were made to interview all full time clinicians: one and often several site visits to the EDs were made at different times, and clinicians who were not contacted initially were telephoned on at least three separate occasions with careful reference to their work rosters so that they were not telephoned while at work or after working through the night.

### **3.5 Data Management**

Hospitals were allocated an alphanumeric code and individuals identified by number only as they were interviewed in each institution. Individuals remained anonymous but were linked to their institution by the alphanumeric code for analysis. A code for identifying public and private facilities was also allocated to each ED. Individual hospitals were not identified and the hospital coding data were stored in a password protected work computer and accessed only by the investigator.

### **3.6 Data analysis**

Statistical analysis of the data were performed using standard statistical methods and with Intercooled STATA 8.0 software (Statacorp LP, College Station, TX, USA).

Univariate analysis of descriptive data were performed. For numeric data, the mean, standard deviation and range were performed. For categorized data, the proportion of EDs meeting each test criteria was calculated. A sub-group analysis of public and private facilities was also performed.

Bivariate analysis was performed to investigate whether an association exists between choice of drug for PS and a number of independent variables, including years of experience of clinicians, anaesthetics experience, ED experience, and public or private facility.

For bivariate analysis some of the data were grouped. Clinicians' responses on the use of drugs were divided into 3 groups based on midazolam and propofol use (all clinicians used one of these 2 agents):

- 1) midazolam but not propofol
- 2) propofol but not midazolam
- 3) midazolam and propofol

Clinicians in each group could also report use of other drugs in addition to propofol and midazolam.

Years of experience was grouped into those with less than 5 years and 5 years or longer experience post MBBCh or equivalent qualification. Similarly ED experience was grouped into less than 3 years and 3 years and greater experience.

For reporting on side effects, "rare" or "never" were grouped together (no side effects), and "occasional" and "frequent" were grouped together (side effects). For reported satisfaction with various aspects of PS practice, "very poor" and "poor" were grouped together as "not satisfied" and "fair", "good", and "very good" were grouped as "satisfied".

A Chi-squared test was performed to determine whether statistically significant association existed between the independent (categorical) variables. A p-value of less than 0.05 was considered statistically significant.

Analysis of variance (ANOVA) test was performed to determine whether an association existed between estimated recovery time (numerical variable) and the choice of drug.

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## Chapter 4 RESULTS

An initial list of hospitals in the metropole with a 24 hour ED was compiled (Appendix E). It consisted of 23 hospitals, 44% (10/23) public and 56% (13/23) private. The final study selection (Appendix F) included 13 units of which 5 were public (50% (5/10) of total public hospitals) and 8 were private (62% (8/13) of total private hospitals). Reasons for non-inclusion were largely EDs employing only part time practitioners (7 EDs: 5 private and 2 public), units which did not see trauma (2 public hospitals) and a unit which saw only paediatric patients.

### 4.1 ED Manager Data

A total of 13 EDs were included in the study. Table 1 gives the numbers of patients seen per unit, estimated number of procedural sedations performed, as well as staffing data.

**Table 1. Personnel and patient numbers in emergency departments**

	Public (n= 5)	Private (n= 8)	Total (n= 13 )
Number of patient visits per month, mean (SD, range)	2898.0 (1623.4; 1000 – 5000)	1693.8 (546.7; 950 – 2500)	2156.9 (1193.6; 950 – 5000)
Number of PS per month, mean (SD, range)	44.0 (20.7; 20 – 70)	41.1 (35.4; 10 – 120)	42.2 (29.60; 10 – 120)
Number of full time nursing staff per ED, mean (SD, range)	7.5 (2.7; 5 – 12)	4.0 (1.1; 2 – 5)	5.4 (2.5; 2 – 12)
Number of patient visits per RN per month, mean (SD, range)	1084.3 (653.6; 333 – 1775)	858.3 (210.1; 600 – 1250)	945.3 (425.7; 333 – 1775)
Number of full time doctors per ED, mean (SD, range)	11.2 (2.8; 9 – 16)	4.1 (2.4; 1 – 9)	6.9 (4.3; 1 – 16)
Number of patient visits per doctor per month, mean (SD, range) *	248.1 (107.0; 111 – 340)	494.4 (213.6; 256 – 950)	399.7 (214.5; 111 – 950)

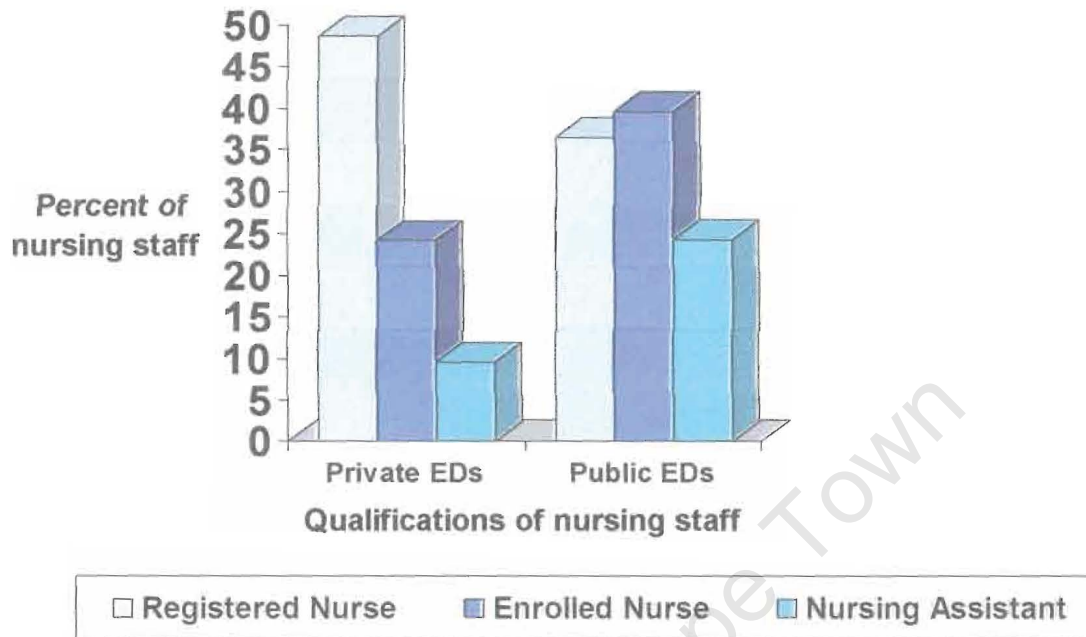
SD, standard deviation

(\* derived by calculating number of patient visits per doctor for each institution and then averaging these to give an overall figure for number of patient visits per doctor per month)

#### 4.1.1 Personnel

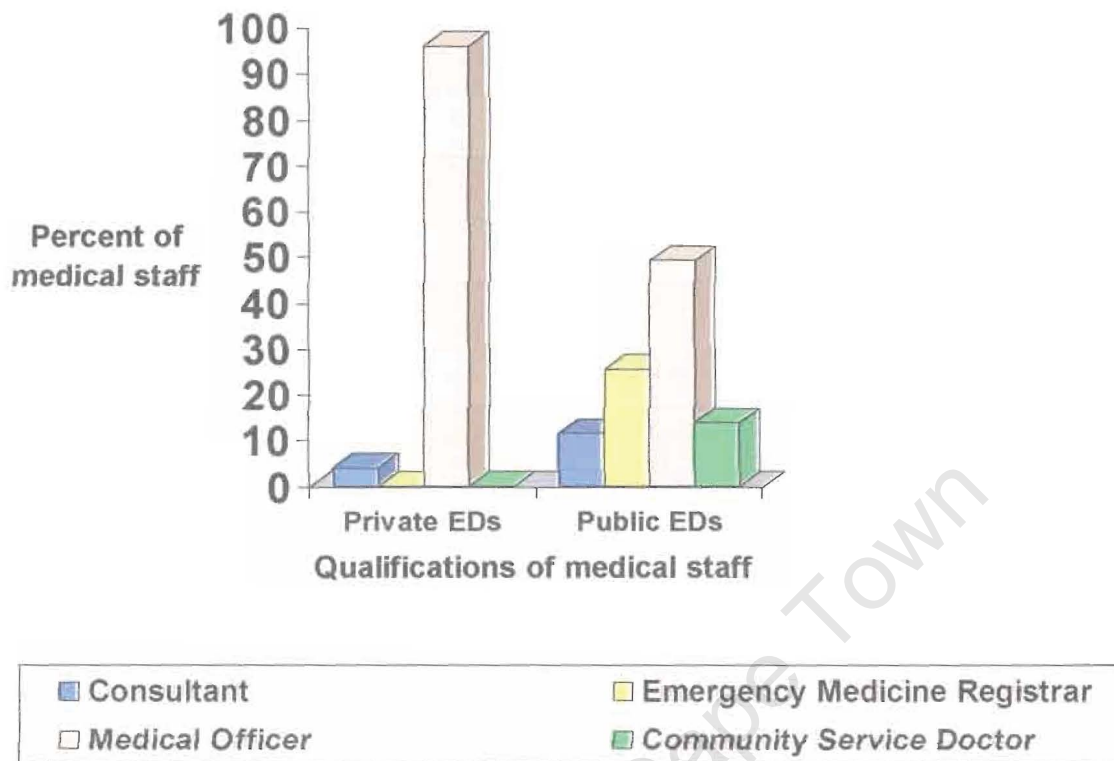
Qualifications of nursing and medical staff in ED's are shown in Figures 1 and 2.

Figure 1. Bar chart of the qualifications of nursing staff in private and public EDs



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**Figure 2. Bar chart of the qualifications of medical staff in private and public EDs**



**4.1.2 Types of Procedures**

The type of procedures performed in the various units varied between public and private sector hospitals. All units performed reduction of shoulder dislocations, and most 77% (10/13) performed elbow and lower limb dislocation reductions. Jaw dislocation reduction was performed in 38% (3/8) private units and 60% (3/5) public units (with the other 2 public units being a trauma only service). 75% of private units referred all fracture reductions for orthopaedic non-ED management, while all public units performed upper and lower limb fracture reduction under PS.

### 4.1.3 Facilities and Equipment

Table 2 summarises the responses by ED managers as to PS facilities and practises, subdivided into private and public sector units.

**Table 2. Procedural sedation facilities and practice in EDs**

	Percentage of unit managers responding "yes"		
	Public (n= 5 )	Private (n= 8 )	Total (n= 13)
Is there a separate area for PS?	60.0% (40% use resuscitation area, 20% specific area)	100% (75% resuscitation area, 25% specific area)	84.6%
Is there adequate resuscitation equipment available at the bedside?	20.0%	100%	69.2%
Does the unit have a fixed (written) protocol for PS?	0.0%	25.0%	15.4%
Is PS performed on paediatric patients (<13 years old)?	60.0%	87.5%	76.9%
Is there 1:1 doctor / nurse monitoring until the patient awakes in all cases?	0.0%	87.5%	53.9%
Are you aware of other drug regimens used internationally for PS which may be superior to your practice?	60.0%	25.0%	38.5%
Do you consider current practice of PS in your unit to be optimal?	40.0%	37.5%	38.5%

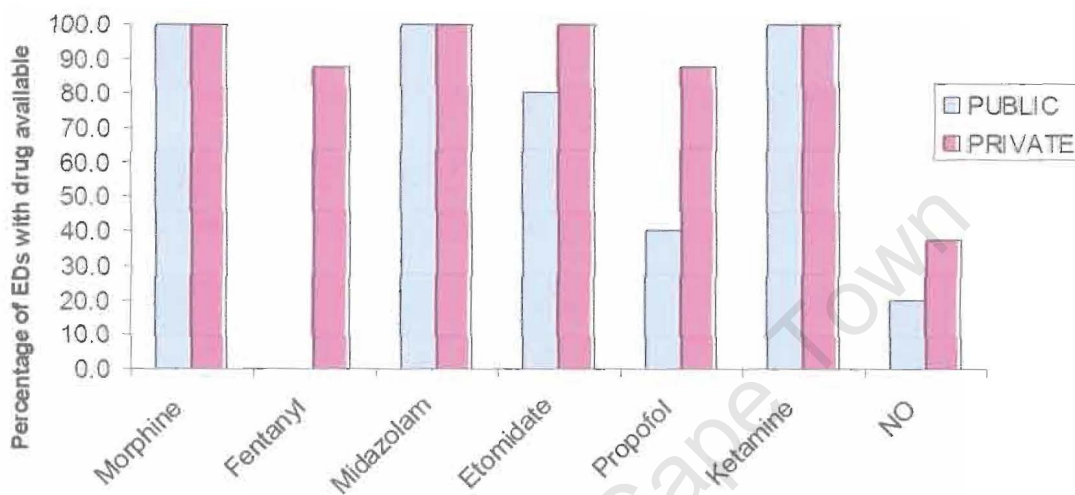
100% of EDs reported that NIBP, cardiac (ECG) monitor and pulse oximetry were available for PS. 39% (5/13) of EDs reported that capnography was also available, all in the private sector.

All EDs had access to theatre, an anaesthetist and orthopaedic surgeon. All but one(93%) had access to an ICU. A single public sector unit had a high care but no ICU.

#### 4.1.4 Drug availability

All units had access to morphine, midazolam, ketamine and 92% (12/13) had access to etomidate. Fentanyl was available to all but one of the private units and to none of the public units (54% overall). Propofol was available in all but one private unit, and available in two of the public units (69% 9/13 overall). Nitrous oxide was accessible in only 31% (4/13) units (Figure 3).

Figure 3. Availability of drugs used for procedural sedation in the ED



## 4.2 Clinicians Data

### 4.2.1 Personnel

A total of 76 clinicians were interviewed overall, out of a possible total of 89 full time ED clinicians, giving 85.4% response rate. 36.8% (28/76) were from the private sector (84.8% (28/33) response rate of private sector clinicians), and 63.2% (48/76) from the public sector (85.7% 48/56 response rate of public sector clinicians).

Clinicians who were not interviewed were not in the ED at any of the investigators visits, and were repeatedly not contactable (at least three phone calls to the individual's personal telephone). Of the 13 clinicians not interviewed, 15.2% (5/33) were from the private sector and were all medical officers, and 14.3% (8/56) were from the public sector: made up of 5 community service medical officers, 2 medical officers and 1 registrar.

Interviews with 56.6% (43/76) of clinicians were held in person, of which 39.5% (17/43) were private sector clinicians, and 60.5 (26/43) public. The remaining 43.4% (33/76) interviews were held telephonically, comprising 33.3% (11/33) private and 66.7% (22/33) public sector clinicians.

The experience of clinicians interviewed is summarised in Table 3.

**Table 3. Qualifications and experience of clinicians working in EDs**

	Working in public sector ED (n= 48)	Working in private sector ED (n= 28)	Total (n= 76 )
Years post MBBCh (or equivalent) qualification, mean (SD, range)	6.6 (5.6; 1 -29)	12.6 (8.1; 4 – 30)	8.8 (7.20; 1 – 30)
Years of experience in ED, mean (SD, range)	2.9 (2.7; 0.5 – 12)	7.2 (6.3; 1 – 30)	4.5 (4.8; 0.5 – 30)
Percentage of clinicians with 6 months or more anaesthetics experience	8.3% (4/48)	32.1% (9/28)	17.1% (13/76)

#### 4.2.2 PS practice and monitoring

Of the clinicians reporting that they do not use a fixed drug protocol for adult PS (21.1% 16/76), 7 were registrars, 2 consultants and 7 medical officers. All 16 had more than five years experience post qualification and 87.5% (14/16) had more than three years ED experience.

Only 13.2% (10/76) of clinicians report that they do not commonly perform both sedation and procedure themselves. As to whether a dedicated nurse was always present during PS, 47.4% (36/76) clinicians said there always was. There was always a dedicated nurse in 77.8% (28/36) of private sector EDs and 22.2% (8/36) in the various public sector EDs. All those clinicians reporting no dedicated nurse were from the public sector EDs (83.3% (40/48) of public sector clinicians report no dedicated nurse).

Table 4 displays the staff level of patient monitoring post PS until the patient awakes. The majority (67%) of clinicians reported that a nurse responsible for multiple patients monitored patients until waking. In a minority of cases (7%, 5/76) a doctor stayed with patients until waking; this was in 4 private EDs and 1 public.

**Table 4. Monitoring of patient by ED staff after PS**

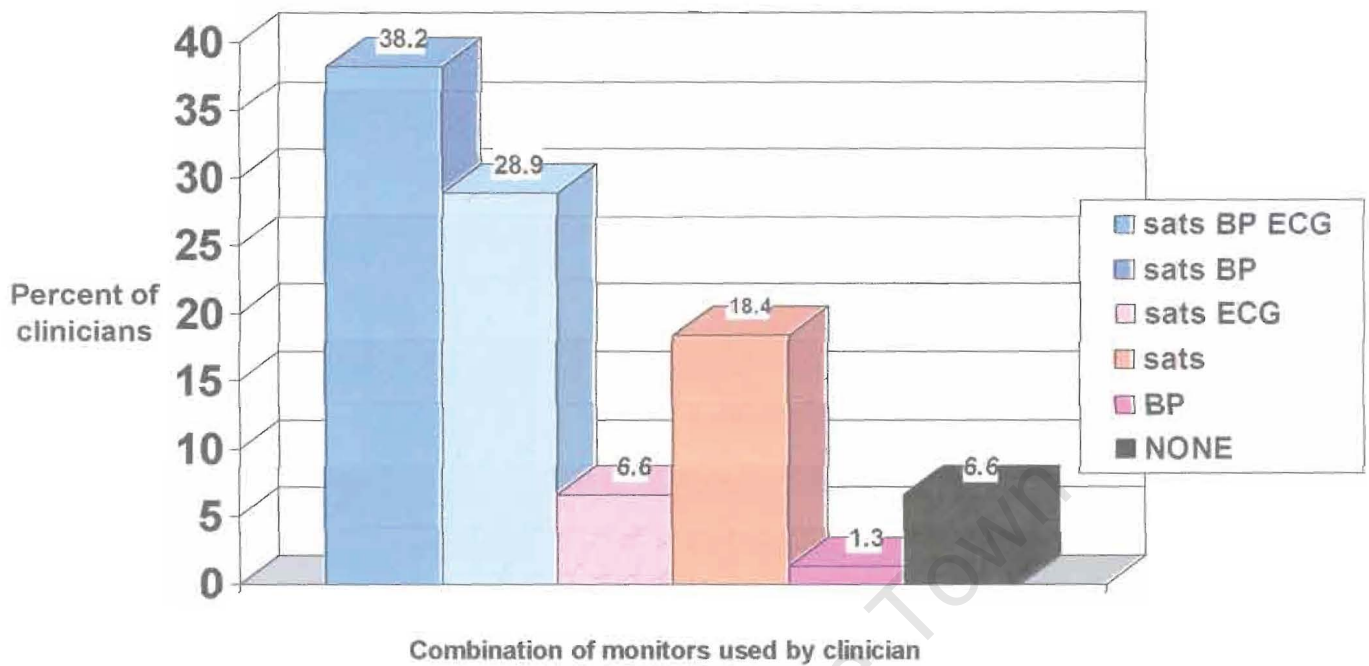
<b>Staff Member monitoring patient after PS</b>	<b>Private EDs (n=28)</b>	<b>Public EDs (n=48)</b>	<b>Total (n=76)</b>
Doctor	14%	2%	7%
Nurse- individual patient	72%	0%	26%
Nurse- multiple patients	14%	98%	67%

The level of monitoring used by clinicians during PS is shown below (Figure 4). 67% of clinicians reported using a minimum of blood pressure and pulse oximetry monitoring.

Of those clinicians who reported use of no monitoring (7%; 5/76), all had qualified less than 5 years ago and had less than 1 year of ED experience. 80% of these clinicians (4/5) were working in a single public sector ED (which did have monitoring equipment available

according to the manager's responses). No clinicians reported regular use of capnography, although this was available in 5 private units.

**Figure 4. Use of monitoring by ED clinicians during PS.**



#### 4.2.3 Drug use

Table 5 summarizes the clinicians' responses to which drugs are commonly used for PS in adults.

Of note is that 87.0% (60/69) of clinicians reporting use of midazolam also report use of morphine, and of those using propofol alone 85.7% (6/7) do not use morphine for PS.

**Table 5. Clinicians reported common use of the following drugs in PS (more than one drug could be reported)**

Class of drug	Drug	Percentage of clinicians (number/total) reporting drug use n=76
Benzodiazepines	Midazolam	90.8% (69/76)
	Diazepam	1.3% (1/76)
Opiates	Morphine	80.3% (61/76)
	Fentanyl	4.0% (3/76)
	Other opiates	5.4% (4/76)
Sedatives (non benzodiazepine)	Propofol	27.6% (21/76)
	Etomidate	7.9% (6/76)
	Ketamine	6.6% (5/76)
Other	Nitrous Oxide	4.0% (3/76)

#### **4.2.4 Association between drug use and clinicians' characteristics**

A bivariate analysis was undertaken to investigate whether an association existed between the choice of drug(s) for PS and characteristics of the clinicians, such as experience, public or private sector employment, and qualifications (Table 6).

All clinicians reported common use of either propofol only 9.2% (7/76), midazolam 72.4% (55/76) or both propofol and midazolam 18.4% (14/76). These three groups were used as the classification of the main sedative drugs for characterizing PS clinicians. There was a statistically significant difference in drug use dependent on each variable.

**Table 6. Characteristics of clinicians reporting use of propofol only; midazolam and propofol; and midazolam only for PS**

Clinicians' characteristic	Propofol only [n =7]	Propofol and midazolam [n =14 ]	Midazolam only [n =55 ]	Total [n= 76]	P-value
Number (%) in public sector	0%	64.3%	70.9%	63.2%	0.001
Number (%) with 5 years or more experience	85.7%	100.0%	52.7%	64.5%	0.002
Number (%) with three years or more ED experience	71.4%	100.0%	45.5%	57.9%	0.001
Number (%) with 6 months or more anaesthetics experience	57.1%	35.7%	7.3%	17.1%	0.001
Number (%) with international experience	71.4%	67.1%	18.2%	30.3%	0.001
Number (%) of registrars and consultants	28.6%	50.0%	14.5%	22.4%	0.016

p-value for chi-square test of association between characteristic of clinicians and drug group used

#### 4.2.5 Complications of PS: reported and drug use associations

Clinicians were asked to indicate which of a list of side effects and complications they had personally experienced, or been present during a PS performed by a colleague when the complication occurred. The scale was "never/ rare/ occasional/ frequent". Complications reported by clinicians to have occurred (any frequency other than never) in their experience are shown in Table 7. Paradoxical reactions, prolonged sedation, apnoea, falling out of bed and dysrhythmia occurred rarely for less than 10% of clinicians. Aspiration had not been recognized by any clinician.

**Table 7. Complications of PS reported by clinicians**

Complication	Percent of clinicians reporting (n=76)
Hypotension (systolic BP<90mmHg)	65.8%
Hypotension requiring intervention	57.9%
Hypoxaemia (sats<90)	64.5%
Hypoxaemia requiring intervention (non intubation)	48.7%
Intubation required	9.2%
Nausea and vomiting	52.6%

The reporting of complications (all those reported as “occasional” or “frequent”) associated with PS is reported in Table 8. The table is sub-divided according to drug use.

There was a difference in incidence of complications for the different drug groups (for example hypotension in 43% for the propofol only group versus 23% in the midazolam only group; and nausea/ vomiting in 14% of the propofol group and 36% in the midazolam group). However, none of the differences were statistically significant.

**Table 8. Clinicians reporting of complications according to choice of drugs for PS.**

Complication	Propofol only [n =7]	Propofol and midazolam [n =14 ]	Midazolam only [n =55 ]	Total [n= 76]	p-value
Hypotension SBP<90mmHg	42.9%	50.0%	21.8%	29.0%	0.081
Hypotension needing intervention	28.6%	14.3%	5.5%	9.2%	0.106
Hypoxaemia sats<90	14.3%	21.4%	32.7%	29.0%	0.473
Hypoxaemia requiring intervention	0%	7.1%	10.9%	9.2%	0.615
Intubation	0.0%	0.0%	0.0%	0%	-
Aspiration	0.0%	0.0%	0.0%	0%	-
Nausea & vomiting	14.3%	28.6%	36.4%	32.9%	0.468
Dysrhythmia/ arrest	0.0%	0.0%	0.0%	0%	-

Clinicians who responded “never” or “rare” were grouped as “no complications”, whilst clinicians reporting “occasional” or “frequent” experience of complications were grouped as “complications”.

“SBP” : systolic blood pressure

“sats<90”: pulse oximetry reading less than 90%

“hypoxaemia requiring intervention”: meaning intervention other than (less invasive than) intubation

p-value for chi-square test of association between reported complications and drug group.

#### 4.2.6 Clinician’s satisfaction with PS

Clinicians were questioned about their satisfaction with PS related to a number of aspects of the procedure. The scale of satisfaction they were asked to use was “very poor/ poor/ fair/ good/ very good”. Their responses are summarized in

Table 9. There were differences in the reported satisfaction of clinicians.

Overall, the majority of clinicians reported being satisfied with PS.

There was no significant difference in the clinicians reported satisfaction related to their choice of drug for PS.

**Table 9. Clinicians satisfaction with PS according to choice of drugs.**

Criteria	Number (%) of clinicians satisfied				p-value
	Propofol only	Propofol and midazolam	Midazolam only	Total	
	[n =7]	[n =14 ]	[n =55 ]	[n= 76]	
Time to effect	100.0%	86.7%	92.7%	92.1%	0.493
Time to recovery	100.0%	85.7%	76.4%	80.3%	0.285
Ease of sedation	85.7%	85.7%	81.8%	82.9	0.922
Ease of procedure	100.0	85.7%	89.1%	89.5%	0.594
Depth of sedation	85.7%	85.7%	83.6%	84.2%	0.976
Side effects and complications	100.0%	92.9%	96.4%	96.1%	0.712
Perceived patient satisfaction	100.0%	92.9%	96.4%	96.1%	0.712

Clinicians who responded "very poor" or "poor" were grouped as "not satisfied", whilst clinicians reporting "fair", "good" or "very good" were grouped as "satisfied".

p-value for chi-square test of association between each satisfaction variable and drug group.

#### 4.2.7 Estimated time to recovery

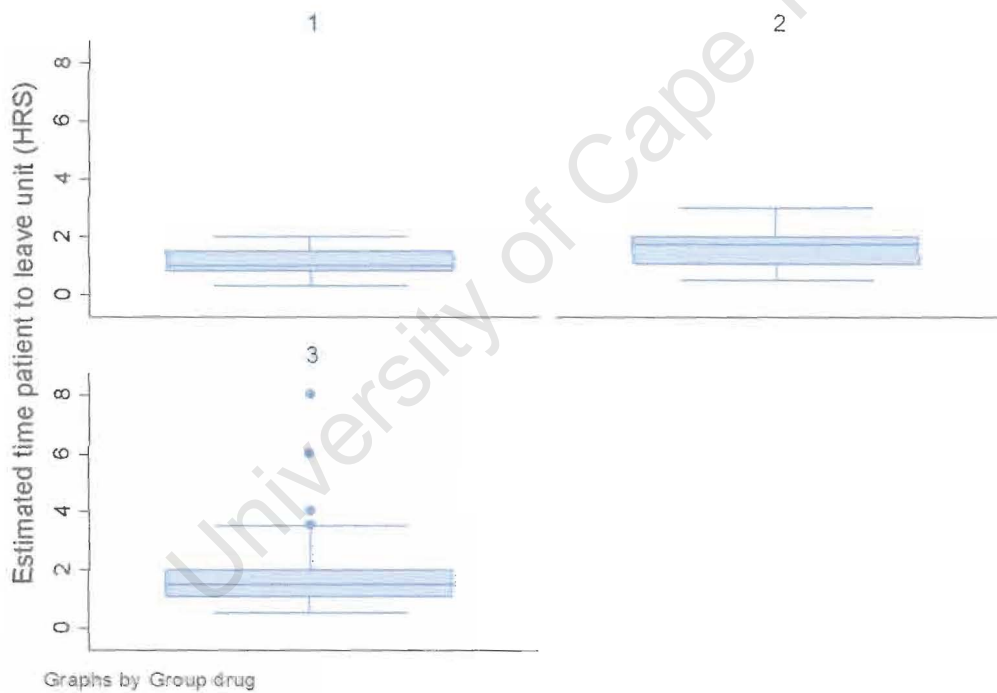
Clinicians were asked to estimate the time taken for patients to recover until they were ready for discharge from the ED (Figure 5). Their responses were subdivided according to drug use in Table 10.

**Table 10. Estimated time (hours) to recovery according to drug group**

Group	n	mean	SD	median	p25	p75	Range
Propofol only	7	1.042	0.556	1.00	0.75	1.50	0.3 – 2.0
Propofol & midazolam	14	1.679	0.799	1.75	1.00	2.00	0.5 – 3.0
Midazolam	55	1.845	1.433	1.50	1.00	2.00	0.5 – 8.0
Total	76	1.741	1.292	1.50	1.00	2.00	0.3 – 8.0

N, population number; p25, 25<sup>th</sup> centile; p75, 75<sup>th</sup> centile

**Figure 5. Estimated recovery time according to drug group**



Groups: 1 = propofol only; 2 = propofol and midazolam; 3 = midazolam only

The estimates of recovery time were normally distributed in groups 1 and 2, but not normally distributed in group 3, with several outlying data points with very high estimates of time to recovery (up to 8 hours). Therefore a non-parametric test (Kruskall-Wallis) was used to compare the populations in the different drug groups. The null hypothesis that the populations have equal medians could not be rejected as  $p=0.1435$ . Therefore from these data there is no evidence of a significant difference in the time to recovery in the three drug groups.

#### 4.2.8 Level of Sedation Obtained

Table 11 summarizes the level of sedation usually obtained in PS as rated by clinicians on a scale of moderate (responds purposefully to commands), deep (responds to repeated noxious stimuli) and very deep (no response to stimuli).

**Table 11. Clinicians reported usual level of sedation for PS**

Level of Sedation	Percent of total clinicians (n=76)	Fraction who report propofol use for each level of sedation usually obtained
Moderate	30.3%	21.7% (5/23)
Deep	67.1%	27.5 (14/51)
Very Deep	2.6%	100% (2/2)

#### 4.2.9 Specific Problems with present PS practice

85% (11/13) of ED managers reported shortcomings of current practice with respect to PS in their unit. Of those reporting sub-optimal practice, the most frequent issues raised were lack of protocols (46%), staffing issues (46% including all public sector hospitals) and lack of training in PS and inadequate area for PS being mentioned by 15%. When asked to specify what international drug regimes may be superior, propofol was specified by three unit managers and ketamine by one manager.

Participating clinicians, when asked to specify problems that had not yet been mentioned (ie. those already mentioned in terms of complications and level of satisfaction) which adversely affected their daily PS practice responded as per Table 12.

**Table 12. Specific Problems with present PS practice reported by clinicians**

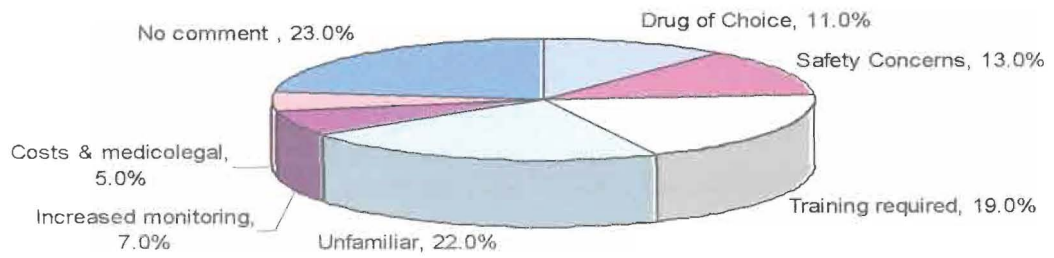
Problem	Public Sector (n=48)	Private Sector (n=28)	Total (n=76)
Drug Availability	41.7%	28.6	36.8%
Staff insufficiency	47.9%	21.4	38.2%
Area for PS	27.1%	7.1	19.7%
Equipment	43.8%	0.0%	26.3%
Protocol	14.6%	25.0	18.4%
Training	0.0%	3.6%	1.3%

#### 4.2.10 Use of propofol as PS agent

Clinicians were specifically questioned as to their knowledge of propofol as a sedation agent. 6.6% (5/76) declared to have no knowledge of propofol, 55.3% (42/76) claimed to have limited knowledge, based largely on theatre anaesthetic use of propofol. The remainder, 38.2% (29/76) claimed to have personal experience with the use of propofol in ED-PS. Of note is that of these "personal experience" clinicians, 31.0% (9/29) do not report common personal usage of propofol in this study.

Figure 6 shows the perceptions of clinicians of the use of propofol in PS. Safety concerns were largely that there are more side effects and complications. Concern was expressed over higher costs for propofol, and of the alleged medico legal requirement for two doctors to use propofol for PS.

**Figure 6. Clinicians' perceptions of propofol as PS agent**



#### 4.2.11 Reported preference of PS on self

Clinicians were questioned as to their preference for use of a sedation agent on themselves. Table 13 summarizes their responses.

**Table 13. Reported clinicians' preference for utilization of sedation agent on self**

Preferred PS agent	Percent (number) clinicians (n=76)
Uncertain	2.6%
Nitrous Oxide	1.3%
Ketamine	2.6%
General Anaesthetic	7.9%
Midazolam	38.2%
Propofol	47.4%

Also of note is that of the 47.4% (36/76) who would prefer propofol PS on themselves, only 47.2% (17/36) of these clinicians report using propofol commonly in their day to day practice on patients.

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## Chapter 5 DISCUSSION

### 5.1 *Discussion of results*

The inclusion of EDs with full time emergency clinicians only has excluded many hospitals, in both the public and private sector. The clinicians in these excluded units are largely full time general practitioners who do after hours work in an ED, or part time only ED practitioners. This may have introduced selection bias into the study as PS practice may differ between full and part time ED staff. This is discussed further in the limitations section (5.2.1).

All managers of EDs meeting the inclusion criteria consented and were interviewed. The intention of the study was not to compare private to public sector hospitals, but they are separated for comparison and clarity where there are obvious differences between the two. The private sector hospitals have less patient visits and better qualified nursing staff. The figures for full time doctors per unit and patients visits per doctor are possibly misleading, in that the private sector hospitals all rely heavily (the majority or at least partially in most units) on part time and locum doctors to supplement the full time staff – data were not collected to reflect this proportion. Public sector hospitals are staffed largely by full time doctors who are represented in the study.

Unit managers were asked to give a figure for PS performed per month. In all cases this was an anecdotal figure and very much an approximation, as no specific records are kept in any of the units. The figures were largely extrapolated by the unit managers from how many PS a day they see on average. The accuracy of these data is therefore suspect. Further studies and better documentation are necessary to give a true reflection of the prevalence of ED PS. One of the private sector units claimed to perform 120 PS per month which is questionable in the light of the other unit figures (the mean number of PS per month in the private sector, excluding this unit is 30). This may be an

exaggeration by this unit, or they may perform many more PS than other private units who tend to refer to theatre for anything other than shoulder dislocation and simple upper limb fractures.

### **5.1.1 Qualifications & Experience**

There are relatively more registered nurses in the private sector, and these would tend to be the nurses available to assist with PS, whereas in the public sector there are seldom nurses available to assist doctors on an individual basis, and those available in the immediate vicinity are less likely to be registered nurses who have the training and skills to properly monitor and assist in complications of PS.

Qualifications of clinicians are as expected: all emergency medicine registrars are in the public sector and make up about one quarter of the public sector clinicians which would perhaps bias the data towards an informed and educated PS practise by registrars who are studying the international literature. This may be balanced by the 13% of community service medical officers in the public sector who would typically spend a maximum of 6 months in an ED, and since they all start their community service year in January, those interviewed in this study are likely to have spent a maximum of five months in an ED. These community service medical officers will consequently not have performed many PS and will rely heavily on verbal protocols, advice, observation and teaching from seniors, and perhaps on undergraduate/ internship teaching.

The experience data of clinicians demonstrates that the public sector has a less experienced workforce (the mean number of years post qualification is half that of the private sector), with a high turnover of many very junior doctor in their first years after qualifying, and working in an ED for the first time. The private sector doctors would tend to have spent some time and gained experience in the public sector before moving to the private EDs. Less than a fifth of clinicians had spent 6 months in anaesthetics, which was thought to be an important influence on how

ED clinicians might perform PS and use drugs which are historically available in theatre only (in the private sector nearly a third of clinicians had anaesthetic experience which might be a contributory factor to different PS practice).

### **5.1.2 Protocol**

Only two units claimed to have a written PS policy, and in neither case were they up to date or readily available in poster or check list format for regular application. Many unit managers claimed to have a verbal policy of at least drug protocols, but there were no firm criteria on patient selection/ monitoring or discharge criteria.

Clinicians were asked whether they used a fixed drug protocol to ascertain the flexibility of their personal protocols, and to gain some understanding of their drug choice if they claimed to use multiple drugs commonly. It is uncertain if the question was well understood or answered and consequently it may not be a useful measure. The clinicians who stated they do not use a fixed protocol tended to be more senior and experienced which may demonstrate that with experience clinicians tend to vary their drug regimes more to suit the individual patient scenarios. International experience is also that there is a wide variation in practice by individual clinicians due to the array of drugs and regimes available and the individual patient's requirements (Miner & Burton 2007, Paris & Donald 2007).

### **5.1.3 Range of procedures performed**

The range of procedures performed in public sector hospitals is wider than in the private sector. Procedures such as manipulation of complex fractures and dislocations, which might in fact benefit from a general anaesthetic and specialist orthopaedic management may be performed in the ED to prevent excess delay before the procedure could be performed in public sector theatres. Private units on the other hand have ready access to specialists and theatre, so the threshold

for referral of an emergency procedure out of the ED is lower, particularly when the patient will be admitted. Cardioversion is becoming a routine ED procedure internationally (Wood & Ferguson 2006), such that in some local units (largely in the private sector) inpatients and non ED patients are brought for semi-elective cardioversion to the ED where there is adequate resuscitation equipment and skills, as well as ED skills in PS available.

#### **5.1.4 Facilities/ Monitoring**

Facilities for PS are again divided between public and private sector units. In the public units, PS is often (80% of time) performed in the general ED area, without immediate access to resuscitation equipment (and often limited or no routine monitoring equipment), while private units tend to have more floor space, and less patient load, allowing use of resuscitation areas or separate areas for PS which are appropriately equipped. These are crucial issues, in particular the lack of resuscitation equipment at the bedside in 80% of public sector units which requires urgent consideration before life-threatening complications of PS occur (if they haven't already) and are not managed adequately due to lack of amenities in the ED.

All the units had access to non invasive Blood Pressure (BP) monitors (although the questionnaire did not specify if this was continuously monitored); a single reading before and/or after a procedure; or as the international standards suggest a minimum of before, during and after the procedure (Godwin et al 2005), and pulse oximetry (sats) which are considered the minimal monitoring necessary unless there is a specific predisposition or pre-existing condition to suggest further monitoring (eg. ischaemic heart disease or a known arrhythmia would benefit from cardiac monitoring) (Godwin et al 2005). Information was not sought on the absolute numbers of functioning monitors, and many public sector clinicians complain of shortages of available monitors, leading to performance of PS without adequate monitors. A three lead cardiac monitor was available in all units, but capnography was limited to some private units only.

Two thirds of the study clinicians complied with the international standards of BP and sats monitoring, although there is no consensus with much possibly unnecessary use of cardiac monitoring. Of much greater concern is the 8% of clinicians who routinely perform PS with no sats monitoring (and this is likely to be an under-reporting by clinicians of their actual practice if they have the insight that they should be performing some monitoring). The clinicians using no monitoring were all very junior and noted to be mainly working in the same public institution, where there is obviously an urgent need for protocols and training in PS.

A third of clinicians do not monitor for hypoxaemia and hypotension (these being the predominant side effects of sedation drugs) and this raises questions over the usefulness of the reported PS complications in this study, as they are not able to assess for them in their routine practice. The reporting of hypoxaemia is almost certainly a serious underestimate in these circumstances.

#### **5.1.5 Personnel involved in PS**

Single physician PS is becoming the standard of care internationally (with the proviso that an appropriately trained assistant is present at all times) (Hogan 2006). This is mirrored in the study population, but is likely due to staffing limitations rather than considered safety standards. The small minority of clinicians who perform PS with two doctors were either junior and inexperienced clinicians who recognized their limitations and asked a colleague for assistance; or more experienced practitioners who insisted on assistance for historical reasons and the luxury of available doctors to assist. The practice of multiple clinicians performing PS is not to be discouraged, and in the cases of complicated procedures, or concern as to the patients pre-sedation condition, it is definitely advised. (Miner & Burton 2007)

Several clinicians expressed concern over the medico legal aspects of deep sedation (or even ketamine sedation) with a single clinician (perhaps as a result of recent local publications suggesting this (Steffanutto & Ruttmann 2006)). Anaesthetic practice in theatre mandates a separate clinician who does nothing but perform the sedation, in addition to the clinician performing the procedure. This is not directly related to PS in an ED, as in all cases of PS the clinician performing the procedure is able to stop the procedure at any time, and perform any support/ resuscitation necessary to stabilize the patient should the need arise (as suggested by monitors and the trained assistant), without endangering the patient's life as a surgeon in the midst of a laparotomy or open heart surgery would do if they abandoned surgery. There is no specific South African directive that applies to ED PS, and expert and international practice would support single clinician PS, again with the proviso of a dedicated trained assistant being present (which is seldom the case in the public sector) (Hogan 2007).

Despite the above considerations, a dedicated nurse is present for less than half of Cape Town's PS. Only three quarters of the private sector clinicians claim to always have a dedicated nurse and the majority of public sector clinicians do not. This is an alarming finding from a clinical and medico-legal perspective, but does not seem to be borne out by a higher than acceptable reported complication rate in this study. Lastly on this point, no clarification was sought as to the qualifications of assisting nurses. Basic life support skills and some knowledge of monitoring (and thus ability to recognize and initiate response to complications) and basic airway skills would be the minimum (Godwin et al 2005), and would ideally be prerequisites upon a registered nurse practising in an ED.

Two thirds of patients were monitored by a non-dedicated nurse until they are "awake". No amplification was sought on when PS was deemed to have finished, and at what stage patient care could be handed over from performing clinician, to monitoring personnel. Anecdotal evidence would assume that the patient was stable, able to protect their own airways, and showing signs of waking up. Godwin et al (2005) show that most PS side effects and complications occur during PS, and in the first 5 minutes after PS, but can occur up to 20 minutes

later. Further studies may be necessary to define post PS monitoring and the personnel and equipment required, as well as the entry and exit criteria for patients being monitored in the South African setting.

### 5.1.6 PS Drugs

Drug availability was good in the private sector, where all units had access to midazolam, etomidate, propofol and ketamine. The public sector units all had midazolam and ketamine, and all but one had etomidate (- startling given that etomidate is the standard rapid sequence induction agent for shocked patients). Propofol was surprisingly accessible, given the apparent resistance from anaesthetists to the use of propofol outside theatre, and the lack of medicine control council licensing of propofol for use outside of anaesthesia and intensive care (Fresenius Kabi 2007). All but one of the private sector units, and 2 (40%) of public units had ED propofol available (although anecdotal evidence suggests that access is limited in the public sector units and once a regularly allocated number of propofol units have been used it is difficult to obtain more). This demonstrates the demand for, and acceptance of propofol by some ED managers and clinicians for routine use.

All clinicians reported that they commonly used either midazolam or propofol for PS, along with various combinations of opiates and other drug choices. It must be borne in mind that some clinicians do not have access to all the drugs they desire and this may have resulted in them reporting common use of other drugs that they use instead of their first choice.

Midazolam was by far the commonest PS drug used. It has a large therapeutic window and is regarded as a safe drug when titrated gradually to effect, but is certainly not without its dangers, and prolonged effect. Midazolam has been widely used in EDs for PS, rapid sequence induction, and sedation of intubated patients, and has thus become familiar to most ED clinicians. It is generally used in combination with an opiate - morphine largely - but also to a very limited extent

in this study with shorter acting opiates such as fentanyl or alfentanil which are perhaps more appropriately short acting for PS. There is some evidence of pethidine use for PS, but less than anecdotal evidence might suggest.

Propofol was used by a quarter of clinicians for PS, and this will be discussed in detail later. Of note is that propofol is not available in all units, and this may have influenced the reported use of other common drugs as well as/ instead of propofol.

There is little utilization of etomidate (its use for PS likely extrapolated from its common use in rapid sequence inductions in the ED) and nitrous oxide. Ketamine (and especially in combination with propofol) may be part of the future array of drugs for adult PS (Messenger et al 2007), but only a single clinician in the study reported common use of the combination.

A trend which was sought and seemed to be confirmed by the data was whether opiates are used less frequently with propofol than with midazolam. The combination of morphine and midazolam is used because of the balance of analgesia and sedation it offers, such that the doses of both drugs are reduced in combination. For procedures such as reduction of dislocations, where there is marked improvement in pain after PS, a non analgesic drug or short acting opioid/ drug combination may be superior as there will be rapid awakening without a prolonged opiate effect (and opiate induced nausea).

Significant associations were demonstrated between propofol use and greater experience and knowledge in emergency medicine, as demonstrated by working in the private sector, years of post qualification experience, ED experience, international experience, as well as anaesthetic experience and position (registrars and consultants were presumed to have a greater knowledge of drugs and more up to date PS knowledge). This confirms that propofol is widely used by senior ED practitioners, likely because of satisfaction with its effect, knowledge and familiarity of the drug, and confidence in management of its

possible complications such as unintentional deeper level of sedation where cardio-respiratory support may be necessary.

### 5.1.7 Complications

It was thought that the best gauge of anecdotal evidence of PS complications was by asking clinicians their impressions of the frequency of complications experienced. This is likely biased by recent experiences which would sway the reporting, and is also a very crude impression of the incidence of complications in day to day practice. The major complications experienced were hypotension, hypoxaemia, and nausea and vomiting (all experienced by at least half of clinicians in their practice). It is hard to relate the incidences of any complications to other studies because of the unique reporting scale for complications which is perhaps a weakness of the study. The literature quotes the incidence of significant hypoxaemia to be 4-8%, and significant hypotension 4% (Burton et al 2007, Sacchetti et al 2007, Duncan 2006). The reported experience of hypoxaemia and hypotension (29% of clinicians report occasional or frequent experiences) appears to be much higher than this. Although the incidence of events needing treatment is only slightly higher, given the lack of monitoring in some units, this is almost certainly an under-estimate.

Intubation was rarely required - 7 clinicians reported having to intubate a patient as a result of PS - out of a total of 76 clinicians performing over 500 PS per month in all the units studied. This seems high relative to other studies (several international studies of thousands of patients report no intubations (Burton et al 2006, Sacchetti et al 2007), but several factors could confound the incidence. Several clinicians may have been present and remember the same patient (since they were asked to note complications experienced in their presence, not necessarily performed by themselves). Intubation could also have been incidental to the PS (ie. required independently of the sedation, or as a result of known pre-existing conditions) and this crucial issue not recalled clearly anecdotally. Lastly inexperienced clinicians are likely to have a lower threshold

for intubation when the airway is compromised, when transient bag-valve mask ventilation may be all that is required. Aspiration was not experienced (or at least not recognized as significant) by any clinician which is in line with other studies (Cheung et al 2007).

Numbers of clinicians using propofol were low, and this may have influenced the lack of significance of association between drug groups and complications. The incidence trends are however interesting, in that hypotension and hypoxaemia are expected to be more prevalent with propofol than midazolam PS. This seems to be the case for hypotension, but hypoxaemia (through the spectrum from low sats readings to intubation) is reflected as occurring more often with midazolam. The delayed onset of action of midazolam can result in hypoxaemia, particularly with an inexperienced clinician who becomes impatient waiting for an initial bolus of midazolam to have effect, and gives another bolus too soon, resulting in a more profound level of sedation and hypoxaemia. Note that none of these implied or suggested interpretations are shown by the data: there was no significance of association between drug groups and complications.

The incidence of nausea and vomiting also appeared lower with propofol use, as might be expected since midazolam is often combined with an opiate with resultant nausea, and propofol has some anti-emetic effects.

#### **5.1.8 Satisfaction with PS**

A different scale of level of satisfaction for various PS issues was used to get an impression of problems in PS practice. The overriding impression is that clinicians are satisfied with present practice. No characteristic showed a more than 20% dissatisfaction (i.e. those with a rating of "very poor" or "poor"). Again the scale is unique so hard to compare, and the allocation of "fair" as a level of satisfaction to the "satisfied" group ("fair", "good" and "very good") means that there are three "satisfied" groups as opposed to two "not satisfied" groups ("very poor" and "poor") and makes it impossible to compare the grouping directly.

No significance of association was found between the drug groups and the level of satisfaction. Numbers for propofol were low, as well as a likely tendency to rate satisfaction subjectively. Clinicians may have rated their satisfaction high because of falsely perceived PS success and efficiency (i.e. knowing no better than their present practice), as well as a tendency to rate as fair/ good rather than express negativity. This is perhaps evidenced by the side effects and complications rating as 96% "satisfied" when in fact according to the complications results, nearly a third of clinicians experienced the common complications (hypotension, hypoxaemia and nausea/vomiting ) as "occasionally" or "frequently" which is hard to correlate other than a falsely high report of satisfaction (unless they regard these side effects as acceptable).

Incidences of interest (although not significantly different between different drug groups) which in a larger and more detailed study might prove to have an association are that propofol users rate propofol with complete satisfaction (100% of clinicians rate it "good" or "very good") for time to effect and recovery; ease of procedure; side effects and complications; and patient satisfaction. Clinicians using midazolam were not unanimous (ie. less than 100% "satisfied") in their satisfaction for any aspect of the drug.

There was no single PS characteristic where propofol users were less satisfied than the total satisfaction (i.e. total number of satisfied clinicians), which might suggest that propofol gives greater PS satisfaction to clinicians who use it commonly, although more studies are required to show this locally as they have in other studies (Frazee et al 2005).

#### **5.1.9 Time to recovery**

"Time to recovery" is a very much anecdotal scoring of clinician's estimates of time to discharge (discussed further under limitations). Clinicians in most EDs have little awareness of time (especially in busy periods), hand over patients

after PS to a monitoring nurse, and often have little follow up or awareness on when the patient wakes and is fit for discharge.

The overall mean time to leave the unit after PS was estimated to be 1.75 hours which is not vastly different from other studies – figures in the region of 1 hour are quoted depending on drug regime (Dunn et al 2006, Symmington & Thakore 2006). Several outlying times to recovery as demonstrated in Figure 6 reinforce that the anecdotal estimates are poor and these times should be measured to give meaningful results. There was no evidence of a significant difference in time to recovery for the different drug groups, although the differences in the estimates possibly suggest a faster recovery with propofol (the propofol only group having a lower mean, standard deviation and range than the other groups). Further studies are required.

As an aside, it was mentioned by several clinicians (all working in the same private sector institution) that flumazenil is used routinely to speed up the time to discharge of patients given midazolam. This was an unexpected finding, and if the numbers were significant (unlikely as it was only mentioned by 3 clinicians) would have an impact on the results – suggesting a faster recovery time for midazolam than would otherwise be expected. This practice is questionable for several reasons: the cost of flumazenil is over R300 per patient, which may exceed the entire PS incident in some cases; flumazenil is not without significant side effects; and the short half life of flumazenil relative to some of the sedating agents may raise concerns as to re-sedation after discharge. Training and better use of the available drugs for PS would be an alternative to this practice.

#### **5.1.10 Level of sedation**

Two thirds of clinicians report usually obtaining deep sedation, which is the usual goal for ED PS (Green 2007). Concern has been expressed that with the use of propofol, a deeper level of sedation than intended can be unintentionally easily obtained due to the narrow therapeutic window of the drug. In this study, the

numbers of clinicians reporting very deep sedation are too low to demonstrate such concerns. ED patients are well placed in terms of skills and equipment to deal with the consequences of transient very deep sedation, so it is not usually a life threatening event when proper monitoring, recognition and clinical management are in place.

#### **5.1.11 Specific Problems with PS practice**

There were some internal inconsistencies in responses of ED managers. For example, although 39% of ED unit managers considered PS practise to be optimal in their units, 85% noted specific shortcomings in their current PS practise when prompted. Most would like to see protocols in place, and more specific training in PS available. These areas need to be dealt with in a universal manner, and this study will provide a basis for ongoing research in this field.

Unit managers and clinicians were in agreement that staffing (largely more nurses and more qualified nurses) was one of the major issues that could be improved for better PS practice, as well as needing specific areas for PS (a lesser issue). Managers however thought that protocols and training were priorities, while only a minority of clinicians concurred. Clinicians would appear to lack the insight that protocols and training are desperately needed, and are more concerned with drug availability (which in some cases, especially public sector EDs, may be inappropriate until adequate protocols and training are implemented). Lack of equipment is another major issue in the public sector which clinicians claim limits their monitoring abilities and thus performance of PS.

#### **5.1.12 Propofol as a PS Agent**

To ascertain what clinicians believe is the optimal PS agent, a scenario was posed to them that they presented that night to a high level ED with a full range of monitoring, equipment, skilled personnel and drugs, with their own first time

dislocated shoulder for reduction. They were then asked what sedation agent they would like to be used on themselves..

Responses were interesting in that almost half of clinicians would request propofol – presumably because they consider it to be the superior drug. This contradicts the fact that at most just over a quarter of clinicians report using propofol commonly in their own practice. There are multiple reasons that this could be: propofol may not be available to them in their ED, they may not be familiar with using the drug themselves despite awareness of its use in PS, they may be unhappy with the safety profile of propofol given the circumstances in their own ED (i.e. skills, monitoring, area), or they may be answering with the response they think is expected, or seems most appropriate to the study (although the investigator specifically avoided any mention of propofol up to this point of the interview unless it was brought up by the clinician).

Midazolam was a close second choice for 38% of clinicians to have used on themselves, showing that it is acceptable to many in terms of its safety and effect. Eight percent requested a general anaesthetic, despite the universal delays to the procedure that this would cause. It is unclear whether this was because of a perceived higher level of care by a dedicated anaesthetist, or the perception of a very deep and pain/ awareness free sedation, although the latter is suspected to be the more prevalent reason. A very small minority asked for ketamine or nitrous oxide, demonstrating again that the major PS agents preferred by the study population are midazolam and propofol.

Following this question, and the large number of clinicians who spontaneously mentioned propofol, the final question was posed as to propofol use and perceptions as an ED PS agent. Only a third of clinicians claimed to have personal experience with propofol for PS, while more than half had limited knowledge from use in theatre/ anaesthetics. This confirms that propofol is still largely an anaesthetic drug and there is little knowledge and training in its use by the average ED clinician. Despite this, half of clinicians requested it to be used

on themselves, so there is awareness of PS with propofol either from international exposure and literature, or from local experiences.

Clinicians were then all asked what they thought of propofol as a PS agent. Responses were mixed. The number claiming propofol to be the drug of choice (11%) is far smaller than might be expected given that half of respondents would request it to be used on themselves. It seems that there are concerns, even from experienced users as to propofol use in PS. Concern seemed to centre around training, facilities, and use of propofol inappropriately by junior clinicians who are not sufficiently experienced or aware of the complications and management thereof when using propofol for PS.

Of note is that only a single clinician mentioned the much debated (largely by anaesthetists) side effect of propofol causing burning on injection. Some authors claim this has an incidence of up to 20% and go to great lengths to prevent it. Suggestions include the addition or pre-treatment with ketamine (or lignocaine) and this may become important as the use of propofol increases and evolves. (Koo et al 2006)

#### **5.1.13 Costs**

Several clinicians were concerned that propofol was a much more expensive agent than others for PS. This may have been true in the past, but prices are now comparable to other agents such as midazolam in both the public and private sector units. The drug cost for a brief PS for the average adult would be: (range of prices public to private sector)

- 1) Propofol- an ampoule of propofol (20ml of 10mg/ml) costs R19 to 30.
- 2) Midazolam would usually be used in a 1mg/ ml (5ml ampoule) which costs R10 to 40.
- 3) Morphine which would commonly be used in conjunction with 2) for a 10mg/ml (1ml ampoule) costs R 1 to 4.

(Personal communication: Victoria Hospital Pharmacy & Constantiaberg Hospital Pharmacy)

Thus cost is not a factor in the choice between these agents, and in fact the costs should be interpreted in the light of duration of ED stay for patients undergoing PS. The evidence from this study was not adequate for comparison of time to recovery from agents, but international literature would suggest time to discharge after propofol PS is less than an hour (Dunn et al 2006), whereas the study mean estimate is 1.5 hours.

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## **5.2 Limitations and assumptions of the study**

### **5.2.1 Study Sample / choice of facilities**

The inclusion criteria excluded many EDs and ED clinicians who were not regarded as practicing emergency medicine full time. This means the survey does not show a complete picture of ED services in the metropole, but a representation of the practice of full time ED staff. It was anticipated that a higher response rate could be achieved from full time staff compared with part time staff, particularly those with other commitments outside the ED. A response rate of 85% amongst full time ED clinicians was achieved in this study.

A secondary objective of this study was to develop PS protocols in line with international practice. Training and implementation of such a protocol would be carried out initially in EDs with full time staff. A follow up study should be conducted to investigate whether PS practice in EDs with part time staff is substantially different from the results reported here.

The selection bias could lead to either an over or under estimation of the standard of PS practice. For example, a greater proportion of private than public sector hospitals were excluded due to purely part time staffing. It is possible that the full time clinicians from that sector are the more competent and up to date, and this would bias the data for the private sector towards a higher standard of PS practice. On the other hand many of the part time private sector clinicians may be up to date and could be involved in anaesthetics and very competent sedationists, leading to an underestimation in the overall private sector quality of PS.

Many simple PS procedures may be performed at a primary health provider level: whether it is by a general practitioner in their rooms, or a day hospital general medical officer. This study has not quantified these PS practises or qualified how they are performed. Anecdotal evidence from both the public and private sector

suggests that little PS is performed outside of the 24 hour EDs for various reasons, but especially because of the lack of X-ray facilities (required for virtually all PS) and lack of time, skills, and monitoring equipment in the generalists' facility.

Paediatric PS, and units performing only paediatric PS, were excluded from the study. Paediatric PS regimes may include drugs seldom used in adults such as chloral hydrate and widespread use of ketamine, as well as the drugs commonly used in adults. The difference between the adult and paediatric drug use may be narrowing with increased use of propofol in paediatrics (Bhargava 2006), and possibly greater use of ketamine in adults. The difference in practice and complexities of identifying units meant that it was not practical to include these data in this study, although by the nature of paediatric patients there is more sedation performed for radiological, diagnostic and therapeutic interventions in children than in adults, and thus wide experience and growing evidence in the literature for paediatric PS. Data collected from ED managers shows that there is widespread performance of paediatric PS in three quarters of the units included, and it should be considered that clinicians who regularly perform PS in paediatrics may have a different approach to adult PS because of this experience with alternative drugs and perhaps the more difficult to manage and rapider onset of complications in this group.

Larger participant numbers would have made the study more useful, and might have shown significance for other associations than those found. To increase the numbers in this study, a wider geographical area such as the entire Western Cape, or South Africa might have been considered. It is questionable whether additional useful data would have been captured, other than geographical differences in practice. Cape Town was chosen as there are a large number of EDs easily accessible, and known to the investigator, and also because the speciality of Emergency Medicine is further advanced in Cape Town than elsewhere in the country, with the largest department, and the greatest number of emergency medicine registrars in the country at present.

### **5.2.2 Interview strategy**

The interview strategy was one of a non-confrontational and non-judgemental assessment of the units and clinicians. Attempts were made to establish the impartial goals of the study and the anonymous nature of the data, but it is possible that responses were guarded and tended towards what participants thought they should be doing rather than their actual practice. The impression of the investigator was that this may have been more of an issue amongst junior and inexperienced staff who felt more threatened by the questioning, whereas the senior staff felt they had the experience and at least equal position to the investigator and were more honest with their responses.

### **5.2.3 Response Rate**

The response rate of the clinicians was good and no specific association could be found in those not interviewed, or in those interviewed personally versus telephonically that might bias the findings.

### **5.2.4 Interpretation of questions**

It is important to note that the entire questionnaire was answered in an anecdotal manner. This was partly the brief survey design, but largely due to the fact that PS is very poorly documented in ED's in Cape Town. Specific questions may have been poorly answered, but given the constraints of an acceptable interview time and depth, and spontaneity in answering, it was difficult to improve upon. Questions which asked for an absolute figure are unlikely to be accurate – such as the number of procedural sedations performed in each unit, and the average time to recovery from PS, as no specific records are kept in EDs.

A limitation of the clinician's questionnaire was that for clinicians who use various different drug strategies to sedate, there was no distinction between the different

times to recovery/ complications and satisfaction for the drugs. The minority of clinicians vary their drug strategy, and when confusion arose they were asked to answer for the strategy they use most commonly, or to use an average figure (for example for recovery time). Some of the interviewees were unhappy with this as they said there were vast differences between drugs and it was difficult to answer. This will have affected the usefulness of the data (but only in a small number of clinicians, as most had a preference for one drug and used another only when the preferred drug was not available (a not uncommon scenario in the public sector) or when specific patient co-morbidity suggested the use of another drug).

Several questions were not posed in the questionnaire which would have provided useful information. Unfortunately due to the brief nature of the interviews, often conducted in busy ED's, it was decided to limit the questionnaire. Other questions which were considered include fasting criteria for PS and the use of supplemental oxygen. Both are considered contentious in the literature, but may have prolonged the interview when clinicians attempt to justify their responses. No evidence was gained during the study as to the practice of fasting regimes. It is likely this is poorly defined area, and many clinicians would not ask a patient about fasting times, or take it into consideration before PS. Problematic patients are likely to be those with a predisposition for emesis, and in particularly intoxicated patients.

Supplemental oxygen use is likewise an unknown factor. It seems likely that the routine use of oxygen is dependant largely on nursing staff and unit protocols (written or otherwise). The impression gained was that supplemental oxygen is used in the majority of patients in the private sector, where there is nearly always a dedicated nursing sister present who would tend to be the one to administer oxygen.

### **5.3 Strengths of the study**

#### **5.3.1 Sample selection**

Over 340 years of full time ED experience are represented by the survey. The survey is representative of full time ED PS practice in the metropole. The response rate for the clinicians was 85% - due to the choice of personally conducted interviews and the fact that only full time clinicians were involved. This is in line with acceptable responses for similar studies. There was no pattern of unit or seniority to the clinicians who were not contacted.

Missing data were minimized due to the high response rate and short questionnaire (all the questionnaires were completed, and this may not have been the case if clinicians had been required to offer more time) and the short time span of the study so that follow up was not an issue.

#### **5.3.2 Personal interviewing for all individuals**

The investigator personally conducted all interviews, and all data sheets were completed by the investigator, thus standardizing the phrasing and explanations of the questions, and the documentation of answers so that the responses were reliable and valid.

More than half of the clinician interviews were conducted in person at the EDs, while the remainder were interviewed telephonically. There was an initial concern that the telephonic interviews would be difficult, in introducing the study, developing a rapport with the clinician, and in particular conveying the scales of frequency of complications and level of satisfaction. This was however unfounded, and the telephonic interviews were generally well accepted and have produced widely comparable data to the personal interviews.

### **5.3.3 Cost of the implementation of the study**

Costs of the study were minimal as there was only a single investigator. Costs were largely transport and telephonic, but were minimal so no external funding was required.

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## **Chapter 6 CONCLUSIONS AND RECOMMENDATIONS**

### **6.1 Conclusions**

This study shows there is widespread daily practice of deep PS in all EDs in the Cape Town Metropole. Performed by a skilled and suitably trained emergency clinician, with the right facilities including dedicated and trained nursing staff, dedicated areas in the ED for PS, adequate monitoring and post procedural care, PS is an extremely safe and cost effective procedure, with high patient and emergency personnel satisfaction (Godwin et al, 2005).

This study shows that the Cape Town metropole's ED services are divided between the public and private sector, with unequal facilities between the two. Although the private sector facilities and staffing are equivalent in many ways to international EDs, their PS practice is often sub-optimal, largely due to the lack of training and protocols which encourage optimal practice. The public sector hospitals are generally poorly staffed both in terms of personnel numbers and qualifications, and lack many basic facilities, in particular adequate and available monitoring and dedicated nursing staff to assist with PS. In some cases, junior clinicians with minimal ED experience are performing PS with little supervision and complete disregard for the potential complications of deep sedation.

Despite this, this study found that the side effects of PS are generally well tolerated and managed. Propofol is rapidly becoming the drug of choice for much international ED PS, owing to its rapid and pronounced effect, with dramatically faster and clearer wake up than any other sedative. In skilled hands, such as trained emergency medicine specialists and their trainees who have in depth knowledge of the drug, its potential complications and the management of life threatening emergencies, the side effect profile of propofol is excellent and it is the preferred drug by most clinicians once they have witnessed its use. The problems of propofol are that in inexperienced hands, the drug has the potential

to induce very deep sedation or general anaesthesia, requiring intensive cardio-respiratory support. Even with judicious use and titration of the drug, patients who are hypovolaemic or shocked are at dire risk of cardiovascular collapse which is a concern when inexperienced clinicians become overly confident with the drug.

ED's and the new specialists in emergency medicine should be proactive and prepare our ED's for modern PS. Propofol is likely to become the standard of care for PS in the ED in South Africa as it is internationally already. For this to happen without a rise in the morbidity and mortality of ED PS, we need to implement systems to optimize PS. Currently most ED's are not run by specialists, but this will change rapidly over the next few years, with ED's becoming a specialist run discipline, which will have PS as one of its core capabilities.

Follow up studies are needed to assess the implementation of training and protocol use. It would be useful if they were able to better quantify PS practise (requiring documentation of PS, whether it is routine or for research purposes only) and thus to not only give a measure of PS practice for future research, but also to allow comparison to international practice. Babl et al (2006) describe their implementation of a paediatric procedural sedation program, with initial consensus development of a manual; teaching session with lecture, demonstration, and assessment; and then a tight protocol development with check sheets for all actions and documentation. They audited their PS practice after implementation and showed much improved staff satisfaction and safer PS practice. It is perhaps optimistic to suggest such an intensive strategy in South African ED's, at least initially, but this is where we should be aiming.

The findings and recommendations of this study, along with suggested universal protocols for PS will be disseminated to South African EDs', via publication in the local peer reviewed journals, and through direct education of ED clinicians.

## **6.2 Recommendations**

- ED managers and emergency medicine specialists need to formulate safe and practical protocols that provide guidelines for safe practice, as well as implementing recording of PS for medico legal, research and quality assurance purposes.
- Training of ED medical personnel early in their ED training is essential and should include specific knowledge of the available drugs, the appropriate target level of sedation, monitoring for side effects and management of complications of PS. Much of this is fundamental to emergency medicine training (which includes pharmacology, anaesthetics and intensive care), but specific short courses in sedation would be of much benefit. Protocols need to be developed at each institutions level, taught, used practically and refined until PS is optimal.
- Training of undergraduates/ interns in basic PS techniques. Newly qualified doctors in South Africa who are practising often alone in isolated hospitals will be called upon to perform PS, and unless they are aware of fundamental safe practice, PS will remain a difficult, painful and often dangerous process often learnt by trial and error. This needs to be addressed at an undergraduate level first, at least theoretically, and then interns should all have some specific practical training in PS, probably most usefully during an ED rotation in their internship. Rational use of basic drugs such as midazolam should probably be emphasized at this level.
- Facilities need to optimize their PS services. This includes dedicated areas for PS (or mandatory use of monitored beds in a resus or high care setting), adequate monitoring available for PS and provision of sufficient ED nurses with adequate training to assist in PS and monitor patient post procedure.
- Drug use in PS needs to be carefully considered and controlled. Access to drugs such as propofol needs to be limited to suitably trained and

experienced clinicians. This is likely a decision to be made within each unit on how to control drug use.

- Paediatric PS needs to be developed simultaneously to enable a seamless service for all ages. There is much common ground between adult and paediatric PS, and protocols do not necessarily have to be developed in isolation.

### **6.3 Suggested Protocol for Procedural Sedation**

Protocols for ED PS need to provide the following basic framework and information, and should ideally be summarized with a flow diagram type algorithm, and have a check-sheet which enforces compliance with various critical items, as well as providing for documentation. Useful protocols which have been used for guidance include: Babl et al 2006; British Association for Emergency Medicine 2004.

A proposed flow diagram protocol is included as Appendix I.

- 1) Patient selection/ Risk (if uncertain discuss with consultant/ senior)
  - American Society of Anaesthesiologists (ASA) assessment or equivalent measure of baseline physiological status
  - rapid assessment of airway of patient and ease of airway management (eg. Mallampati score or similar)
  - significant medical co-morbidity (eg. cardiac/ respiratory disease)
  - hypovolaemia/ shock/ sepsis
  - fasting time
  - urgency of procedure
  - specific exclusion criteria dependant on drug choice
  - consent (verbal or written)

2) Facilities for PS:

- resuscitation Equipment (including advanced airway equipment, bag valve mask, and standard resuscitation drugs)
- bed with tilt mechanism
- oxygen
- suction

3) Monitoring Equipment

- pulse oximetry
- non invasive blood pressure
- 3-lead ECG monitor accessible when required
- capnography ideal but not mandatory
- documentation of all parameters before, then every 5 minutes until end of post procedural monitoring

4) Drug Choice: available drugs to consider include: (+- synopsis of each drug)

- midazolam
- propofol
- etomidate
- nitrous oxide
- ketamine

5) Personnel

- trained clinician with knowledge and experience in chosen drug
- second clinicians when available or concern over possible difficulty in sedation or procedure.
- dedicated nurse – enrolled or registered with training in PS
- consultant or senior available for advice or on site in difficult cases

6) Documentation - checklist type documentation ideal (see examples Appendix G & H)

- reminds clinicians and nursing staff of protocol
- provides for documentation of data/ times

- remains with patients notes as medico legal record
- data readily available for future research and audit.

7) Monitoring post procedure

- patient remains in PS area or moved to dedicated monitoring area
- dedicated trained personnel (preferably same as assisted in procedure) remains with patient until fit for discharge
- monitoring continues as during procedure with documentation every 5 minutes
- monitoring until all vital parameters have returned to normal (on room air)

8) Discharge Criteria

- awake and orientated to time, person and place
- able to walk unsupported (or return to pre-sedation ambulation)
- tolerates oral fluids
- discharge to care of responsible adult where possible
- patient to be advised to avoid dangerous activities (driving, operation of machinery, childcare for 24 hours).

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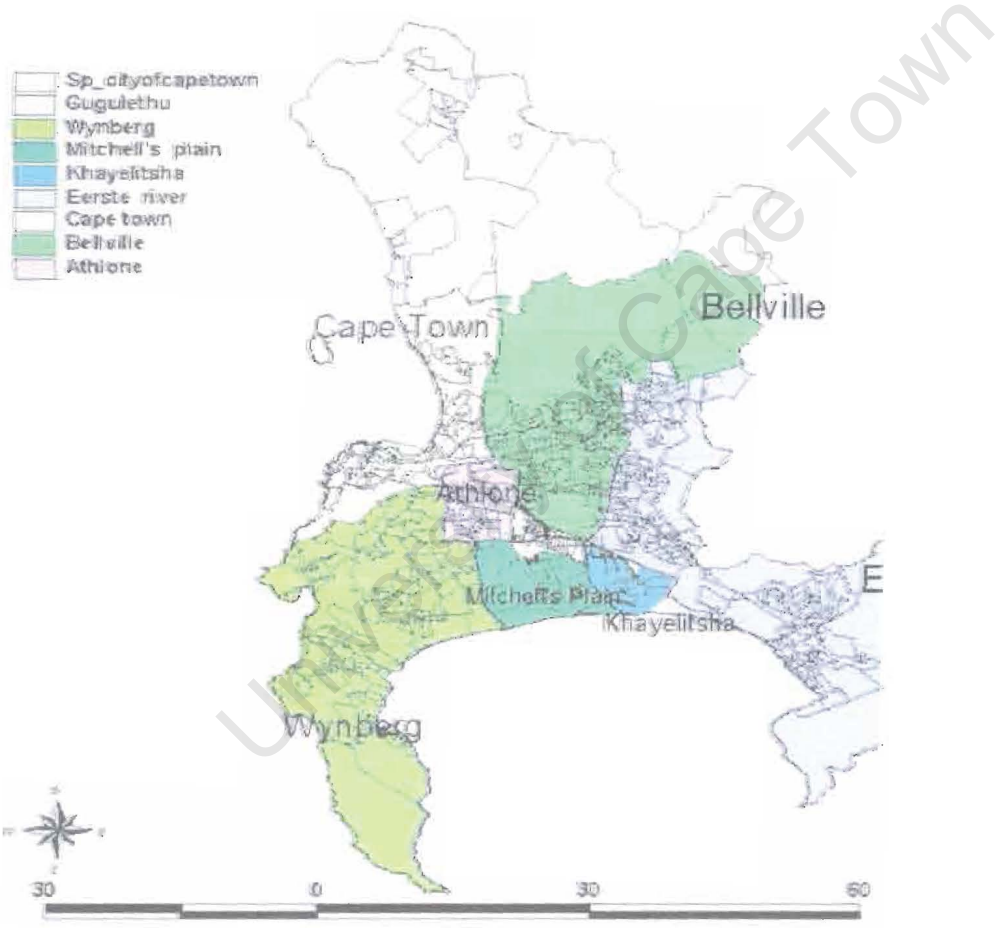
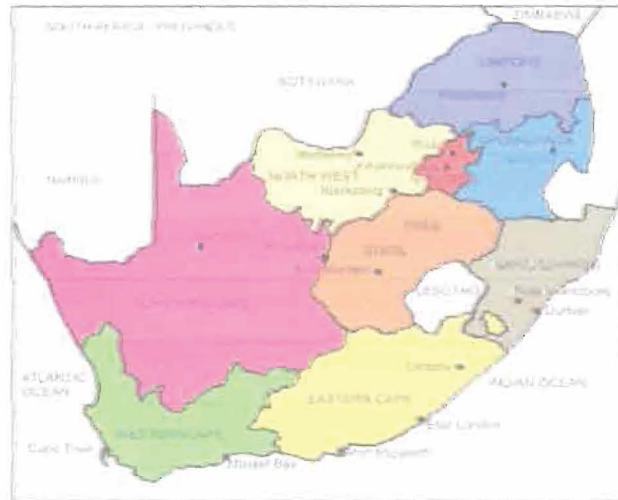
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# APPENDICES

Appendix A: Map of South Africa, showing Cape Town, and the Cape Town Metropole.



## Appendix B: Emergency Department Manager Questionnaire

### A. Study information:

---

- A1) Date of interview .....
- A2) Hospital Code (A-Z) .....

### B. Emergency Department General Information

---

- B1) Number of patient visits per month .....
- B2) Number of procedural sedations performed per month .....
- B3) Type of procedures performed:
- Dislocation:  shoulder  elbow  lower limb  jaw
- Reduction fracture  Upper Limb  Lower Limb  Other.....
- B4) Is procedural sedation performed on paediatric patients (<13 yrs old)?  Yes  No
- B5) Number of nursing staff in department (average per shift)  
Qualifications of nursing staff (enter number in each category)
- Registered nurse  Enrolled nurse  Nursing assistant
- B6) Number of medical staff in department .....
- Qualifications of medical staff ( enter number in each category)
- Consultant  EM Reg  Medical Officer  Community Service

### C. Emergency Unit facilities and equipment

---

- C1) Is there a separate area used for procedural sedation?  Yes  Yes :Resus  No
- C2) Is there adequate resuscitation equipment available at bedside?  Yes  No
- C3) Please indicate which of the following equipment is available for PS ( tick boxes)?
- NIBP  pulse oximetry  cardiac (ECG) monitor  capnography
- C4) Which of the following back-up facilities / specialists are available (tick boxes)?
- Theatre  ICU  Anaesthetist  Orthopaedic Surgeon

**D. Protocol for procedural sedation**

---

D1) Does the unit have a fixed (written) protocol for procedural sedation?  Yes  No

D2) Is there 1:1 doctor/nurse monitoring until the patient awakes in all cases?  Yes  No

Comments.....

**E. Drugs for procedural sedation**

---

E1. Are you aware of other drug regimes used internationally for procedural sedation which may be superior to your unit's practice?  Yes  No

Specify.....

E2. Please indicate if any of the following drugs are NOT available in the dept (tick boxes)

Fentanyl

Midazolam

Etomidate

Propofol

Ketamine

Nitrous oxide

E3. Do you consider current practice of procedural sedation in your unit to be optimal?

Yes  No

E4. If not, please state what you consider to be the shortcomings of current practice

.....  
.....  
.....

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## Appendix C: Study information sheet for Emergency Department Staff

Hello,

I am doing an MPhil dissertation in the Division of Emergency Medicine of the University of Cape Town. I am investigating the current protocols for procedural sedation in emergency departments in the greater Cape Town metropole. It is anticipated that the information gained from this study will be used to assist in developing new evidence-based protocols for procedural sedation.

Common procedural sedations performed are reductions of dislocations and manipulations of closed fractures. The investigation will include information on the current drugs in use, training and experience of medical officers, and satisfaction with current methods.

*Ethical approval has been obtained for the study from the UCT Ethics Committee.*

Hospitals will not be identified in the study, and individuals will remain anonymous – you will be identified in the data collection by a number only and not by name.

If you are happy to participate in the study, the following will happen:

I will first be briefly interviewing the clinical managers of the various emergency departments, to ascertain basic general information on the facilities, numbers of procedures performed and staff in the unit.

I will then contact you to arrange a suitable time to interview you either personally (in the unit if possible) or telephonically to administer a brief questionnaire (this will take no more than five minutes). The information provided will be treated confidentially; information will not be linked to you personally or to your particular facility in the analysis or any reports compiled from this data.

You may decline to participate in the study without giving a reason. It will not have any adverse consequences to you.

If you have any queries regarding the study, more information may be obtained from:

Dr. Peter Hodkinson,  
Department of Emergency Medicine,  
University of Cape Town,  
Cape Town.

Tel. 082 853 6116. [pwhodkinson@gmail.com](mailto:pwhodkinson@gmail.com)

Thank you.

**Appendix D: Emergency Department Clinicians Questionnaire**

**A. Clinician information:**

---

- A1) Date of interview ..... Hospital Code .....
- A2) Interview Number : .....
- A3) Position:  Consultant  Medical Officer  Registrar  COSMO
- A4) Do you work full or part-time in the emergency unit?  Full-time  Part-time
- A5) How many years ago did you qualify (MBBCh or equivalent)? .....
- A6) How many years have you worked primarily in an emergency unit? .....
- A7) Do you have 6 months or more of full-time anaesthetics experience?  Yes  No

**B. Procedural sedation general information**

---

- B1) Have you carried out 1 or more procedural sedations in the past 3 months?  Yes  No
- B2) Do you use a fixed protocol for procedural sedation?  Yes  No
- B3) Which monitoring do you routinely use for PS:  
 NIBP  pulse oximetry  cardiac (ECG) monitor  capnography
- B4) Do you commonly perform BOTH the sedation AND the procedure yourself?  Yes  No
- B5) Is there always a dedicated nursing staff member present when you perform PS?  Yes  No
- B6) Who remains with the patient until they are awake?  
 Doctor  Nurse allocated to individual patient  Nurse responsible for multiple patients
- B7) What is your estimate of the average time to recovery of patients to be able to leave the unit? .....
- B8) Do you have experience with other PS protocols/ drugs used elsewhere (overseas)?  Yes  No

**C. Drugs used for procedural sedation**

---

- C1. Please indicate which of the following drugs you commonly use for procedural sedation (tick boxes)
- Opiates  Morphine  Fentanyl  other .....
- Midazolam  Other benzodiazepine – specify .....
- Etomidate  Ketamine
- Propofol  Nitrous oxide  Other.....

**D. Complications of procedural sedation**

D1. Please indicate which of the following complications you have experienced when performing procedural sedation?

	Frequent	Occas	Rare	Never
hypotension SBP <100	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
hypotension requiring intervention	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
hypoxia (sats <90)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
hypoxia requiring intervention	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
intubation required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
aspiration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
nausea & vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
dysrhythmia / arrest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

other, please specify .....

**E. Satisfaction with current practice**

E1. Please indicate your level of satisfaction with your current procedural sedation practice (tick):

	Very poor	Poor	Fair	Good	Very good
1a. Time to effect	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1b. Time to recovery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1c. Ease of achieving sedation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1d. Ease of performance of procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1e. Depth of sedation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1f. Side effects and complications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1g. Perceived patient satisfaction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

E2 Level of sedation:  Moderate (responds purposefully commands)  
 usually obtained  Deep (responds to repeated noxious stimuli)  
 Very Deep (no response stimuli and may require cardio-resp support)

E3. Are there specific problems with present PS practice not yet mentioned? Specify: .....

E4 Response when prompted: What form of PS would you like done on yourself?.....  
 Do you have any knowledge of propofol use?.... What do you think of it as a PS agent?.....

## Appendix E: Cape Town Metropole: Hospitals with 24hr Emergency Facilities

2 Military

Cape Town Mediclinic

City Park (Chris Bamard)

Claremont Clinic

Constantiaberg MediClinic

Durvanville MediClinic

EersteRivier

False Bay

Gatesville Mellomed

GFJooste

Groote Schuur

Karl Bremmer

Kuilsrivier Netcare

Louis Leipold

Milnerton MediClinic

Mitchells Plain Pvt/Melomed

N1 City

New Somerset

Panorama

Red Cross Children's

Tygerburg

Victoria

Vincent Palotti

University of Cape Town

## **Appendix F: Hospitals meeting Study Inclusion Criteria**

### **Cape Town Metropole: Hospitals with 24hr Emergency Facilities and Full Time Emergency Department Staff.**

Cape Town Mediclinic

Claremont Clinic

Constantiaberg MediClinic

Durbanville MediClinic

GFJooste

Groote Schuur

Kuilsrivier Netcare

Milnerton MediClinic

N1 City

New Somerset

Panorama

Tygerburg

Victoria

University of Cape Town

## Appendix G: Example of Procedural Sedation Checklist (for ketamine)

(from British Association for Emergency Medicine 2004)

Example:

### EMERGENCY DEPARTMENT SEDATION RECORD

Date: \_\_\_\_\_ A&E No: \_\_\_\_\_ Patients Name: \_\_\_\_\_ DOB: \_\_\_\_\_

Details of procedure to be performed: \_\_\_\_\_

Reason for sedation: \_\_\_\_\_

Personnel present (and roles): \_\_\_\_\_

Details of sedation technique planned:

Isolated Sedation only	yes/no	Sedation with block/LA	yes/no
Conscious Sedation Analgesia	yes/no	Block/Analgesia	yes/no
Sedation/Inhalational	yes/no	Other (specify)	

Checklist:

ASA Status: (circle status)

Consent	yes/no (written yes/no)	ASA 1 (Fit & healthy; no systemic disease)
Procedure explained	yes/no	ASA 2* (Mild systemic disease; not debilitating)
Check last meal/drink	yes/no when:	ASA 3* (Significant systemic disease; limiting)
Check equipment	yes/no	ASA 4* (Risk not suitable without operator)
Monitoring used	yes/no	ASA 5* (Resuscitation simultaneous with surgery)
Care on discharge	yes/no * = Qualifies:	

Baseline observations:

Pulse: \_\_\_\_\_ Resp Rate: \_\_\_\_\_ SaO2: \_\_\_\_\_ GCS: \_\_\_\_\_

Details of Sedation Procedure:

Drug:	Route:	Initial Dose:	Subsequent Doses:
1.			
2.			
3.			
4.			

I.V Access gained: yes/no      Details: \_\_\_\_\_  
 Oxygen given: yes/no  
 Entonox/N2O: yes/no

Details of complications & further interventions during/following sedation/recovery:

Nausea/vomiting	yes/no
Delayed recovery	yes/no
Recovery Agitation	yes/no
Distress Score:	

Recovery Observations:

Pulse: \_\_\_\_\_ Resp Rate: \_\_\_\_\_ SaO2: \_\_\_\_\_ GCS: \_\_\_\_\_

Time Sedation given: \_\_\_\_\_ Time recovered: \_\_\_\_\_ Time Discharged: \_\_\_\_\_



## Appendix I: Proposed Flowchart Protocol: Adult Procedural Sedation

